

PD-ABF-021  
15N 80223

QUARTERLY AND FINAL REPORT  
FOLLOW-ON TECHNICAL ASSISTANCE  
TO MEDIPHARM INDUSTRIES, LTD.  
KAMPALA, UGANDA

A Report Prepared by PRITECH Subcontractor:  
PROGRAM FOR APPROPRIATE TECHNOLOGY IN HEALTH  
(PATH)

TECHNOLOGIES FOR PRIMARY HEALTH CARE (PRITECH) PROJECT

Supported By The:

U.S. Agency for International Development  
CONTRACT NO: AID/DPE-5969-Z-00-7064-00  
PROJECT NO: 936-5969

AUTHORIZATION:  
AID/S&T/HEA: 10/13/92  
ASSGN NO: SUP 228-UG

QUARTERLY AND FINAL REPORT  
March 1, 1992 - July 31, 1992

QUARTERLY AND FINAL REPORT: PRITECH Task Assignment No. SUP-228-UG  
The following report for Management Sciences for Health (Cost  
Reimbursement Subcontract No. DPE-5969-003) is divided into three  
sections:

1. Project Activities
2. Project Expenditures
3. Attachments

1. Project Activities

During the reporting period, much of PATH's follow-on technical assistance to Medipharm focused on the provision of assistance in mediating/ troubleshooting unanticipated difficulties with key party collaboration and rejected batches.

Promotion

PATH worked with Medipharm to develop a revised monthly sales forecast for 1992-1993. Medipharm will use the sales forecast to create its cash flow statement. For the purpose of future promotion efforts and to improve projection capabilities, staff assisted Medipharm with comparisons of projections to actual sales figures.

ORADEX sales figures for the period March 1, 1992 through June 30, 1992 total 135,277 packets. Attachment A provides a synopsis of actual versus anticipated sales of ORADEX for the period October 1991 through June 1992.

Staff provided extensive assistance to Medipharm, USAID/Kampala, and UNICEF in resolving difficulties encountered with the sale of Medipharm's excess production capacity to UNICEF. As agreed by key

parties in Uganda at project initiation, purchase of Medipharm's excess production capacity by UNICEF was considered vital to Medipharm's financial stability until its private sector sales of ORADEX consumed the bulk of its production. As of late July, confirmation was received from UNICEF that it is now authorized to purchase Medipharm's excess sachets and is processing purchase orders for the local procurement.

During the reporting period, Medipharm reported recurrent sales of the Ministry of Health (MOH) public sector ORS packets in private shops and pharmacies. As sales of the MOH public sector ORS pose a significant threat to the success of Medipharm's private sector product ORADEX, extensive effort was also provided by PATH staff to bring this issue to the forefront for the attention of key parties in Uganda and to assist Medipharm and its distributor, ARMTRADES, in investigating the source of the leakage. During a meeting between USAID/Kampala, UNICEF, the MOH, the Danish Red Cross, and Medipharm, Dr. Musonge of UNICEF reported that he sent a very strong letter to the Chief Pharmacist and the Director of Medical Services (copies of which were also sent to the District Medical Officers) in which he stated the importance of monitoring that public sector ORS is not sold. It was agreed that Dr. Musonge will follow up this letter and establish enforcement criteria for shops found selling public sector ORS sachets.

With the assistance of Sjoerd Postma, sales representatives of both Medipharm and ARMTRADES participated in a Case Management/Supervisory Skills course conducted by Control of Diarrheal Diseases (CDD) managers.

A promotion technical assistance visit to Uganda was carried out by Fletcher Catron and Khalid Mahmood May 25-June 4, 1992. The objectives and outcome of the visit are detailed in the trip report, submitted to PRITECH on July 30, 1992, provided as Attachment B.

## Production

As a result of the absence of the quality control (QC) manager for several months, as well as a short supply of laboratory glassware, the QC unit did not keep up with the analysis required for the increased production level and the increased in-process testing. Extensive assistance was provided to Medipharm to help reduce the QC backlog and identify the cause for QC analysis results which indicated that the product was out of specifications.

A production technical assistance visit to Uganda was carried out by Khalid Mahmood May 25-27, 1992. The objectives and outcome of the visit are detailed in the trip report, submitted to PRITECH on July 30, 1992, provided as Attachment C.

Because of Medipharm's lack of revenue from the anticipated purchase of excess ORS capacity by UNICEF, Medipharm had insufficient funds to pay a contractor for electrical wiring installations for the dust extractor. PATH technical staff provided assistance to Medipharm by providing instructions and layout drawings for the dust extractor. Installation of the dust extractor is a critical piece of equipment to ensure Medipharm's ORS quality and productivity.

In March 1992 Medipharm was requested by the Ugandan government to "make a positive contribution" toward the amendment of the Uganda Pharmacy and Drugs Act (1970)/Regulation (1974) in order to meet international technological developments and modern industrial pharmaceutical practice. With the assistance of Medipharm, the Ministry of Health will be preparing a background paper on pharmaceutical legislation to be presented to the Parliament. PATH sent a fax to USAID/Kampala indicating that, "Due to the breadth of such an undertaking and the ultimate impact an effective Ugandan pharmaceutical drug act could have on the CDD and child survival initiatives in Uganda, this activity warrants significant

consideration by donors such as USAID, UNICEF, and WHO." PATH conveyed its interest in assisting Medipharm and the Ugandan government in this undertaking. Such a request as this to Medipharm is a clear indication of their leadership roll in the pharmaceutical industry in Uganda.

With the assistance of Sjoerd Postma, Medipharm staff Nakabuye Justine Florence attended a "Stock Control and Warehousing Techniques Course" offered by the Eastern and South African Management Institute March 3-27, 1992.

As a result of a visit and informal audit by representatives from "Tech Change '92," sponsored by DANIDA and private Danish companies, Medipharm was invited to participate in and exhibit its products at the "Tech Change '92 Exhibition and Contact Forum," a trade show held at the Exhibition Centre, Herning, Denmark, June 2-4, 1992. Participants in the trade show are comprised of selected companies in developing countries. Rogers Collins, General Manager of Medipharm, attributed its recognition from the Danish representatives "as a climax to PATH's work and I think all of you who have been concerned with the Project will feel proud of this development."

#### Other

At the request of David Puckett, USAID/Kampala, a proposal was submitted for additional technical assistance to Medipharm through June 30, 1993, as well as a budget for procurement of raw materials and packaging materials for 2.5 million ORS sachets (final proposals provided as Attachment D). USAID/Kampala is seeking funding to cover the costs associated with further assistance to Medipharm.

## 2. Project Expenditures

Total project expenditures through July 31, 1992, are estimated at \$153,719. Please note that this amount may vary slightly as PATH's final expenditure reports for July 1992 were not available at the writing of this report. Total budget expended is approximately 94 percent against an anticipated expenditure rate of 100 percent. An expenditure report for the period November 13, 1991 through July 31, 1992 is provided as Attachment E. Additional expenditures known to date to be received include outstanding costs for QC analysis tests and travel.

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17

**ORADEX SALES SUMMARY**  
**SALES BY ARMTRADES AND MEDIPHARM**  
**MONTHLY SALES: BUDGET VS. ACTUAL**  
**OCTOBER 1991-SEPTEMBER 1992**

	ARMTRADES			MEDIPHARM			TOTAL CUMULATIVE		
	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET
1991									
OCTOBER	20,000	9,487	47%	2,000	6,536	327%	22,000	16,023	73%
NOVEMBER	5,000	15,513	270%	4,000	12,371	309%	9,000	25,884	289%
DECEMBER	15,000	6,385	43%	6,000	11,980	200%	21,000	18,365	87%
FIRST QTR.	40,000	29,385	73%	12,000	30,887	257%	52,000	60,272	116%
1992									
JANUARY	20,000	13,095	65%	7,000	15,428	220%	27,000	28,523	106%
FEBRUARY	25,000	7,245	29%	9,000	5,804	64%	34,000	13,049	38%
MARCH	30,000	9,907	33%	10,000	9,874	99%	40,000	19,781	49%
SECOND QTR.	75,000	30,247	40%	26,000	31,106	120%	101,000	61,353	61%
SIX MONTHLY	115,000	59,632	52%	38,000	61,993	163%	113,000	121,625	79%
APRIL	35,000	21,561	62%	10,000	9,851	99%	45,000	31,412	70%
MAY	30,000	31,450	105%	11,000	13,204	120%	41,000	44,654	109%
JUNE	30,000	27,013	90%	11,000	12,417	113%	41,000	39,430	96%
THIRD QTR.	95,000	80,024	84%	32,000	35,472	111%	127,000	115,496	91%
JULY	30,000		0%	11,000		0%	41,000	0	0%
AUGUST*	30,000		0%	11,000		0%	41,000	0	0%
SEPTEMBER*	30,000		0%	11,000		0%	41,000	0	0%
FOURTH QTR.	90,000	0	0%	33,000	0	0%	123,000	0	0%
12 MONTH TOTAL	300,000	139,656	47%	103,000	97,465	95%	403,000	237,121	59%

## \*Assumptions:

- The August & September 1992 budget is not adjusted for the price increase.
- If the ex-factory price is increase to 213 Ush in August, the revised total budget will be: August: 25,000 sachets; September: 32,000 sachets.

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**TRIP REPORT**

**Technical Marketing Assistance Visit to  
Medipharm Industries  
Kampala, UGANDA**

Dates of In-Country Work:  
May 25-June 4, 1992

Prepared by:  
Khalid Mahmood  
Fletcher Catron

Program for Appropriate  
Technology in Health (PATH)  
for PRITECH  
July 1992



## TABLE OF CONTENTS

I. Objectives . . . . .	1
II. Summary of Findings . . . . .	1
III. Sales Management . . . . .	3
IV. Selling . . . . .	4
V. Promotion . . . . .	8
VI. Advertising . . . . .	9
VII. Sales . . . . .	11
VIII. Distribution . . . . .	12
IX. Strategic Business Plan for 1992 Fourth Quarter, 1993, and Beyond .	13
X. Meetings with other Agencies/Groups . . . . .	18

### List of Attachments

- A - ORADEX Sales Summary (October 1991-September 1992)
- B - ORADEX Profit and Loss (P&L) Statement (with no price change [actual and projected])
- C - ORADEX Regional Demographics
- D - ORADEX Sales Tracking By Demographics
- E - ORADEX Sales Tracking by Customer
- F - ORADEX Customer Card
- G - ORADEX Sales Summary (October 1992-December 1993)
- H - ORADEX Profit and Loss (P&L) Statement (with proposed price change)
- I - Letter from Permanent Secretary Dr. Muzira
- J - Contacts List

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## I. Objectives

The objectives of the visit to Medipharm are listed below:

1. Review sales management and progress on ORADEX sales targets with ARMTRADES; analyze regional sales results to determine cause of below-target sales and suggest specific remedial programs.
2. Travel with ARMTRADES and Medipharm sales staff for one day to evaluate sales presentation and suggest improvements.
3. Draft list of marketing activities and set goals for the last quarter of 1992, 1993, and 1994 for Medipharm and ARMTRADES.
4. Meet with UNICEF to agree on total ORS need forecast for 1993 and 1994. Obtain UNICEF's approval of current pro forma invoice for US\$30,000 of ORS.
5. Investigate the possibility of Foods & Beverages, Ltd., (F&B) as an additional distribution outlet for ORADEX. Meet with DANIDA Essential Drugs Programme to promote ORADEX for use in their drug kits.
6. Meet with Sjoerd Postma of PRITECH/Uganda and coordinate development of sales training for Kampala pharmacists in ORS and diarrheal disease case management.
8. Meet with USAID/Kampala to determine status of follow-on technical assistance proposal.

## II. Summary of Findings

The statistics for the first six months (ending March 1992) of the sale of Medipharm's private sector rehydration product, ORADEX, are as follows (see Attachment A):

- ARMTRADES sold 59,632 sachets, or 52 percent of their projected sales.
- Medipharm sold 61,993 sachets, or 163 percent of their projected sales.
- Total sales were 121,625 sachets, or 79 percent of the total combined sales projections.

The ORADEX product line has been losing money since April 1992 (see Attachment B for ORADEX Actual and Projected Profit and Loss Statement). If the current trend continues, it is expected that Medipharm will lose 10.1 million Ugandan Shillings (US\$) (US\$8,127) on a sale of US\$47.9 million (US\$42,494) for the period January 1992-December 1992, which represents a selling loss of 11 percent. Price

increases were not initiated because of Medipharm's and ARMTRADES' concern with market sensitivity during product introduction.

On the positive side, ORADEX brand recognition is high; it is believed that the low introductory pricing has boosted product acceptance and created consumer awareness. Price adjustments are now being considered. Inflation has already caused one price increase in January 1992 since product introduction.

Over one-half million sachets of public sector blue label ORS are stored in Medipharm's warehouse and are ready to be picked up by UNICEF. These sachets represent about US\$24,500 worth of labor and overhead expenses and also represent stagnant capital that is not being utilized. This has been a serious drain on Medipharm's resources and was a result of an uncertain commitment of the number of sachets required by UNICEF and the Ministry of Health. Currently, UNICEF is awaiting approval from Copenhagen for the procurement of locally produced ORS. Medipharm has submitted a proforma invoice for approximately US\$30,000 of blue label ORS; approval of this purchase was expected June 15, but has not yet occurred.

The Ugandan economy, as measured by gross domestic product (GDP), is experiencing vigorous growth, and unemployment levels are decreasing. Industrial output has increased ten-fold for most industries over the past year, and disposable income is increasing relative to prior periods. However, at the same time, there is high inflation and rapid devaluation of the Ugandan Shilling (about 100 percent per annum) relative to hard currencies. The consumer price index (CPI) for the Kampala region (Kampala, Jinja, and Mbale) increased by 100 percent over a period of 27 months.<sup>1</sup> The CPI included the expenditures of high- as well as low-income groups (earning less than USh50,000, or US\$50 per month).

Most pharmacies, shops, and street vendors that were informally surveyed readily recognized ORADEX. Nonetheless, informal surveys of shops and pharmacies carrying medical supplies almost always offered Kaolin Pectate as the first choice of therapy for the treatment of diarrhea. As is common in other sites where ORS is newly introduced into private sector outlets, there is consumer confusion as to whether ORS is diarrhea medication or if it simply treats dehydration. Future advertising and health education efforts should continue to promote ORS as the first line of diarrheal disease case management and as concomitant therapy with other anti-diarrheals and antibiotics.

Travel with ARMTRADES sales staff to rural towns and villages showed an impressive distribution of ORADEX and related promotional materials, although distributor performance requires management and substantial improvement to meet sales targets which seem to be highly realistic and

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<sup>1</sup>Statistical bulletin No. CPI/2. Ministry of Planning and Economic Development, Uganda. March 1992.

achievable. Observations and recommendations for improvement are presented in Sections III and IV, Sales Management and Selling.

Two potentially important outlets, which previously have not been targeted for distribution, are food stores and street vendors that sell related over-the-counter pharmaceutical products, such as common cold and indigestion remedies manufactured by multinational companies.

### III. Sales Management

#### A. Current Status

Prior to the visit, in order to analyze the problems of the distributor's low sales, PATH designed sales management analysis forms and sent them to ARMTRADES (see Attachments C, D, and E - "ORADEX Regional Demographics," "ORADEX Sales Tracking By Demographics," and "ORADEX Sales Tracking By Customer"). The purpose of collecting this information was to identify and remove the possible causes that are a constraint to realizing full market potential.

The sales data collected provided the following sales profile:

- 80 to 90 percent of the sales are generated in only one or two regions of the country. Within the first six months of product launch, Kampala was the only region to generate more than 70 percent of these sales.

This indicates that sales efforts outside the major city of Kampala were very low.

- In March and April 1992, when sales in two new regions/districts were generated, the sales in the Kampala and Jinja areas, which had generated about 80 percent of the sales, fell substantially.

This indicates that when sales efforts were made outside Kampala, they were made at the expense of Kampala. Sales efforts in one area should not jeopardize the sales efforts of other areas.

- Despite a 33 percent increase in the price of ORADEX in January 1992, ARMTRADES' sales increased steadily in March and April 1992. In addition, regions categorized as "low income" represented as much as 39 percent of the sales in March 1992 and 35 percent of the sales in April 1992.

This fact is contrary to the distributor's complaint/perception that the price of ORADEX is too high.

- The customer profile data indicated that of the top ten customers listed for the period September 1991-April 1992, not one customer was served twice.

This observation can be indicative of a lack of customer service and sales efforts.

- As was evidenced by the "ORADEx Sales Tracking by Customer" form that ARMTRADES filled out, ARMTRADES does not seem to have a target number of sales calls, customer profiling, or target vs. actual reports of the number of sales calls.

#### B. Recommendations/Action Items

1. ARMTRADES will make a diligent effort to increase sales in the northern (Gulu, Masindi, Lira, Luwero) and southwestern (Mbarara and Masaka) regions by employing additional resources. Also, resources utilized in an area not presently served will not be taken and used at the expense of other areas, i.e., when sales of one area go up, the sales of another area should not go down.
2. ARMTRADES will make a list of ten "A" customers (those customers who generate 50 percent or more of the sales) in every district using the "ORADEx Customer Card" introduced by PATH (see Attachment F). These "A" customers will be the priority customers, and at least one sales call, preferably two, will be made on these customers every month. The customer profile will be reviewed every month.
3. In order to coordinate the sales management, monitor the competitive activity, and set a strategy for future sales periods, it was agreed that ARMTRADES' sales and marketing staff will meet with the sales and marketing staff of Mediparm the second Tuesday of every month at 10:00 a.m. at the ARMTRADES offices.
4. ARMTRADES will complete the sales management forms provided to them and send them by fax to PATH by the fifth day of each month.
5. ARMTRADES will make a realistic goal of serving/visiting the "A" customers and tracking this goal on the "ORADEx Sales Tracking by Customer" form.

#### IV. Selling

##### A. Current Status

ORADEx brand recognition is very strong because of the heavy investment in promotion and advertising, complemented by the

efforts of the Ministry of Health to publicize oral rehydration therapy in seminars and public awareness programs. Selling and distribution efforts are the key elements to achieve the market potential; however, currently, selling and distribution channels are not being utilized to match the market demand. The resources allocated by the distributor are roughly one-fifth the effort required to meet the targeted sales calls.

#### 1. ARMTRADES Sales Calls

The Mbarara and Masaka regions collectively constitute about 62 percent of Uganda's population. Approximately 33 percent of the country's shops and pharmacies are located in these regions. In particular, Mbarara is an area of relatively high economic activity. In order to explore the causes of low sales in this area and determine whether full market potential is being realized, the resources allocated, as measured in the number of sales calls, were examined in detail for the Mbarara region.

It is estimated that the number of sales calls allocated to this region is one-fifth of the calls that are required to realize the market potential in this area. This is determined as follows:

Sales calls allocated: Mr. Mayinja, managing director of ARMTRADES, informed us in the meeting on Tuesday, May 26, that one salesperson is allocated to serve the Mbarara region (population 4.1 million). He confirmed that in this region one salesperson can make a maximum of 100 calls per month (5 sales calls per day x 20 days per month).

Sales calls required: There are 1,800 shops and pharmacies in the district. If only 30 percent, or 540, of the shops, pharmacies, and/or stockists are targeted and these targeted shops, pharmacies, and/or stockists are visited once every month, at least 540 sales calls will be required every month. This calculation indicates that at least five sales people are required to serve this area in order to serve 30 percent of the shops and pharmacies once every month.

This is required just to sustain the sales. If additional calls are desired to increase sales and customer base, it will be in addition to the 540 calls per month. This is far less than the 100 calls that one sales person presently allocated to this area makes.

If ARMTRADES' estimate of three sales calls per customer per month is used (as reported on the "ORADDEX Sales Tracking by Customer" form), then the number of sales calls required per month in the Mbarara region will be 540 customers x 3 calls per month = 1,620 sales calls. This will further increase

the ratio of sales calls required to sales calls made. However, these numbers were not used to calculate the sales calls required and to determine the short fall of selling resources.

## 2. Medipharm Quality of Selling

Travel with Medipharm sales staff underscored the need for Medipharm to continue to develop a systematic approach to weekly sales circuits in Kampala and the surrounding suburbs. K. Mahmood and F. Catron traveled with two of Medipharm's sales people to pharmacies and clinics around Kampala. The intent of this visit was to evaluate the sales people for product knowledge, presentation skills, presentation material, and sales skills.

Medipharm sales staff had simple product detail aids and did not have any other written product or diarrheal disease information while making presentations to doctors or clinic staff. Product knowledge and knowledge of anti-diarrheal products was minimal. Medipharm sales staff were not able to recognize the product categories, chemical names, nor mode of action of several different kinds of anti-diarrheal products found in the pharmacies.

One person from Medipharm and one person from ARMTRADES were trained by the WHO-supported CDD seminar on diarrheal diseases June 1-10 in Mbale. This seminar is expected to improve the product knowledge of the sales people.

Because Medipharm had never managed an intensive sales program, there was a complete lack of organizational and planning skills and tools for sales management, competitive surveillance, and customer profiling.

PATH introduced the "ORADEx Customer Card" to the Medipharm sales staff. This card will form the basis of sales planning and management. Information obtained from this card will be used for sales forecasts, seasonality effect in sales, competitive information, customer profiling, and identifying the "A," "B," and "C" customers (those customers that generate 70 percent or more, 20 percent or less, and 10 percent or less sales, respectively).

## 3. ARMTRADES Quality of Selling

ARMTRADES sales staff are knowledgeable but also need improvement in presenting ORS as a commercial product positioned as the first step in therapy and as concomitant therapy. While their product knowledge was greater than Medipharm's staff, both groups will require additional

technical literature, sales management, planning skills, and product training in ORS as well as in competitive products.

B. Recommendations/Action Items

1. ARMTRADES should increase its sales staff in the Mbarara region so that a minimum of one sales call per month is made to at least 30 percent of the total pharmacies and shops. Currently, less than one-sixth of the sales calls can be made to the targeted customers in this district.

An estimate of sales calls required in every district should be determined. This requirement should be compared with the resources allocated, and if there is a short fall, the resources should be increased.

2. Medipharm sales staff should continue to survey the Ugandan market for all competing anti-diarrheal products and understand the technical difference between ORS and the competition to better present why ORADEX is the WHO-recommended first line treatment for diarrheal disease. Continued use of the PATH-introduced customer card will form the basis of sales planning and management.
3. PATH will again send both ARMTRADES and Medipharm sales staff copies of the following technical documents to upgrade their product/disease knowledge:
  - "Dialogue on Diarrhea," published monthly by AHRTAG London. (Previous issues provide useful information in a simple language).
  - "A Manual for the Treatment of Diarrhoea (for use by physicians and other senior health workers)," WHO/CDD/SER/80.2, Rev. 2, 1990.
  - "Guidelines for Cholera Control," WHO/CDD/SER/80.4.
  - "The Rational Use of Drugs in the Management of Acute Diarrhoea in Children," WHO.
  - "The Treatment of Acute Diarrhoea - Information for Pharmacists," WHO.
4. Both Medipharm and ARMTRADES sales staff should do monthly pharmacy and shop surveys to keep informed of competitive product pricing and promotion. Each quarter, they should formulate a strategy to compete with anti-diarrheals.
5. Medipharm and ARMTRADES should make a monthly, weekly, and daily sales plan by consulting the "ORADEX Customer Card." Preference should be given to "A" customers if a compromise

in time has to be made. The customer card must be filled out completely before leaving the site of the sales call.

6. To give a professional image to the company, Medipharm and ARMTRADES staff must have printed business cards and should be well organized before entering the pharmacy or the doctor's clinic. New studies, product brochures, promotional materials, and samples, when available, should be made readily available before entering the clinic or the pharmacy.
7. If additional funds are available for assistance to Medipharm, PATH proposes that a product detail aid brochure for advertising and promotion be developed. The brochure will outline the benefits of ORS and serve as educational material for pharmacists. It will also help the sales staff in marketing to doctors, pharmacists, and shopkeepers by presenting technical material in easy-to-understand language supplemented by pleasing graphics. These brochures will be left behind after the sales visit. Doctors and pharmacists and others who desire more technical information should be offered copies of technical studies that are published by UNICEF/WHO and are available from the UNICEF/CDD offices at Kampala.
8. PATH has requested PRITECH to include a pharmacists training in next year's CDD plan. The training of pharmacists is essential because in Uganda a majority of the sales are generated by people who walk into a shop or pharmacy and ask the pharmacist/shopkeeper for a drug to treat common ailments. The training will only include the influential pharmacists who are the leaders. Most of the pharmacists can only be trained/convinced/converted by the Medipharm and ARMTRADES marketing and sales staff through the use of professional product presentations and the distribution of studies, reports, and expert opinions that point out ORS as the first line of therapy.

## V. Promotion

### A. Current Status

The current ORADEX product promotional materials in place are: the poster, 1992 calendar, pop-up box, and metal signs. These items combine to form very effective point-of-sale promotions for the product and create a visual linkage from outside the shop or pharmacy to the product inside on the shelf. Retailers who were interviewed with ARMTRADES sales staff said that the most important product promotion was the metal sign and the calendar, but also stated that the poster, which gave detailed product usage instructions, was very helpful.

## B. Recommendations/Action Items

In the proposed PATH marketing technical assistance to Medipharm, financing to procure 5,000 promotional calendars will be included along with other advertising materials for July 1, 1992-June 30, 1993. There currently remains a stock of metal signs and posters for continued distribution to pharmacies and retail outlets that sell ORADEX.

Included in PATH's proposed technical assistance to Medipharm for July-December 1992 and January-June 1993 is funding for a new product promotion detail brochure that will highlight relevant diarrheal disease case management information for the shop owner or pharmacy attendant. This brochure is intended to (1) fill the need for promotional materials for sales persons to give to prospective clients and (2) answer the concerns of shop owners and pharmacy attendants about basic diarrheal disease case management issues.

During this visit, shop and pharmacy surveys conducted by both ARMTRADES and Medipharm pointed out the need for additional bulk purchase incentives. PATH proposes, in addition to routine price increases, a bonus or promotional offer to pharmacists and shopkeepers. See Section IX.B.1.a., Price, for more details.

## VI. Advertising

### A. Current Status

Current ORADEX advertising includes radio ads, bus posters, and metal signs outside of shops and pharmacies that carry the product, in addition to newspaper advertisements in the nations two most circulated periodicals. This aggressive campaign is to be largely credited for the sales accomplished to date for ORADEX.

Radio ads: The ad was produced in Luganda, 4 R's, and Luo and has become extremely popular. Children in villages have been singing the melodic jingle, and several persons remarked that this was the "best radio ad in Uganda" at this time. Air play has been paid for through June 30, 1992.

The advertisements are played in the following manner on the "After the News" program in different regions of the country with broadcasts in the respective languages:

- 1) Luganda - 390 spots; twice daily between January and June.
- 2) 4 R's - 195 spots; once daily between January and June.
- 3) Luo - 195 spots; once daily between January and June.

Bus Posters: 30 adhesive posters were made and attached to the large multi-passenger buses that travel up country. These posters are all still clearly visible and are carried throughout Uganda.

Metal Signs: 14,000 metal signs were printed, of which approximately 8,000 have been distributed. The signs have been very popular with shop owners and were visible in several sites in the smallest village visited on the trip with ARMTRADES sales staff.

Newspaper Advertisements: Between September 1991 and June 1992, a printed advertisement for ORADEx has appeared in both New Vision and MUNNO during alternating weeks. These are the two most circulated daily periodicals in Uganda.

With guidance from PATH, Medipharm has worked effectively with Media Consultants, Ltd., to assist with the design and coordinate the development of the radio advertisements and printing of newspaper advertisements. Medipharm has also collaborated with UNICEF in the design and printing of the metal signs, which were printed in Nairobi. While Medipharm has gained experience in designing and managing the production of advertising materials, it will benefit from assistance from Media Consultants (or the advertising/public relations firm of their choice) in future advertising decisions. Materials should be designed directly in response to meeting a specific objective, such as increased brand awareness.

Medipharm must still work to understand the cost of producing these materials and the importance of timely production schedules. Radio advertisement production was delayed due to schedule conflicts with Medipharm and delays in submitting revised comments.

#### B. Recommendations/Action Items

In the proposed PATH marketing technical assistance to Medipharm, PATH has included assistance in procuring advertising through June 1993 with funds provided through USAID/Kampala. This effective advertising campaign for July 1992-June 1993 should continue to include the radio ads, bus posters, metal signs, and newspaper advertisements in the daily periodicals New Vision and MUNNO.

This campaign has created tremendous brand awareness and product acceptability. Continuation through 1992 will maintain materials and image continuity at this important stage of product introduction.

In addition, PRITECH has offered to make available a small amount of funds to supplement the advertising budget for the

production of small round stickers for the PSVs (Passenger Service Vehicle) which operate as independent taxis throughout Kampala and the surrounding areas. It is known that working class people frequent this form of transportation, and that these persons are also target purchasers of ORS for their children.

## VII. Sales

The sales management analysis made during this visit indicates that the combined sales projections/forecasts for Medipharm and ARMTRADES are accurate and achievable.

Based on the past nine months actual sales data and a forecast of the market conditions, the sales budget for the period August 1992-December 1992 was reviewed and adjusted. The two main factors that were considered to revise the sales budget were:

1. The expected decline in sales in August and September 1992 due to a large price increase effective August 1, 1992.
2. Medipharm's sales capabilities, based on actual sales, which was underestimated in the original budget.

The revised targeted sales through September 1992 is 378,000 sachets. Sales for the period October 1992-December 1992 (final quarter 1992) have been budgeted so that a fresh sales period, which matches the calendar year, can be started. The sales for this final quarter have been budgeted at 103,000 sachets (see Attachment G). The targeted sales through December 1992 (378,000 for October 1991-September 1992 plus 103,000 for October-December 1992) is 481,000 sachets.

Sales targets for 1991-1992 and 1992-1993 have been divided into six regional targets for ARMTRADES' six sales territories. Medipharm serves only Kampala, and thus has one monthly target figure. While the combined figure for both Medipharm and ARMTRADES has been realistic, Medipharm has sold a much greater percentage of the total than anticipated. Corrected figures for 1992-1993 will reflect a greater portion of the total to be sold by Medipharm.

ARMTRADES sales have been less than projected, and this was the focus of meetings with Mr. Mayinja as well as traveling with his sales staff to Iganga and Jinja. Improved distributor performance will be key aspects in evaluating continued use of an independent distributor. Medipharm has expressed interest in handling more of the distribution outside of Kampala unless the distributor generates the projected sales.

Since brand recognition is high, selling, distribution, and servicing customers will be key factors in maintaining the customer

base and in expanding the market of ORADEX. Advertising and promotion will be crucial to complement and reinforce the selling distribution effort to achieving sales targets. Since funding product advertising ended on June 30, 1992, pending funding from USAID/Kampala will be crucial in continuing to meet these targets.

Continued funding for this project will determine if Medipharm and ARMTRADES will receive additional technical assistance in refining sales techniques and analyzing sales data from the six sales regions throughout Uganda. This data will help maximize sales promotion efforts and shape future sales projections.

## VIII. Distribution

### A. Current Status

Under the direction of PATH, Medipharm has contracted to distribute ORADEX through ARMTRADES, Ltd., a locally owned pharmaceutical distribution firm. ARMTRADES was chosen as a product distributor since Medipharm had no national distribution capability or current regular contact with pharmacies and clinics outside of Kampala. Currently, Medipharm and ARMTRADES are having difficulty coordinating sales territories and credit facilities to various clients throughout Uganda.

Two Medipharm sales staff also currently distribute ORADEX throughout Kampala using their own sales delivery van. They sell to small shops and pharmacies with whom they have had sales relations for their line of products in the past. In addition, through their main office dispensary, wholesale products are available to shop owners who travel to Kampala from rural areas.

Given the limited effectiveness of ARMTRADES in meeting the sales targets for 1992, Medipharm has considered alternative distribution capabilities. Medipharm has a desire, but lacks the resources, to expand distribution with its own sales staff outside of Kampala.

During this visit, preliminary discussions were held with Foods & Beverages, Ltd., a national commodities distribution firm. F&B is very interested in distributing ORADEX. Specific recommendations regarding this option are provided in Section IX.B., Meeting the Objectives of the Strategic Plan.

### B. Recommendations/Action Items

Evaluation of distributor performance in late 1992 and 1993 should be tied directly to the sales goals set forth by Medipharm and PATH. If Medipharm wishes to expand its distribution, it will be encouraged to do so upon providing a detailed plan for effective rural distribution and product

delivery. In the meanwhile, every effort should be made to work with ARMTRADES to promote effective distribution and sales skills for ORADEX.

Negotiations should continue with F&B for ORADEX distribution. While primarily a dry goods distribution firm, F&B offers a uniquely effective transportation system to rural Uganda and an understanding of the special "social" nature of this product.

IX. Strategic Business Plan for 1992 Fourth Quarter, 1993, and Beyond

A. Medipharm's Strategic Objectives for the Future

1. Stop incurring losses from ORADEX by achieving at least 20 percent selling profit every month from August to December 1992 in order to absorb the 12-month period loss.
2. Maintain a minimum of 12-15 percent selling profit through 1993 and beyond on ORADEX product line.
3. Ensure that the distributor meets or exceeds sales forecast starting immediately.
4. Increase sales by realizing upside sales potential and selling directly to other channels, such as F&B which has a network in the rural areas and street vendors who have high potential. This volume should be at least one-half of the distributor sales.
5. Introduce colored/flavored ORS by September 1993. This will be critical to increase acceptability of ORS and to maintain a competitive edge with the increase in imported products into the country.
6. Stop or drastically reduce the leakage of public sector ORS to the private sector by carefully monitoring and following up with the Ministry of Health, newspapers, and authorities (see Section IX.B.5.a. for further details).

B. Meeting the Objectives of the Strategic Plan

1. Objectives 1 and 2

a. Price

As Attachment B indicates, if the price is not increased immediately, Medipharm will lose US\$1.2 million in August 1992; by the end of December 1992, Medipharm will incur a loss of US\$10.1 million on the sale of ORADEX.

Therefore, PATH proposes the following price increase in ORADEX effective immediately:

USh213.00	Ex-Factory Price (88.5 percent increase)
11.00	Distributor handling charge (5 percent)
<u>48.00</u>	Distributor Margin (22.5 percent)
USh272.00	Ex-Distributor price (can be rounded to USh275.00)

The suggested retail price will be USh350.

Presently, the retail price of ORADEX is USh200. Relative to other over-the-counter pharmaceuticals, this price is very low. For example, a 5-gram sachet of simple digestive salts consisting mainly of citric acid and sodium bicarbonate sells for USh100 (as compared to 27.9 grams of ORADEX which contains more expensive raw materials).

During the visit, F. Catron and K. Mahmood surveyed small shops, pharmacies, and street vendors to see whether general common merchandise and competing products were priced comparably to ORADEX. The following are examples of products and their prices:

<u>Product</u>	<u>Price</u>
Diadis Antidiarrheal Tablets (Furazolidone 100 mg)	150 USh/tablet
Furazolidone Suspension 60 ml	1,200 USh
Dialin (Pectin & Kaolin) 60 ml	800 USh
Jansen Immodium Suspension 30 ml	3,000 USh
Jansen Immodium Tablets	150 USh/tablet
Lomotil Tablets	70 USh/tablet
Andrews Liver Salts 5 grams (?)	100 USh/sachet
Dextrosol Glucose 15 grams	100 USh/sachet
Flambo Glucose Energy Drink 100 grams	350 USh/packet
Cigarettes	3 for 200 USh
Light Bulb (100 watts)	1,200 USh
Beer (12 oz. bottle)	1,200 USh
Soda (Coke/Miranda)	450-600 USh

The cost of other consumer products, food, and pharmaceuticals which are in the same economic segment as ORADEX have increased by at least 100-200 percent over one year, whereas the ORADEX price would have increased only 25 percent in 8 months by August 1992. This is also supported by the CPI.

It is expected that initial sales will decline slightly due to the increase in price. However, this will be offset as a result of:

23

- 1) higher resources in sales and customer service and sales management.
- 2) bonuses proposed to the pharmacists and shopkeepers. The shopkeepers will be given 10 free sachets for every 100 that they sell. This bonus is proposed for three months; however, the sales must be monitored closely. The results of the bonus must also be monitored for future action.
- 3) Medipharm and ARMTRADES taking the time to explain to the shopkeepers and pharmacists that the price increase was necessary due to the inflation, and despite the inflation and price increase of every other product, the price of ORADEX had not been increased for more than eight months. A simple one-page letter explaining this should be written and distributed to all the shopkeepers and pharmacists.

b. Profitability

The ORADEX product line must start generating profit immediately if Medipharm is to remain sustainable and survive. The effect of the price increase proposed in the above section will make Medipharm survive as a company. Even with the price increase instituted by August 1992, Medipharm will only make 9 percent selling profit for the period January 1992-December 1992 (see Attachment H).

The price should be reviewed accordingly every month, and a strategy for price increases or pharmacists bonuses should be made according to the impact of the inflation on the selling profit. It is anticipated that there will not be a need for a price increase for another 6 months. See Attachment H for a projection on profitability for the period ending December 1992. (This scenario assumes a price increase of US\$100 in August and a bonus of 10 free sachets for every 100 sachets sold for 3 months.)

The P&L Statement in Attachment H indicates that even at a sales level of 25,000 sachets, Medipharm will not lose money and will generate a net profit which is crucial for the mere existence of the company at this time.

2. Objective 3

Recommendations for meeting Objective 3 are presented in Sections III, IV, and VIII: Sales Management, Selling, and Distribution, respectively.

### 3. Objective 4

#### a. Foods & Beverages, Ltd.

In a meeting with the General Manager of F&B, Mr. Levi Zimbe, and the Marketing Manager, Mr. Sunday Ojambo, the possibility of distributing ORADEx through F&B depots wholesale to pharmacies and shop owners was discussed at length. F&B is very interested in the product and is fully aware of the "social" nature of the promotion that must accompany ORS. Three years ago, F&B assisted PATH and UNICEF with a distribution experiment. F&B is familiar with the product storage and transportation requirements.

Medipharm should immediately follow up on F. Catron's June 4 conversation with Mr. Levi Zimbe and Mr. Sunday Ojambo. Medipharm should propose a special product price of:

US\$213.00	Ex-Medipharm Factory Price (88.5% increase)
<u>62.00</u>	Foods & Beverages Distributor Margin (29%)
US\$275.00	Ex-F&B Wholesale Price to Pharmacists and Shop Owners

The new suggested retail price of US\$350 per sachet will also be in effect for these retailers.

It is anticipated that the proposed price structure and increased product distribution through F&B will achieve the immediate goals of profitability and sales volume.

#### b. Reduction of Public Sector Sachets

The leakage of public sector sachets into the private sector outlets for very low prices threatens to undermine profitable sales of ORADEx for both Medipharm and ARMTRADES.

Discussions were held with the Uganda Essential Drug Programme (EDP) regarding control of these "leakages." Meetings were held with Dr. J. B. Asheim and Dr. Bernard Osmond of the EDP on Monday, June 1, 1992, in which several items were discussed. The Essential Drug Programme would like to drop ORS from their drug kits, since typically EDP does not supply drugs which are manufactured locally. These kits which are imported annually, contain essential drugs found to be in short supply throughout Uganda. The kits are distributed to regional health centers and hospitals, who must account for the use of the drugs prior to receiving a new kit. Currently the EDP imports 13,000 kits, each of which are

pre-packed in Europe and contain 150 sachets of ORS. Thus, the EDP provides 1,950,000 sachets of ORS through this program.

The EDP is currently reconfiguring its allocation system. It will soon decrease the allocation from the current 3,250 kits per quarter to 3,000-2,500 kits per quarter. This will result in a net annual decrease in ORS from 1,950,000 sachets a year to approximately 150,000 fewer sachets going to their "clients." The EDP is well aware of the drug leakage problem, and has experienced similar problems with a variety of the kit components.

To determine whether the EDP will delete the ORS from these kits, a member of the EDP Steering Committee will visit the Medipharm factory on Friday, June 19. If the facility and production capacity appear suitable, a recommendation will be made to the EDP to stop inclusion of imported ORS, and for an interim period of one or two years, EDP should purchase ORS from Medipharm.

#### 4. Objective 5

##### a. Colored/Flavored ORS

There is a great influx of foreign goods, beverages, and pharmaceuticals into Uganda; peoples' taste are changing rapidly. This may effect the acceptability of ORADEX, because ORADEX tastes bland.

In addition, due to the improved buying power and hence the profit margins, it is likely that some companies may start importing colored/flavored ORS into Uganda. Because this product will not be directed by the CDD/UNICEF/USAID/Kampala, it may not have the quality that Medipharm products have and it may also compromise the positioning that the CDD and the Ministry of Health desires and has so carefully built. If Medipharm introduces colored/ flavored ORS, its positioning will be more closely aligned with the CDD/UNICEF objectives.

Medipharm must be ahead of the competition and prepare to launch a colored/flavored ORS product by October 1993. This product must be carefully prepared for acceptability and positioning and so that it does not jeopardize its existing products.

## 5. Objective 6

### a. Leakage of Public Sector Sachets into Private Sector Market

Another key element in both Medipharm and ARMTRADES meeting sales projections is the cautious monitoring by the Ministry of Health of leakage of the public sector blue label ORS sachets into the private sector.

Unless adequate quantities of ORS are distributed and accounted for by the regional health centers and hospitals, commercial introduction and sustainability of ORADEX is not assured. On Saturday, May 31, in a meeting with Dr. Fred Musonge, Director of the National CDD Program, this concern was discussed at length.

Dr. Musonge is aware of the evidence that public sector ORS sachets continue to leak into private sector outlets. The Ministry of Health is considering a new licensing procedure for pharmacies and shops, which will encourage ethical drug sales practices and implement a system of inspections. The point was made very clearly to Dr. Musonge that this leakage could seriously undermine the viability of local ORS production. Attachment I is a letter from Permanent Secretary Dr. Muzira expressing awareness and concern over the situation.

This leakage must constantly be monitored. Medipharm and ARMTRADES have been instructed to gather information on the vendor, product price, and quantity on stock when their sales representatives encounter this ORS in the field.

## X. Meetings with Other Agencies/Groups

### A. USAID/Kampala

Two meetings were held with USAID/Kampala representative, Mr. David Puckett. During the first of these meetings, revisions to a proposal for ongoing technical assistance in raw material procurement, ORS production, quality control, and marketing were discussed in detail. A revised proposal will be sent to USAID/Kampala in July.

A debriefing meeting with USAID/Kampala was conducted on Tuesday, June 2. Mr. Puckett expressed satisfaction with the progress of Medipharm production and sales. PATH presented data on problems encountered with quality control procedures and specific actions being taken to address these concerns.

Production has been temporarily halted to determine how batch consistency can be improved.

Mr. Puckett was made aware that Medipharm is at a critical period in product introduction and will require additional assistance in quality control as well as marketing in order to create sustainable ORS production for both the public and private sectors. USAID/Kampala's response to the pending proposal for additional technical assistance will determine whether PATH can provide this assistance.

#### B. UNICEF

On Tuesday, May 26, a meeting was held with UNICEF representatives, Dr. Livingstone Byarugaba and Dr. Colin Glennie. Also present were Mr. Rogers Collins, Mr. Peter Ssalimukasa, and Mr. Charles Kiwendo of Medipharm, Dr. Fred Musonge of the CDD Program, Mr. David Puckett of USAID/Kampala, and Mr. Sjoerd Postma of PRITECH/Uganda. The purpose of the meeting was to discuss the question of whether UNICEF would approve the purchase of US\$30,000 of ORS from Medipharm and to clarify when UNICEF would provide Medipharm with a firm statement of ORS requirements for the next three to five years for production planning purposes.

UNICEF will make a decision about the first question by early July, as approval is pending from Copenhagen. S. Postma agreed that the 3.5 million sachets figure may overstate the national public sector requirements.

A statement of long-term ORS requirements is being worked on by UNICEF, the CDD, and PRITECH and should be issued in the coming months. We have asked that this statement be given to Medipharm and PATH immediately for use in production and raw material requirement forecasting. Current raw material supplies (including raw materials which are en route to Uganda) will be finished in July or August 1993. By January 1993, orders should be placed for new raw materials to ensure arrival prior to finishing current supplies.

Finally, the group discussed the continuing leakage of public sector sachets. The CDD program will continue to monitor the situation and try to determine how the sachets are leaking into the private sector.

**ORADEX SALES SUMMARY**  
**SALES BY ARMTRADES AND MEDIPHARM**  
**MONTHLY SALES: BUDGET VS. ACTUAL**  
**OCTOBER 1991-SEPTEMBER 1992**

	ARMTRADES			MEDIPHARM			TOTAL CUMULATIVE		
	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET
1991									
OCTOBER	20,000	9,487	47%	2,000	6,536	327%	22,000	16,023	73%
NOVEMBER	5,000	13,513	270%	4,000	12,371	309%	9,000	25,884	288%
DECEMBER	15,000	6,385	43%	6,000	11,980	200%	21,000	18,365	87%
FIRST QTR.	40,000	29,385	73%	12,000	30,887	257%	52,000	60,272	116%
1992									
JANUARY	20,000	13,095	65%	7,000	15,428	220%	27,000	28,523	106%
FEBRUARY	25,000	7,245	29%	9,000	5,804	64%	34,000	13,049	38%
MARCH	30,000	9,907	33%	10,000	9,874	99%	40,000	19,781	49%
SECOND QTR.	75,000	30,247	40%	26,000	31,106	120%	101,000	61,353	61%
SIX MONTHLY	115,000	59,632	52%	38,000	61,993	163%	153,000	121,625	79%
APRIL	35,000	21,561	62%	10,000	9,851	99%	45,000	31,412	70%
MAY	30,000	31,450	105%	11,000	13,204	120%	41,000	44,654	109%
JUNE	30,000	27,013	90%	11,000	12,417	113%	41,000	39,430	96%
THIRD QTR.	95,000	80,024	84%	32,000	35,472	111%	127,000	115,496	91%
JULY	30,000		0%	11,000		0%	41,000	0	0%
AUGUST*	30,000		0%	11,000		0%	41,000	0	0%
SEPTEMBER*	30,000		0%	11,000		0%	41,000	0	0%
FOURTH QTR.	90,000	0	0%	33,000	0	0%	123,000	0	0%
12 MONTH TOTAL	300,000	139,656	47%	103,000	97,465	95%	403,000	237,121	59%

\*Assumptions:

1. The August & September 1992 budget is not adjusted for the price increase.
2. If the ex-factory price is increased to 213 Ush in August, the revised total budget will be: August: 25,000 sachets; September: 32,000 sachets.

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29

PROFIT AND LOSS (P&L) STATEMENT FOR ORADEX PRODUCT LINE  
 MEDIPHARM INDUSTRIES (EA) LTD.  
 000 UGANDA SHILLINGS (USH.) EXCEPT WHERE NOTED  
 NO CHANGE IN PRICE

	ACTUAL (JAN. 1992 - JUNE 1992)						PROJECTED (JULY 1992 - DECEMBER 1992)						12 MONTH
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
GROSS SALES (UNITS)	28,523	13,049	19,781	31,412	44,654	39,430	41,000	41,000	41,000	45,000	44,000	35,000	423,849
EX-FACTORY PRICE USH.	113	113	113	113	113	113	113	113	113	113	113	113	
GROSS SALES	3,223	1,475	2,235	3,550	5,046	4,456	4,633	4,633	4,633	5,085	4,972	3,955	47,895
BONUS (None)	0	0	0	0	0	0	0	0	0	0	0	0	0
EXCHANGE RATE TO US\$	900	900	900	1,050	1,050	1,050	1,200	1,200	1,200	1,300	1,300	1,300	
NET SALES	3,223	1,475	2,235	3,550	5,046	4,456	4,633	4,633	4,633	5,085	4,972	3,955	47,895
NET SALES (US\$)	3,581	1,638	2,484	3,381	4,806	4,243	3,861	3,861	3,861	3,912	3,825	3,042	42,494
per unit cost (US\$)	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	
per unit cost (UGSh.)	99	99	99	116	116	116	132	132	132	143	143	143	
COST OF GOODS SOLD	2,824	1,292	1,958	3,644	5,180	4,574	5,412	5,412	5,412	6,435	6,292	5,005	53,440
GROSS PROFIT MARGIN	399	183	277	(94)	(134)	(118)	(779)	(779)	(779)	(1,350)	(1,320)	(1,050)	(5,544)
% gross profit	12%	12%	12%	-3%	-3%	-3%	-17%	-17%	-17%	-27%	-27%	-27%	-12%
ADVERTISING, SELLING & PROMOTIONAL EXPENSES (ASP)													
direct selling as % of sales	120 4%	132 9%	145 6%	160 5%	176 3%	194 4%	213 5%	234 5%	257 6%	283 6%	311 6%	342 9%	2,567 5%
direct advertising as % of sales	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%	0 0%
direct promotion as % of sales	25 1%	30 2%	50 2%	75 2%	100 2%	125 3%	150 3%	200 4%	250 5%	250 5%	250 5%	250 6%	1,755 4%
TOTAL ASP as % of sales	145 4%	162 11%	195 9%	235 7%	276 5%	319 7%	363 8%	434 9%	507 11%	533 10%	561 11%	592 15%	4,322 9%
DISTRIBUTION 0.5% OF SALES	16	7	11	18	25	22	23	23	23	25	25	20	238
TOTAL COMMERCIAL EXPENSES as % of sales	161 5%	169 11%	206 9%	253 7%	301 6%	341 8%	386 8%	457 10%	530 11%	558 11%	586 12%	612 15%	4,560 10%
SELLING PROFIT 000s Ush.	238	14	71	(347)	(435)	(459)	(1,165)	(1,236)	(1,309)	(1,908)	(1,906)	(1,662)	(10,104)
SELLING PROFIT US\$ % selling profit	264 7%	16 1%	79 3%	(330) -10%	(414) -9%	(437) -10%	(971) -25%	(1,030) -27%	(1,091) -28%	(1,468) -38%	(1,466) -38%	(1,278) -42%	(8,127) -21%

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	
KAMPALA	1,014,000	H	10	1,000	-	10,000	50%	50
GULU	3,913,100	L	2	750	-	4,050	19%	69%
MBALE	1,516,600	L	2	900	-	2,450	12%	81%
MBARARA	4,069,800	M	4	1,800	-	2,050	9.5%	
JINJA	2,525,800	M	4	1,100	-	1,000	4%	
MASAKA	2,642,600	L	2	1,500	-	900	4%	
TOTAL	10,582,700	-----				21,550	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	CUM %
1	KAMPALA	KAMPALA	775,500	H	6	2,500	-	7,800	36%	36
2	LIRA	GULU	498,500	L	1	380	-	4,000	19%	54
3	KIBOGA	KAMPALA	140,800	M	1	400	-	3,150	14%	68
4	MBALE	MBALE	700,000	L	1	400	-	1,700	7%	75
5	BUSHENYI	MBARARA	734,800	L	2	300	-	650	3%	78
6	IGANDA	JINJA	944,000	M	2	400	-	500	2.3%	
7	JINJA	JINJA	294,900	M	2	600	-	480	2.2%	
8	MASAKA	MASAKA	831,300	L	2	700	-	400	1.8%	
9	MUBENDE	MASAKA	497,500	L	1	200	-	300	1.4%	
10	TORORO	MBALE	554,000	L	1	800	-	270	1.2%	

\* Income level. H = high, M = middle, L = low

Attachment C

16

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	
MBARARA	4,069,800	M	4	1,400	-	2,800	29%	28%
MASAKA	2,842,600	L	2	1,200	-	2,200	23%	53%
KAMPALA	1,814,800	H	19	3,950	-	2,007	20%	73%
JINJA	2,525,800	M	3	900	-	1,250	12%	65%
GULU	3,913,100	L	2	600	-	750	8%	73%
MBALE	1,616,600	L	2	750	-	600	6%	79%
TOTAL	16,582,700	-----				9,907	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	CUM %
1	MBARARA	MBARARA	329,600	M	2	750	-	2,400	24%	24
2	MASAKA	MASAKA	831,300	L	2	700	-	2,100	21%	45
3	KAMPALA	KAMPALA	773,500	H	6	2,500	-	2,007	20%	65
4	JINJA	JINJA	944,000	M	2	400	-	1,000	10%	75
5	LIRA	GULU	498,300	L	1	380	-	500	5%	80
6	MBALE	MBALE	706,600	L	1	400	-	450	4.5%	
7	BUSHENYI	MBARARA	734,300	L	1	400	-	400	4%	
8	MUBENDE	MASAKA	497,500	L	1	200	-	350	3.5%	
9	JINJA	JINJA	284,900	M	2	600	-	250	2.5%	
10	TORORO	MBALE	554,000	L	1	800	-	150	1.5%	

\* Income level: H = high, M = middle, L = low

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ORADFX REGIONAL DEMOGRAPHICS

Sales Period FEBRUARY 1990

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	CUM
KAMPALA	1,314,800	H	19	4,200	-	5,220	59%	59%
JINJA	2,525,800	M	3	1,800	-	1,750	20%	79%
MBALE	1,516,800	L	2	1,000	-	750	9%	88%
MBARARA	4,069,800	M	4	2,000	-	700	8%	96%
MASAKA	2,642,650	L	2	1,650	-	425	5%	
GULU	3,913,100	L	2	1,300	-	-	-	
TOTAL	16,582,700	-----				8,845	100%	

7,245

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	CUM %
1	KAMPALA	KAMPALA	775,500	H	6	2,500	-	5,220	59%	59
2	JINJA	JINJA	284,900	M	2	600	-	1,500	16%	65
3	MBALE	MBALE	706,600	M	1	400	-	750	8.4%	74.9%
4	MBARARA	MBARARA	974,600	M	2	600	-	500	5.5%	
5	IGANGA	JINJA	944,000	M	2	400	-	250	2.8%	
6	MASAKA	MASAKA	831,300	L	2	700	-	250	2.8%	
7	MUBENDE	MASAKA	497,500	L	1	200	-	200	2.2%	
8										
9										
10										

\* Income level: H = High, M = middle, L = Low

ORANEX REGIONAL DEMOGRAPHICS

AMTRAPAES LTD

Sales Period JANUARY 1992

TOP SIX REGIONS

REGIONS	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	COM.
KAMPALA	1,514,800	H	19	4,000	-	7,370	56%	56
JINJA	2,525,800	M	3	1,800	-	2,550	19.5%	76
MBARARA	4,069,800	M	4	1,650	-	1,850	14%	89
MASAKA	2,642,600	L	2	1,500	-	750	6%	
MBALE	1,616,600	L	2	1,000	-	575	4%	
GULU	3,913,100	L	2	810	-	-	-	
TOTAL	16,582,700	-----				13,095	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	COM
1 KAMPALA	KAMPALA	773,500	H	6	2,500	-	7,370	56%	56
2 IDALGA	JINJA	944,00	M	2	400	-	1,500	11%	60
3 JINJA	JINJA	284,900	M	2	600	-	1,000	7.5%	74
4 MBARARA	MBARARA	929,600	M	2	750	-	950	7.2%	82
5 BUSHENYI	MBARARA	734,800	L	2	300	-	930	7.1%	
6 NUBENDE	MASAKA	497,500	L	1	200	-	350	2.6%	
7 MASAKA	MASAKA	831,300	L	2	700	-	300	2.2%	
8 MBALE	MBALE	705,600	L	1	400	-	200	1.5%	
9 TORORO	MBALE	544,000	L	1	500	-	180	1.3%	
10 PALISA	MBALE	356,000	L	1	200	-	80	.6%	

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	COM.
KAMPALA	1,914,800	H	19	4,200	-	3,335	52%	52%
JINJA	2,525,800	M	3	1,300	-	1,150	18%	70%
MBARARA	4,069,800	M	4	1,950	-	1,000	16%	86%
MASAKA	2,642,600	L	2	1,600	-	750	12%	
MBALE	1,616,600	L	2	1,200	-	150	2%	
GULU	3,913,100	L	2	800	-	-	-	
TOTAL	16,582,700	-----				6,385	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	COM.
1	KAMPALA	KAMPALA	773,500	H	6	2,000	-	3,335	52%	52
2	JINJA	JINJA	284,900	M	2	600	-	400	6%	58
3	IGANDA	JINJA	944,000	M	2	400	-	300	4.6%	63
4	MUKONO	JINJA	816,200	M	1	250	-	300	4.6%	68
5	MBARARA	MBARARA	929,600	M	2	750	-	280	4.3%	
6	FUSHENYI	MBARARA	734,800	L	1	300	-	250	3.9%	
7	KABALE	MBARARA	412,800	L	1	100	-	230	3.6%	
8	MASAKA	MASAKA	831,300	L	2	700	-	200	3.1%	
9	MPIGI	MASAKA	915,400	L	1	50	-	200	3.1%	
10	MBALE	MBALE	706,600	L	1	400	-	150	2.3%	

\* Income level: H = high, M = middle, L = low

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	
KAMPALA	1,514,800	H	19	4,000	-	9,113	68%	68
MBARARA	4,029,800	M	4	1,900	-	2,000	15%	83%
JINJA	2,223,300	M	3	1,400	-	1,150	8.5%	92%
MASAKA	2,642,600	L	2	1,650	-	1,100	8%	
MBALE	1,616,600	L	2	1,200	-	150	1%	
GULU	3,913,100	L	2	800	-	-	-	
TOTAL	16,528,700	-----				13,513	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES
1	KAMPALA	KAMPALA	773,500	H	6	2,500	-	7,000	51.8%
2	KIBOGA	KAMPALA	140,800	L	2	400	-	2,113	15.6%
3	MBARARA	MBARARA	929,600	M	2	750	-	1,000	7.4%
4	KABALE	MBARARA	734,800	L	1	300	-	900	6.6%
5	JINJA	JINJA	284,900	H	2	600	-	550	4%
6	IGANGA	JINJA	944,00	M	2	400	-	400	2.9%
7	MUKONO	JINJA	816,200	M	1	250	-	200	1.4%
8	MASAKA	MASAKA	831,300	L	2	700	-	200	1.4%
9	MUBENDE	MASAKA	477,500	L	1	60	-	180	1.3%
10	RAKAI	MASAKA	382,000	L	1	120	-	60	

\* Income level: H = high, M = middle, L = low

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# ORADEX REGIONAL DEMOGRAPHICS

ARMTRADES

Sales Period OCTOBER 1991

## TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	CUM.
KAMPALA	1,814,800	H	19	4,000	-	6,405	68%	68
MASAKA	2,642,600	L	2	1,600	-	1,115	12%	80%
JINJA	2,525,800	M	3	1,400	-	945	10%	90%
MBALE	1,516,600	L	2	1,200	-	700	7%	
MBARARA	4,069,800	M	4	1,900	-	320	3%	
GULU	3,913,100	-	2	800	-	-	-	
<b>TOTAL</b>	<b>16,582,700</b>	<b>-----</b>				<b>9,485</b>	<b>100%</b>	

## TOP 10 DISTRICTS IN SALES (UNITS)

RANK	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES
1	KAMPALA	KAMPALA	773,500	H	6	2,500	-	4,000	42%
2	MASINDI	KAMPALA	253,500	L	2	200	-	2,405	25%
3	MASAKA	KAMPALA	831,300	L	2	700	-	600	6%
4	MUBENDE	MASAKA	497,500	L	1	200	-	500	5%
5	JINJA	JINJA	284,900	M	2	600	-	420	4.4%
6	MUKONG	JINJA	816,200	M	1	250	-	350	3.6%
7	MBALE	MBALE	706,600	L	1	400	-	300	3%
8	TORORO	MBALE	544,000	L	1	500	-	300	3%
9	MBARARA	MBARARA	929,600	H	2	750	-	180	1.8%
10	KASESE	MBARARA	343,000	M	1	600	-	120	1.2%

TRADEX REGIONAL DEMOGRAPHICS

Sales Period SEPTEMBER 1991

TOP SIX REGIONS

REGION	POPULATION	INCOME LEVEL*	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES	COM.
MACAKA	2,642,600	L	2	1,500	-	10,137	75%	75%
NBARARA	4,869,800	M	4	1,800	-	1,575	12%	87%
KAMPALA	1,314,800	H	9	4,000	-	1,346	10%	97%
JINJA	2,525,900	M	3	1,300	-	300	2%	99%
TOTAL	11,853,000	-----				13,358	100%	

TOP 10 DISTRICTS IN SALES (UNITS)

	DISTRICTS	REGION	POPULATION	INCOME LEVEL	NO. OF HOSPITALS	NO. OF SHOPS/ PHARMACIES	OTHER	SALES IN SACHETS	% OF TOTAL SALES
1	MACAKA	MACAKA	2,642,600	L	2	1,500	-	10,137	75%
2	NBARARA	NBARARA	4,869,800	M	4	1,800	-	1,575	12%
3	KAMPALA	KAMPALA	1,314,800	H	9	4,000	-	1,346	10%
4	JINJA	JINJA	2,525,900	M	3	1,300	-	300	2%
5									
6									
7									
8									
9									
10									

\* income level: H = high, M = middle, L = low

## ORADEX SALES TRACKING BY DEMOGRAPHICS

Prepared by ARMTRADES Sales period APRIL 1992  
 Prepared by ARMTRADES Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	-
2	SHOPS/PHARMACY	21,561	100%	-
3	OTHER	-	-	-
	TOTAL	21,561	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	10,951	50%	
2	JINJA	1,000	4%	
3	MASAKA	960	4%	
4	MBARARA	2,050	9.5%	
5	MPALE	2,550	12%	
6	GULU	4,050	19%	
	TOTAL	21,561	100%	
NAME OF CUSTOMERS				
1	CADMER PHARM	5,000	23%	
2	KANYA DRUGSTORE	1,400	6.5%	
3	SOPHILIA PHARM	1,000	4.6%	
4	FELISTER	1,000	4.6%	
5	GODWIN PHARM	1,000	4.6%	
6	MWASE	1,000	4.6%	
7	UNIPHARM	500	2.3%	
8	BUSIMBI	400	1.8%	
9	OTHERS (40)	10,261	47%	
10				
	TOTAL	21,561	100%	

GRADE: SALES TRACKING BY DEMOGRAPHICS

Dist: ARMTRADES Sales period MARCH 1992

Prepared by ARMTRADES Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	9,907	100%	
3	OTHER	-	-	
	TOTAL	9,907	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	2,007	20%	
2	JINJA	1,250	12%	
3	MASAKA	2,500	25%	
4	MBARARA	2,800	28%	
5	MBALE	600	6%	
6	GULU	750	8%	
	TOTAL	9,907	100%	
NAME OF CUSTOMERS				
1	RENA PHARM	1,000	10%	
2	KAMIRI CLINIC	1,000	10%	
3	KISAKYE PHARM	1,000	10%	
4	GODWIN	1,000	10%	
5	RWENZORI	500	5%	
6	MANAFWA	500	5%	
7	LUGAZI B.S	500	5%	
8	ADUMI DRUGSTORE	400	4%	
9	OTHERS (15)	4,007	48%	
10				
	TOTAL	9,907	100%	

GRADE: SALES TRACKING BY DEMOGRAPHICS

District: ARMTRADES LTD Sales period: FEBRUARY 1992  
 Prepared by: ARMTRADES LTD Date: \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	7,245	100%	
3	OTHER	-	-	
	TOTAL	7,245	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	5,220	72%	
2	JINJA	1,750	24%	
3	MASAKA	425	5%	
4	MBARARA	700	9%	
5	MBALE	750	10%	
6	GULU	-	-	
	TOTAL	7,245	100%	
NAME OF CUSTOMERS				
1	SAFECARE CLINIC	1,000	13.8%	
2	STELLA MARIS	1,000	13.8%	
3	UPJO	500	6.9%	
4	NOBEL	500	6.9%	
5	MWASE	300	4%	
6	GEMINI	250	2.7%	
7	JASABA	200	2.7%	
8	K.K. DRUG STORE	200	2.7%	
9	MEDICARE	200	2.7%	
10	OTHERS (20)	3,095	43%	
	TOTAL	7,245	100%	

ORADEX SALES TRACKING BY DEMOGRAPHICS

DISTRIB. BY ARMTRADES LTD

Sales period JANUARY 1992

Prepared by ARMTRADES LTD

Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	13,095	100%	
3	OTHER	-	-	
	TOTAL	13,095	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	7,370	56%	
2	JINJA	2,550	19.5%	
3	MASAKA	750	6%	
4	MBARARA	1,850	14%	
5	MBALE	575	4%	
6	GULU	-	-	
	TOTAL	13,095	100%	
NAME OF CUSTOMERS				
1	WELLCOME	1,000	7.6%	
2	RURAL HPHARM	1,000	7.6%	
3	BATICO	1,000	7.6%	
4	SOPHILIA PHARM	1,000	7.6%	
5	KISAKYE PHARM	1,000	7.6%	
6	KEVINE PHARM	1,000	7.6%	
7	IGANGA DRUGSTORE	500	3.8%	
8	KYOTERA D.S	500	3.8%	
9	SEMA D.C	200	1.5%	
10	OTHERS (30)	5,895	4.5%	
	TOTAL	13,095	100%	

ORADEX SALES TRACKING BY DEMOGRAPHICS

Prepared by ARMTRADES LTD Sales period DECEMBER 1991  
 Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	6,385	100%	
3	OTHER	-	-	
	TOTAL	6,385	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	3,335	52%	
2	JINJA	1,150	18%	
3	MASAKA	750	12%	
4	MBARARA	1,000	16%	
5	MBALE	150	2%	
6	GULU	-	-	
	TOTAL	6,385	100%	
NAME OF CUSTOMERS				
1	PIVOTI MED.	1,000	15.6%	
2	RWENZOLI MED.	850	13%	
3	MUWANGA&BROS.	750	12%	
4	WAIDA	500	7.8%	
5	MINI DRUGSTORE	500	7.8%	
6	BAKUSEKAMA	500	7.8%	
7	SAVELIFE CLINIC	400	6%	
8	MAVINA	350	5.4%	
9	KIWANGALA	250	3.9%	
10	OTHERS (15)	1,285	20%	
	TOTAL	6,385	100%	

43

GRADEX SALES TRACKING BY DEMOGRAPHICS

Prepared by ARMTRADES LTD Sales period NOVEMBER, 1991  
 Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	13,513	100%	
3	OTHER	-	-	
	TOTAL	13,513	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	9,113	68%	
2	JINJA	1,150	8.5%	
3	MASAKA	1,100	8%	
4	MBARARA	2,000	15%	
5	MBALE	150	1%	
6	GULU	-	-	
	TOTAL	13,513	100%	
NAME OF CUSTOMERS				
1	CRUSADER	1,000	7.4%	
2	SANYU	1,000	7.4%	
3	GOOD SAMARITAN	1,000	7.4%	
4	DUNKI	500	3.4%	
5	JOHNSON	400	2.9%	
6	BUWEKULA	400	2.9%	
7	MUNAKUKAAMA	350	2.5%	
8	BUSINGYE	350	2.5%	
9	BUBOTYC	300	2.2%	
10	OTHERS	8,213	60%	
	TOTAL	13,513	100%	

44

ORADER SALES TRACKING BY DEMOGRAPHICS

1990 ARNTRADES LTD Sales period OCTOBER 1991

Prepared by ARNTRADES LTD Date

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	9,487	100%	
3	OTHER	-	-	
	TOTAL	9,487	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	6,405	69%	
2	JINJA	945	10%	
3	MASAKA	1,115	12%	
4	MBARARA	320	3%	
5	MBALE	700	7%	
6	GULU	-	-	
	TOTAL	9,487	100%	
NAME OF CUSTOMERS				
1	PHARM MEDIC	1,000	10.5%	
2	EQUATOR PHARM.	1,000	10.5%	
3	CENTURY RAMA	800	8.4%	
4	CHANORE	500	5.2%	
5	ABEDEN	500	5.2%	
6	SIDCO	600	6%	
7	MULONDO	500	5.2%	
8	KINTU	400	4.2%	
9	DUSE PHARM	500	5.2%	
10	OTHERS	3,687	39%	
	TOTAL	9,487	100%	

GRADE: SALES TRACKING BY DEMOGRAPHICS

District: ARMTRADES LTD

Sales period SEPTEMBER 1991

Prepared by ARMTRADES LTD

Date \_\_\_\_\_

DEMOGRAPHICS		SALES PERFORMANCE		
		SALES IN SACHETS	% OF TOTAL SALES	ESTIMATED % OF TOTAL PURCHASED FROM US
TYPE OF CUSTOMERS				
1	HOSPITALS	-	-	
2	SHOPS/PHARMACY	13,358	100%	
3	OTHER	-	-	
	TOTAL	13,358	100%	
GEOGRAPHICAL LOCATIONS (REGION)				
1	KAMPALA	1,346	10%	
2	JINJA	300	2%	
3	MASAKA	10,137	75%	
4	MBARARA	1,575	12%	
5	MBALE	-	-	
6	GULU	-	-	
	TOTAL	13,358	100%	
NAME OF CUSTOMERS				
1	BYANSI PHARM	5,000	37%	
2	KITC PHARM	5,000	37%	
3	OTHERS (18)	3,358	25%	
4				
5				
6				
7				
8				
9				
10				
	TOTAL	13,358	100%	

**GRADEX SALES TRACKING BY CUSTOMER  
(CUSTOMERS PROVIDING 50% OR MORE OF SALES)**

DISTRIBUTOR ARMTRADES LTD

PAGE 1 OF 2

YEAR 1997

CUSTOMER	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC	TOTAL
<b>NYAKA</b>													
SALES TARGET													
SALES ACTUAL													
NO. CALLS TARGET													
NO. CALLS ACTUAL													
<b>LYANSI PHARM</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	-	-	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
<b>GEUTRUST</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	500	500	200	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
<b>MBARARA</b>													
<b>MUSIMU ENT</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	500	-	200	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-

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47

Attachment E

**ORADIX SALES TRACKING BY CUSTOMER  
(CUSTOMERS PROVIDING 50% OR MORE OF SALES)**

YEAR 1992

DISTRIBUTOR ARMTRADES LTD

PAGE 1 OF 2

MONTH	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC	TOTAL
<b>ASAKA</b>													
SALES TARGET													
SALES ACTUAL													
NO. CALLS TARGET													
NO. CALLS ACTUAL													
<b>LYANSI PHARM</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	-	-	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
<b>OBUTRUST</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	500	500	200	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
<b>SHARARA</b>													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	500	-	200	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-

25

**ORADIX SALES TRACKING BY CUSTOMER  
(CUSTOMERS PROVIDING 50% OR MORE OF SALES)**

YEAR 1992

DISTRIBUTOR ARMTRADES LTD

PAGE 1 OF 2

CUSTOMER	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC	TOTAL
NAME													
SALES TARGET													
SALES ACTUAL													
NAME: MASAKA													
NAME: EYANSI PHARM													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	-	-	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
NAME: OBUTRUST													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	500	500	200	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
NAME: EUSIMU ENT													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	500	-	200	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-

49

**ORADEX SALES TRACKING BY CUSTOMER  
(CUSTOMERS PROVIDING 50% OR MORE OF SALES)**

YEAR 1992

DISTRIBUTOR ARMTRADES LTD

PAGE 1 OF 1

CUSTOMER	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC	TOTAL
NAME:													
SALES TARGET													
SALES ACTUAL													
NO. CALLS TARGET													
NO. CALLS ACTUAL													
MASAKA													
NAME: EYANSI PHARM													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	-	-	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-
NAME: OBUTRUST													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	500	500	200	-	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3									
MLARARA													
NAME: BUSINDU ENT													
SALES TARGET	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	1,000	12,000
SALES ACTUAL	-	500	-	200	-	-	-	-	-	-	-	-	-
NO. CALLS TARGET	3	3	3	3	3	3	3	3	3	3	3	3	36
NO. CALLS ACTUAL	3	3	3	3	-	-	-	-	-	-	-	-	-

50



**ORADEx SALES BUDGET**  
**FOR ARMTRADES AND MEDIPHARM**  
**MONTHLY SALES: BUDGET VS. ACTUAL**  
 October 1992 - December 1993

	ARMTRADES			MEDIPHARM			TOTAL CUMULATIVE		
	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET	# SACHETS BUDGET	ACTUAL	% OF BUDGET
<b>1992</b>									
OCTOBER	26,000		0%	12,000		0%	38,000	0	0%
NOVEMBER	23,000		0%	12,000		0%	35,000	0	0%
DECEMBER	20,000		0%	10,000		0%	30,000	0	0%
<b>FINAL QTR 1992</b>	<b>69,000</b>	<b>0</b>	<b>0%</b>	<b>34,000</b>	<b>0</b>	<b>0%</b>	<b>103,000</b>	<b>0</b>	<b>0%</b>
<b>1993</b>									
JANUARY	35,000		0%	15,000		0%	50,000	0	0%
FEBRUARY	45,000		0%	18,500		0%	63,500	0	0%
MARCH	48,000		0%	19,500		0%	67,500	0	0%
<b>FIRST QTR.</b>	<b>128,000</b>	<b>0</b>	<b>0%</b>	<b>53,000</b>	<b>0</b>	<b>0%</b>	<b>181,000</b>	<b>0</b>	<b>0%</b>
<b>PRICE ADJUSTMENT EFFECTIVE APRIL 1, 1993</b>									
APRIL	40,000		0%	17,500		0%	57,500	0	0%
MAY	40,000		0%	17,500		0%	57,500	0	0%
JUNE	45,000		0%	20,000		0%	65,000	0	0%
<b>SECOND QTR</b>	<b>125,000</b>	<b>0</b>	<b>0%</b>	<b>55,000</b>	<b>0</b>	<b>0%</b>	<b>180,000</b>	<b>0</b>	<b>0%</b>
<b>SIX MONTHLY</b>	<b>253,000</b>	<b>0</b>	<b>0%</b>	<b>108,000</b>	<b>0</b>	<b>0%</b>	<b>361,000</b>	<b>0</b>	<b>0%</b>
JULY	50,000		0%	20,000		0%	70,000	0	0%
AUGUST	50,000		0%	20,000		0%	70,000	0	0%
SEPTEMBER	55,000		0%	22,500		0%	77,500	0	0%
<b>THIRD QTR</b>	<b>155,000</b>	<b>0</b>	<b>0%</b>	<b>62,500</b>	<b>0</b>	<b>0%</b>	<b>217,500</b>	<b>0</b>	<b>0%</b>
OCTOBER	55,000		0%	22,500		0%	77,500	0	0%
NOVEMBER	50,000		0%	20,000		0%	70,000	0	0%
DECEMBER	40,000		0%	17,500		0%	57,500	0	0%
<b>FOURTH QTR</b>	<b>145,000</b>	<b>0</b>	<b>0%</b>	<b>60,000</b>	<b>0</b>	<b>0%</b>	<b>205,000</b>	<b>0</b>	<b>0%</b>
<b>12 MONTH TOTAL</b>	<b>553,000</b>	<b>0</b>	<b>0%</b>	<b>195,500</b>	<b>0</b>	<b>0%</b>	<b>783,500</b>	<b>0</b>	<b>0%</b>

**ASSUMPTIONS:**

1. October 1992-December 1992 sales are not included in the 12 month total. Jan. 1993 starts a new period.
2. The price increase in August 1992 will result in a decline in sales in August through October 1992.
3. Profitability will be nearly zero by March 1993. Hence a price increase in April 1993 is budgeted. This will result in a slight decline in sales for April and May 1993.
4. Assumes an increase in distributor resources, better sales management, radio/print ads & use of ORS detail aid brochure.

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52

PROFIT AND LOSS (P&L) STATEMENT FOR ORADEX PRODUCT LINE  
 MEDIPHARM INDUSTRIES (EA) LTD.  
 000 UGANDA SHILLINGS (USH.) EXCEPT WHERE NOTED  
 (Proposed price change in August of 100Ush with bonus)\*\*

	ACTUAL (JAN. 1992 - JUNE 1992)						PROJECTED (JULY 1992 - DECEMBER 1992)						12 MONTH
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
GROSS SALES (UNITS)	28,523	13,049	19,781	31,412	44,654	39,429	41,000	25,000	32,000	38,000	35,000	30,000	377,848
EX-FACTORY PRICE USH.	113	113	113	113	113	113	113	213	213	213	213	213	
GROSS SALES	3,223	1,475	2,235	3,550	5,046	4,455	4,633	5,325	6,816	8,094	7,455	6,390	58,697
BONUS (10 free/100 sold)	0	0	0	0	0	0	0	2,500	3,200	3,800	0	0	9,500
EXCHANGE RATE TO US\$	900	900	900	1,050	1,050	1,050	1,200	1,200	1,200	1,300	1,300	1,300	
NET SALES	3,223	1,475	2,235	3,550	5,046	4,455	4,633	4,793	6,134	7,285	7,455	6,390	56,673
NET SALES (US\$)	3,581	1,638	2,484	3,381	4,806	4,243	3,861	3,994	5,112	5,604	5,735	4,915	49,353
per unit cost (US\$)	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	0.11	
per unit cost (UGSh.)	99	99	99	116	116	116	132	132	132	143	143	143	
COST OF GOODS SOLD	2,824	1,292	1,958	3,644	5,180	4,574	5,412	3,300	4,224	5,434	5,005	4,290	47,137
GROSS PROFIT MARGIN	399	183	277	(94)	(134)	(119)	(779)	1,493	1,910	1,851	2,450	2,100	9,537
% gross profit	12%	12%	12%	-3%	-3%	-3%	-17%	28%	28%	23%	33%	33%	17%
ADVERTISING, SELLING & PROMOTIONAL EXPENSES (ASP)													
direct selling	120	132	145	160	176	194	213	234	257	283	311	342	2,567
as % of sales	4%	9%	6%	5%	3%	4%	5%	4%	4%	3%	4%	5%	5%
direct advertising	0	0	0	0	0	0	0	0	0	0	0	0	0
as % of sales	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
direct promotion	25	30	50	75	100	125	150	200	250	250	250	250	1,755
as % of sales	1%	2%	2%	2%	2%	3%	3%	4%	4%	3%	3%	4%	3%
TOTAL ASP	145	162	195	235	276	319	363	434	507	533	561	592	4,322
as % of sales	4%	11%	9%	7%	5%	7%	8%	8%	7%	7%	8%	9%	8%
DISTRIBUTION 0.5% OF SALES	16	7	11	18	25	22	23	27	34	40	37	32	292
TOTAL COMMERCIAL EXPENSES	161	169	206	253	301	341	386	461	541	573	598	624	4,614
as % of sales	5%	11%	9%	7%	6%	8%	8%	9%	8%	7%	8%	10%	8%
SELLING PROFIT 000s USH.	238	14	71	(347)	(435)	(460)	(1,165)	1,032	1,369	1,278	1,852	1,476	4,923
SELLING PROFIT US\$	264	16	79	(330)	(414)	(438)	(971)	860	1,141	983	1,425	1,135	3,749
% selling profit	7%	1%	3%	-10%	-9%	-10%	-25%	19%	20%	16%	25%	23%	9%

\*\* BONUS SCHEDULE: August, September and October 10 free achets for every 100 sold. Withdraw in November and review sales closely.

FILE:KM:qpro/data/ugumarkt/dexp&Ls/1292BON2.WQ1  
 14-Jul-92 14:56:02

TELEGRAMS: "MEDMIN."  
TELEPHONES: GENERAL OFFICE 20201.  
ACCOUNTS OFFICE 20201.  
TELEX NO.: 61372 HEALTH UGA.



THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH.

P.O. BOX 8,

ENTEBBE, UGANDA.

IN ANY CORRESPONDENCE OR  
OTHER SUBJECT PLEASE QUOTE NO. PHC/A/17

20th May, 1992.

Attachment I

  
Mr. Colin Glennie,  
Senior Health Project Officer,  
UNICEF,  
KAMPALA.

RE: SALE OF ORS DONATED TO THE MINISTRY OF HEALTH

I have to refer to your letter REF: H/1115 of 26th March, 1992 in which you informed me that UNICEF Donated ORS is being sold in many shops through-out the country at very low prices. This makes the sale of ORADEX almost impossible.

I share with you the same view that the leakage of ORS into the market undermines Medipharm's ability to manufacture and sell ORADEX locally. This is a very serious matter which we have to act on very quickly. I have personally seen some ORS packets marked UNICEF being sold in some drug shops and pharmacies in this country. When I asked some of the shop keepers, I was informed that this was easily available to them for sale.

ORS like many other essential drugs are being distributed to hospitals and to health centres and dispensaries through the District Medical Officers. During our recent supervisory mission with the Hon. Minister of Health, we found that some of the drugs were being syphoned out of the Hospitals and sold in the private drug shops and dispensaries. We have apprehended quite a number of officers who misappropriated drugs. Following that, we set up a Monitoring Task Force which pays surprise visits to health units in every district to see how the drugs given to them are utilised. The Task Force looks at the records available and also examines the number of patients attending a particular unit. In addition to this, we have trained Assistant Inspectors of Drugs to monitor and inspect drugs in every district. We have also strengthened the security at the Central Medical Stores. We have also held a number of seminars for DMOs, DNOs, and other members of the health team to ensure that they are vigilant on the use of Government Drugs and UNICEF donated ORS.

I believe that with these measures put in place and with the assistance of Health Unit Management Committees and the R.Cs, we shall be able to stop the sale of UNICEF donated ORS in many shops. I am ready to discuss this matter with my colleagues who are associated with the delivery of health services.

  
Dr. E.G.N. Muzira  
PERMANENT SECRETARY/  
DIRECTOR OF MEDICAL SERVICES

54

The Permanent Secretary,  
Ministry of Local Government,  
KAMPALA.

Mr. David Puckett  
USAID - KAMPALA.

Mr. Collin Rogers,  
Medipharm - KAMPALA.

Ag. Chief Pharmacist,  
CENTRAL MEDICAL STORES

Project Coordinator,  
Uganda Essential Drugs Management Programme  
ENTEBBE.

CDD Manager,  
ENTEBBE.

The Ag. Chief Inspector of Drugs,  
Wandegeya - KAMPALA.

95

**CONTACTS LIST**

**USAID/Kampala**  
David Puckett  
P.O. Box 7007  
42 Nakasero Road  
Kampala  
UGANDA

Phone: 011 256 41 244 087  
Fax: 011 256 41 233 417 or 011 256 41 242 83  
Telex: 973 61163 WHITAK

**PRITECH/Uganda**  
Sjoerd Postma  
c/o American Embassy  
42 Nakasero Road  
Kampala  
UGANDA

Phone: 011 256 42 20047  
Fax: 011 256 42 21101

**UNICEF/Uganda**  
Dr. Livingstone Byarugaba  
Dr. Colin Glennie  
P.O. Box 7047  
Kampala  
UGANDA

Phone: 011 256 41 234 591  
Fax: 011 256 41 259 146  
Telex: 973 61199 UNICEF  
Cable: CHILDFUND

**Ministry of Health**  
**Control of Diarrheal Diseases Program**  
Dr. Fred Musonge  
P.O. Box 8  
Entebbe  
UGANDA

**Uganda Essential Drug Programme**  
Dr. J. B. Asheim  
Dr. Bernard Osmond  
P.O. Box 16  
Entebbe  
UGANDA

Phone: 011 256 42 20745  
Fax: 011 256 42 21062  
Telex: 973 62114 UNEPI UG

**Medipharm Industries, Ltd.**  
Rogers Collins  
Central P.O. Box 6218  
Travin House  
Plot No. 5 William Street  
Kampala  
UGANDA

Phone: 011 256 41 242 998 or 234 554  
Fax: 011 256 41 245 580 (post office)  
Telex: 973 61146 ZEBRA UG or 973 61541 FREBA UG  
Cable: MEDIPHARM--Kampala

**ARMTRADES Ltd.**  
A. R. Mayinja  
2, Parliament Avenue  
P.O. Box 3852  
Kampala  
UGANDA

Phone: 011 256 41 233 525  
Fax: 011 256 41 255 504  
Telex: 974 61051 ARMTRA UGA

**Media Consultants**  
Mike Daugherty  
P.O. Box 213  
Kampala  
UGANDA

Phone: 1002 56 41 231 212  
Fax: 011 256 41 258 115

**Foods & Beverages, Ltd.**  
Sunday W. Ojambo  
P.O. Box 7013  
Kampala  
UGANDA

Phone: 011 256 41 234 621 or 234 622  
Telex: 973 61168  
Cable: FOODBEV

**TRIP REPORT**

**Technical Production Assistance Visit to  
Medipharm Industries  
Kampala, UGANDA**

**Dates of In-Country Work:  
May 25-27, 1992**

**Prepared by:  
Khalid Mahmood**

**Program for Appropriate  
Technology in Health (PATH)  
for PRITECH  
July 1992**



## TABLE OF CONTENTS

I. Objectives . . . . .	1
II. Summary of Findings . . . . .	1
III. Identification of Possible Causes for Batches Outside Specified Ranges . . . . .	2
IV. Review of Batches Outside Specified Ranges . . . . .	4
V. Troubleshooting QC Equipment, Methods, and Procedures . . . . .	5
VI. Removal of Causes that Contribute to Low Productivity and Quality . . . . .	8
VII. Equipment Installation . . . . .	8
VIII. Preventive Maintenance Program . . . . .	8
IX. Inventory Management . . . . .	9
X. Meetings with USAID/Kampala . . . . .	9

### List of Attachments

- A - Statistical Analysis of Batches Outside Specified Ranges
- B - Cause and Effect Analysis (fishbone diagram) for Batches Outside Specified Ranges
- C - Statistical Analysis of Validation Batches
- D - Flowchart of Sampling Technique
- E - Determination of Particle Sizes for ORS Bulk Powder
- F - Determination of Particle Sizes for Sodium Chloride, Potassium Chloride, Glucose, and Sodium Citrate

## I. Objectives

1. Evaluate production and identify the possible causes for the oral rehydration salts (ORS) batches tested by Medipharm's quality control (QC) lab to be outside the specified ranges\*.
2. Review the batches found to be outside the specified ranges when tested at Medipharm's QC lab. Collect sachets from seven batches to send to a reference lab for validation. Compare the results of Medipharm's lab with those of the reference lab, and present a plan of action and recommendations based on the comparison.
3. Troubleshoot QC equipment, methods, and procedures.
4. Review recommendations made during the previous visit regarding the removal of causes that contribute to low productivity and quality.
5. Review/evaluate the preventive maintenance program and spare parts inventory system.
6. Review the installation of the new equipment and the production planning and inventory control system.

## II. Summary of Findings

Medipharm has had roughly 500,000 approved ORS sachets in its inventory since March 1992. These sachets were produced after a commitment was made by UNICEF to purchase up to 2.0 million sachets; however, UNICEF decided to purchase only 300,000 sachets during a meeting May 30, 1992. As a result of this delay, Medipharm is in a severe financial crisis because of the US\$30,000 (approximately) invested in producing the sachets, and because this capital is sitting idle in the warehouse in a hyper-inflationary environment.

Thirty-one batches produced since January 1992 have tested to be outside the specified ranges when tested at Medipharm's QC lab. Investigations are underway, per the PATH QA Policies and Guidelines Policy #01-04 "Batch Investigations and Disposition," to confirm these results and rectify the problem(s). During the visit, production was stopped until the possible causes of the 31 batches testing to be outside the specified ranges were identified/evaluated and corrected.

---

\* It is likely that these values are actually not out of specifications due to inaccurate QC assays.

The QC department is 26 batches behind production because of: (1) inability to support increased productivity in production, (2) inability to absorb additional testing of in-process sachets, (3) voltage stabilizer not having been installed, (4) stoppers for new glassware not having arrived until March 1992, and (5) QC manager being on a two-month leave of absence. Samples from seven batches (two outside the specified ranges and five within the specified ranges) were collected for validation testing at an independent lab.

The production planning and inventory management systems were evaluated, and comments and suggestions were provided for making efficient, 12-month horizon decisions.

The spare parts inventory and preventive maintenance program were evaluated. Most machines now have a spares inventory Kardex, machine history card, and schedule of preventive maintenance, and most machines are serviced using preventive maintenance. These procedures have significantly reduced unscheduled breakdowns and wear and tear on spare parts.

### III. Identification of Possible Causes for Batches Outside Specified Ranges

At the time of the visit, 18 batches had tested to be outside the specified ranges, and several more batches had been produced but had not been tested because of the QC backlog. Since then, 13 more batches have been outside the specified ranges, totaling 31 batches. (See Attachment A for the statistical analysis and distribution of results of most of these batches).

At PATH's recommendation, production was stopped until the possible causes of the batches outside the specified ranges were identified/evaluated, using cause and effect analysis, and corrective actions taken to remove the causes. Cause and effect analysis was performed to identify the most likely causes that contributed to the batches being outside the specified ranges (see diagram in Attachment B).

The observations and recommendations of the most critical causes identified are listed below:

1. Excessive ORS dust is generated during the form-fill-seal (FFS) operation which may blend in the mix during filling and cause uneven material mix. Therefore, the Torit dust extractor should be installed before any more batches are produced.
2. The speed of the FFS machine was increased in March 1992, which may have contributed to the 31 batches being outside the specified ranges. Based on previous production records, Medipharm should set the speed of the FFS machine to coincide with the speed at which production batches were within the specified ranges.

3. Polyethylene (PE) liners should be placed in the new stainless steel drums to prevent moisture build-up which may affect the flow pattern of the bulk powder and cause uneven particle distribution. These liners will also protect the bulk powder for long holding periods because raw materials may react with containers under high moisture and temperature conditions.
4. Medipharm should always check to make sure that the correct pulleys are used on the Fitzpatrick mill to generate the correct rpm.
5. Currently, if one bag of raw materials is found to have moisture content above the minimum, Medipharm dries all the bags. If sodium citrate is dried more than necessary and its moisture content drops below a certain level, it increases the content of the sodium citrate, which may affect the pH and sodium content and the osmolality.

Just before milling, Medipharm should test every bag for moisture content, and make the decision whether to dry the contents based on the result of the moisture content tests. This will also save on energy costs.

6. According to WHO/CDD/SER 85.8, glucose must not contain more than one percent moisture content; however, with the second consignment of raw materials in February, glucose containing less than one percent moisture looked and felt damp on visual and tactile inspection. Therefore, the moisture content specification limits were tightened, and currently, if glucose contains more than 0.4 percent moisture, it is dried.

Medipharm should not over-dry the glucose because some moisture is required for the bonding/mixing of the material.

7. Often times, bulk powder is mixed and stored for as much as seven to ten days prior to being packed into sachets. Over the weekend, the air conditioning is not turned on, and thus, temperature and humidity will rise, which in turn can increase the moisture content of the bulk powder if it is not properly sealed.

Medipharm should check for an increase in the moisture content of the bulk powder that is stored over the weekend. Medipharm should also make sure that the drums in which the materials are stored are tightly sealed and that the PE liners do not have pinholes.

8. Medipharm should closely monitor the timing of the mixer to ensure that mixing time does not vary from the validated time. The automatic timer should be installed, and if there is a problem in installation, PATH should be informed of the specifics of the problem.

Once the causes are removed, Medipharm will mix and fill one batch. If the batch passes after testing the final products, Medipharm will produce ten more batches, making sure to test each batch for final products before producing the next batch.

#### IV. Review of Batches Outside the Specified Ranges

Seven batches (five within the specified ranges and two outside the specified ranges) consisting of eight sachets each were collected and sent to an independent reference lab for validation. (See Attachment C for the descriptive statistics of the assay results of the seven batches tested by Medipharm and the reference lab).

The results in Attachment C indicate that Medipharm's data are inconsistent and that the assay results of the Medipharm QC lab may have errors of precision and accuracy. The following points are to be noted in the comparison of the assay values:

1. For batch number 203034, Medipharm's lab found 6 values of sodium and 9 values of chloride to be outside the specified ranges. For batch number 203064, Medipharm found 6 values of sodium, 7 values of potassium, and 2 values of chloride to be outside the specified ranges. The reference lab found all values of all five elements for both of these batches to be within the specified ranges. In addition, the reference lab found 100 percent of the sodium values distributed around the mean interval in 6 out of 7 batches; 88 percent of values in the seventh batch were in the mean interval.
2. Batch number 203064, sample number 12, when tested by Medipharm shows 59.83 mmol/l to be the low value for sodium and 13.51 mmol/l to be the low value for potassium. When balancing the materials, the value of chloride for sample number 12 should be as proportionately low as the sodium and potassium values. The value of chloride should have been in the range of 53.6 mmol/l, but was assayed by Medipharm's QC lab to be 74.65 mmol/l.
3. Medipharm's calculated values for citrate are unusually low and do not correspond with the values of sodium, potassium, and chloride (which are used to calculate citrate). Only 1 out of 20 values were found to be within the specified ranges. For the reference lab, the calculations more closely match the assay results of the values of sodium, potassium, and chloride; 7 out of 8 values are within the specified ranges.
4. If the ORS bulk powder for this batch is not homogeneous, some of the assay values would have been high and some would have been low. However, all the values of sodium and potassium, when tested at Medipharm's QC lab, are low, which further substantiates the suspicion that the assay results produced by Medipharm's QC lab are inaccurate and imprecise.

V. Troubleshooting QC Equipment, Methods, and Procedures

- A. Medipharm's QC lab has depleted its raw material reference standards; hence, unknown reference materials are being used as standards. It is recommended that Medipharm purchase small amounts of analytical grade sodium chloride, potassium chloride, sodium citrate, and glucose to make secondary reference standards as stated in the PATH QA Policies and Guidelines Manual. Medipharm should send this procedure for creating the secondary reference standards to PATH for review and comments.
- B. Currently, one sachet is used to test sodium, potassium, and chloride, and another sachet is used to test glucose, which does not permit evaluation of the assays by theoretical calculation. It is, therefore, recommended that Medipharm investigate the possibility of using the same sachet for testing all five elements.
- C. The Medipharm QC lab's assay variations are most likely a result of precision and accuracy errors. Sections 02-01, 02-02, 02-03, and 02-04 of the PATH QC Manual provide guidelines to eliminate precision and accuracy errors.
- D. During the February 1992 visit, PATH provided comments on Medipharm's "chloride determination protocol by ion-analyzer" through its letter of September 3, 1991. Medipharm was to review these comments and send comments or queries to PATH. Medipharm is advised to do this urgently. It is also recommended that Medipharm change the electrodes after one year's use.
- E. Since the assay results are most likely neither precise nor accurate, it is recommended not to retest any batch unless there is a known error in testing.
- F. After reviewing the results of the batches that are outside the specified ranges, PATH recommends that Medipharm change the sampling technique of the final products for the next 40 consecutive batches per the following protocol (a flowchart of this method is presented in Attachment D).

During this procedure, it is not necessary that Medipharm carry out the current in-process testing for sodium and potassium.

- 1. As the sachets are being formed-filled-sealed, pick 16 subgroups of 6 sachets for a total of 96 sachets. For example, if a batch is produced in 4 hours, or 240 minutes, pick 6 sachets at an interval of 15 minutes each.
- 2. Collect the sachets that are produced during each interval in separate boxes. Mark each box clearly as "Subgroup 1" or "Subgroup 2," etc.

3. Number the sachets picked for sampling, in sequence, i.e., 1A, 1B, 1C, 1D, 1E, and 1F for the first subgroup picked at the beginning of the production, and, 16A, 16B, 16C, 16D, 16E, and 16F for the sixteenth subgroup picked at the end of the production.
4. Test the first sachet from each subgroup (16 sachets—1A..16A), which will leave 80 sachets. If all 16 sachets are within the specified ranges, return the remaining 80 sachets to the batch, and release the batch.
5. If any of the 16 sachets are outside the specified ranges, test the second sachet from each subgroup (16 sachets—1B..16B), which will leave 64 sachets. If all 16 sachets are within the specified ranges, return the remaining 64 sachets to the batch, and release the batch.
6. If any of the 16 sachets are outside the specified ranges, test the third and fourth sachets from each subgroup (32 sachets—1C..16C + 1D..16D), which will leave 32 sachets. If all 32 sachets are within the specified ranges, return the remaining 32 sachets to the batch, and release the batch.
7. Review the pattern of the subgroups of samples that are within and outside the specified ranges. If some subgroups have passed steps 1, 2, and 3 (see Attachment D), then release those subgroups EXCEPT for the subgroups immediately preceding and following the subgroups that have failed to pass the tests. For example, if subgroups 1-8 and 10-16 passed steps 1, 2 and 3, but subgroup 9 failed, release subgroups 1-7, and quarantine subgroups 8, 9, and 10 (subgroup 8 preceded and subgroup 10 followed subgroup 9 which failed). This procedure is in reference to PATH QA Policies and Guideline Policy #01-03, "Partial Batch Release."
8. Return all the sample sachets from the released batches to the batch (each respective box) and quarantine the subgroups that are outside the specified ranges.

Collect the fifth sachet from each of the subgroups that are outside the specified ranges and send them to an independent reference lab for testing. Keep the sixth sachet of each subgroup as a reference sample.

#### G. Particle Size

It is possible that excessive particle size variation is a cause of the batches that are outside the specified ranges. In order to analyze the particle size of the ingredients, the following experiment was carried out during the visit.

One kg of mixed bulk powder was manually passed through screens of varying sizes (results of this experiment are provided in Attachment E). In addition, each of the four ingredients was passed through the same screens (see Attachment F for the results). The following chart summarizes the observations.

	% Particles Larger than 0.180 mm	% Particles Smaller than 0.125 mm
Bulk Powder	55	25
Sodium Chloride	94	3
Potassium Chloride	88	2
Glucose	46	29
Sodium Citrate	65	20

In conclusion, the particles sizes for sodium chloride, potassium chloride, and sodium citrate were found to be in the normal ranges. The glucose particles, however, were too fine (more than 29 percent of the particles are smaller than 0.125 mm). In order to improve the mixing and flow, glucose particles should be approximately 1 mm in size. To achieve this, glucose should be milled with a 2-5 mm screen at medium speed. This method should be validated before producing a batch.

This underscores the need to ensure that glucose ordered and delivered in the next consignment be crystalline/granular, not powder. It is recommended that a reminder reiterating this request be sent to the vendor with whom the order has been placed.

#### H. Milling of Tri-Sodium Citrate Dihydrate

In Catherine Bitali's report of July 7, 1992, regarding the cause and effect analysis, the action plan noted in 2.b. calls for milling tri-sodium citrate at high speed and at medium speed using a 5-mm screen, which will reduce the particle size.

Milling the tri-sodium citrate dihydrate with a 5-mm screen will not reduce the particle size. PATH recommends that a 1-mm screen be used to reduce the particle size to smaller than 1 mm.

PATH also recommends that Medipharm's "Raw Material Milling and Sifting Record and Procedure Using Fitzpatrick Machine" form include a diagram that illustrates the pulley combinations for low, medium, and high speed of the mill, which is done by repositioning the belts on the multi-step flywheel and motor sheaves. This will reduce the possibility of error in setting the milling speeds.

## VI. Removal of Causes that Contribute to Low Productivity and Quality

Medipharm's attempt to remove the causes, identified during the last visit, of low productivity and quality was impaired because of its serious financial crisis. Medipharm is facing a financial crisis because it has not received the anticipated cash from the UNICEF purchase of excess capacity ORS and because its capital is tied up.

Medipharm is implementing some aspects of the action plan to remove the causes, but because of the lack of management action, the results are not being taken to fruition. For example, Medipharm production staff are filling out the in-process forms, but they are not utilizing the benefit of the data. The In-Process Weight Variation form is not filled out accurately, and the production supervisor and manager are still not involved in the filling process. Most importantly, the recommendation made in the last trip report stating:

*"Within 15 minutes of the completion of each batch, the production and packaging technicians, production supervisor, and QC and production managers must review the in-process data; the same should be done as soon as the assay results are known and plotted. Data interpretation and evaluation should not take, in most cases, more than 5-10 minutes"*

has not been implemented. Because this very important function was not performed, the in-process data were not reviewed in a timely manner to either determine a trend or to convene a production/QC/higher management meeting to plot a course of action, even after 12 batches had tested to be outside the specified ranges. As a result, 31 batches were mixed/produced that were outside the specified ranges.

## VII. Equipment Installation

The Torit dust extractor and voltage stabilizer could not be installed because of Medipharm's lack of funds. As suggested by PATH, it was decided that Medipharm's technician, rather than the outside consultant as originally planned, will install the dust extractor using the installation drawings provided by PATH to Medipharm.

Similarly, it was decided that Medipharm's new electrician is capable of also installing the electrical wiring for the QC lab so that the voltage stabilizer can be also installed.

## VIII. Preventive Maintenance Program

Medipharm has made substantial progress in the preventive maintenance program. Medipharm has added a very capable technician,

Mr. Jacob Muasa, to this program and has hired a qualified electrician. The technician performs most services using the preventive maintenance schedules developed for each machine, and while servicing, also fills out the machine history cards accurately. Most services are performed according to schedules following PATH's principle of servicing the machine before it breaks down so that production time is not lost and spare parts are not worn out from lack of lubrication and adjustment.

A spare parts inventory Kardex for most machines has been made; however, this system is at a crucial stage of implementation because minimum order quantities and the frequency of breakdowns must be calculated from the machine history cards, and the parts must be ordered. Medipharm has depleted most of its spare parts that were acquired for them with the machines. There is a long lead time for spare parts in Uganda (3-6 months) because of the foreign exchange requirements.

#### IX. Inventory Management

The materials management department has been established, and the first draft of the production and inventory control work sheet that computes the production planning and materials requirements of products for the future 12-22 months was developed. However, the materials manager, Justin Seguya, is also involved with other functions in the factory, and as a result, could not troubleshoot the planning work sheet to the extent that was required. The draft work sheet indicated that Medipharm materials management has not yet utilized the benefit of this system. In addition, some numbers are computed incorrectly. Since this was the first work sheet worked out or the first time that this concept has been applied, after a few reviews and critiques, Medipharm is expected to utilize the full benefit of this system.

#### X. Meetings with USAID/Kampala

Two meetings were held with USAID/Kampala representative, Mr. David Puckett. During the first of these meetings, revisions to a proposal for ongoing technical assistance in raw material procurement, ORS production, quality control, and marketing were discussed in detail. A revised proposal will be sent by PATH to USAID/Kampala in July.

A meeting with USAID/Kampala was conducted on Thursday, May 28. PATH presented data on problems encountered with quality control procedures and the specific actions being taken to address these concerns.

Mr. Puckett was informed that Medipharm is at a critical period in achieving sustainability and will require additional assistance in

quality control as well as marketing in order to create sustainable ORS production for both the public and private sectors.

PATH will provide the additional technical assistance to Medipharm, pending the availability of funds from USAID/Kampala.

KMR01072

MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 201007

SAMPLE NUMBER	Na		K		Cl	Citrate (calc)	Glucose
	Bulk	Product	Bulk	Product	Product	Product	Product
1	90.17	90.81	20.10	20.30	82.65	9.49	112.05
2	93.54	87.85	19.37	19.46	81.16	8.72	113.09
3	92.19	76.68	20.10	18.92	69.09	8.84	111.00
4		88.16		19.19	84.35	7.67	112.05
5		88.66		20.40	81.70	9.12	117.28
6		88.78		20.34	80.63	9.50	112.05
7		88.65		20.47	81.21	9.30	112.05
8		89.46		20.43	82.17	9.24	114.14
9		76.17		19.96	67.68	9.48	115.19
10		87.62		20.22	82.19	8.55	112.05
11		89.58		19.38	81.79	9.06	112.05
12		88.22		19.42	81.90	8.58	114.14
13		88.46		20.13	78.48	10.04	115.19
14		87.47		20.25	80.48	9.08	112.05
15		86.98		19.80	81.75	8.34	112.05
16		77.01		18.70	64.81	10.30	112.05
17		89.87		19.68	83.33	8.74	115.19
18		89.05		19.60	82.81	8.61	113.09
19		86.20		20.31	79.05	9.15	113.09
20		89.41		19.36	80.33	9.48	109.95
SPEC(MIN-MAX)					80.0(74.4-85.6)	9.9(9.2-10.6)	111.0(103.2-118.8)
SUM	275.90	1735.09	59.57	396.32	1587.56	181.29	2259.80
MINIMUM	90.17	76.17	19.37	18.70	64.81	7.67	109.95
MAXIMUM	93.54	90.81	20.10	20.47	84.35	10.30	117.28
AVERAGE	91.97	86.75	19.86	19.82	79.38	9.06	112.99
STD	1.3848	4.3786	0.3441	0.5271	5.3281	0.5806	1.6845
RSDX	1.51%	5.05%	1.73%	2.66%	6.71%	6.40%	1.49%
FREQUENCY DISTRIBUTION							
>= -7% and < -2%	0.00	4.00	1.00	9.00	0.00	6.00	0.00
>= -2% and < 2%	1.00	13.00	2.00	11.00	7.00	1.00	14.00
> 2% and <= 5%/7%	2.00	0.00	0.00	0.00	10.00	1.00	6.00
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	3.00	17.00	3.00	20.00	17.00	8.00	20.00
>= -7% and < -2%	0.00%	23.53%	33.33%	45.00%	0.00%	75.00%	0.00%
>= -2% and < 2%	33.33%	76.47%	66.67%	55.00%	41.18%	12.50%	70.00%
> 2% and <= 5%/7%	66.67%	0.00%	0.00%	0.00%	58.82%	12.50%	30.00%

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2

MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 202033

SAMPLE NUMBER	Na Bulk	Na Product	K Bulk	K Product	Cl Product	Citrate (calc) Product	Glucose Product
1	84.31	89.17	20.47	19.72	83.06	8.61	109.95
2	88.20	88.41	20.10	19.69	84.26	7.95	106.81
3	93.39	91.30	21.20	19.74	80.79	10.08	108.91
4		89.97		19.91	82.15	9.24	112.05
5		88.70		19.55	80.81	9.15	108.91
6		90.84		19.79	82.32	9.44	114.41
7		88.75		19.71	82.13	8.78	109.95
8		87.29		19.67	79.62	9.11	104.72
9		90.44		19.70	83.69	8.82	111.00
10		91.87		19.87	83.83	9.30	108.91
11		92.33		20.06	82.70	9.90	109.95
12		89.77		20.08	81.43	9.47	108.91
13		100.26		21.01	90.27	10.33	109.95
14		96.03		20.33	85.35	10.34	107.86
15		90.61		19.97	82.00	9.53	109.95
16		92.30		20.20	83.27	9.74	108.91
17		92.42		20.31	83.20	9.84	105.76
18		90.34		19.91	83.44	8.94	111.00
19		97.33		20.66	87.32	10.22	108.91
20		91.13		19.80	82.30	9.54	109.95
<b>SPEC(MIN-MAX)</b>					<b>80.0(74.4-85.6)</b>	<b>9.9(9.2-10.6)</b>	<b>111.0(103.2-118.8)</b>
<b>SUM</b>	265.90	1829.26	61.77	399.68	1663.94	188.33	2186.77
<b>MINIMUM</b>	84.31	87.29	20.10	19.55	79.62	7.95	104.72
<b>MAXIMUM</b>	93.39	100.26	21.20	21.01	90.27	10.34	114.41
<b>AVERAGE</b>	88.63	91.46	20.59	19.98	83.20	9.42	109.34
<b>STD</b>	3.7195	3.0890	0.4570	0.3572	2.3067	0.6050	2.0574
<b>RSD%</b>	4.20%	3.38%	2.22%	1.79%	2.77%	6.43%	1.88%
<b>FREQUENCY DISTRIBUTION</b>							
>= -7% and < -2%	1.00	1.00	0.00	3.00	0.00	6.00	4.00
>= -2% and < 2%	1.00	11.00	2.00	15.00	4.00	4.00	15.00
> 2% and <= 5%/7%	1.00	5.00	1.00	2.00	14.00	3.00	1.00
	----	----	----	----	----	----	----
	3.00	17.00	3.00	20.00	18.00	13.00	20.00
>= -7% and < -2%	33.33%	5.88%	0.00%	15.00%	0.00%	46.15%	20.00%
>= -2% and < 2%	33.33%	64.71%	66.67%	75.00%	22.22%	30.77%	75.00%
> 2% and <= 5%/7%	33.33%	29.41%	33.33%	10.00%	77.78%	23.08%	5.00%

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11

MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 203043

SAMPLE NUMBER	Na		K		Cl Product	Citrate (calc) Product	Glucose Product
	Bulk	Product	Bulk	Product			
1	89.50	96.27	18.70	21.05	91.65	8.56	111.00
2	90.86	86.72	19.02	20.13	81.10	8.58	107.86
3	97.58	87.48	19.38	20.53	80.77	9.08	111.00
4		91.56		20.13	82.41	9.76	106.81
5		79.14		19.71	68.46	10.13	113.09
6		89.67		19.48	81.28	9.29	109.95
7		91.84		20.71	81.40	10.38	109.95
8		90.54		20.71	82.33	9.64	109.95
9		102.64		21.38	98.33	8.56	112.05
10		89.79		20.31	83.63	8.82	108.91
11		90.02		21.27	83.05	9.41	108.91
12		89.03		20.42	84.55	8.30	111.00
13		95.23		21.15	94.31	7.36	107.86
14		90.09		20.46	84.56	8.66	111.00
15		95.09		21.21	92.38	7.97	108.91
16		88.72		20.36	84.77	8.10	108.91
17		88.94		21.31	87.12	7.71	108.91
18		89.24		19.67	86.19	7.57	109.95
19		95.72		21.21	95.60	7.11	109.95
20		92.00		20.38	86.70	8.56	109.95
SPEC(MIN-MAX)					80.0(74.4-85.6)	9.9(9.2-10.6)	111.0(103.2-118.8)
SUM	277.94	1819.73	57.10	411.58	1710.59	173.55	2195.92
MINIMUM	89.50	79.14	18.70	19.48	68.46	7.11	106.81
MAXIMUM	97.58	102.64	19.38	21.38	98.33	10.38	113.09
AVERAGE	92.65	90.99	19.03	20.58	85.53	8.68	109.80
STD	3.5323	4.5563	0.2778	0.5668	6.4500	0.8827	1.4527
RSDX	3.81%	5.01%	1.46%	2.75%	7.54%	10.17%	1.32%
FREQUENCY DISTRIBUTION							
>= -7% and < -2%	0.00	2.00	3.00	2.00	0.00	3.00	3.00
>= -2% and < 2%	2.00	9.00	0.00	8.00	4.00	1.00	17.00
> 2% and <= 5%/7%	0.00	3.00	0.00	10.00	7.00	2.00	0.00
	-----	-----	-----	-----	-----	-----	-----
	2.00	14.00	3.00	20.00	11.00	6.00	20.00
>= -7% and < -2%	0.00%	14.29%	100.00%	10.00%	0.00%	50.00%	15.00%
>= -2% and < 2%	100.00%	64.29%	0.00%	40.00%	36.36%	16.67%	85.00%
> 2% and <= 5%/7%	0.00%	21.43%	0.00%	50.00%	63.64%	33.33%	0.00%

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22

MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 203046

SAMPLE NUMBER	Na			K			Cl Product	Citrate (calc) Product	Glucose Product
	Bulk	In-process	Product	Bulk	In-process	Product			
1	88.85	93.53	88.48	19.02	19.43	21.19	81.90	9.26	109.95
2	91.46	92.14	89.06	19.38	20.54	20.50	83.84	8.60	108.91
3	91.46	93.45	90.32	19.02	19.73	19.84	81.44	9.57	108.91
4		90.67	76.21		18.34	20.33	62.89	11.22	111.00
5		89.14	90.65		18.75	20.66	80.33	10.33	111.00
6		90.63	92.34		20.28	20.74	80.66	10.81	107.86
7		93.92	71.83		19.73	20.20	58.01	11.34	111.00
8		90.35	89.20		21.36	20.84	79.63	10.14	109.95
9		89.46	89.28		20.09	21.12	81.17	9.74	109.95
10		90.46	87.74		19.71	20.23	80.09	9.29	109.95
11		93.22	92.59		18.81	21.44	79.16	11.62	109.95
12		98.98	87.62		18.06	20.56	79.98	9.40	109.95
13		85.52	89.82		20.09	19.37	79.60	9.86	109.95
14			89.53			18.21	81.19	8.85	109.95
15			91.41			19.51	81.01	9.97	112.05
16			92.70			21.03	81.70	10.68	118.33
17			92.84			20.35	81.58	10.54	109.95
18			92.68			21.29	80.06	11.30	109.95
19			91.82			21.21	80.56	10.82	117.28
20			93.75			20.23	80.09	11.30	111.00
SPEC(MIN-MAX)	89.5(83.2-94.0)			20.1(18.7-21.5)			80.0(74.4-85.6)	9.9(9.2-10.6)	111.0(103.2-118.8)
SUM	271.77	1191.47	1779.87	57.42	254.92	408.94	1574.89	204.64	2216.84
MINIMUM	88.85	85.52	71.83	19.02	18.06	18.21	58.01	8.60	107.86
MAXIMUM	91.46	98.98	93.75	19.38	21.36	21.44	83.84	11.62	118.33
AVERAGE	90.59	91.65	88.99	19.14	19.61	20.45	78.74	10.23	110.84
STD	1.2304	3.0652	5.3387	0.1697	0.8903	0.7593	6.2301	0.8772	2.4839
RSD%	1.36%	3.34%	6.00%	0.89%	4.54%	3.71%	7.91%	8.57%	2.24%
FREQUENCY DISTRIBUTION									
>= -7% and < -2%	0.00	1.00	1.00	3.00	3.00	2.00	0.00	4.00	1.00
>= -2% and < 2%	1.00	6.00	9.00	0.00	6.00	6.00	15.00	3.00	17.00
> 2% and <= 5%/7%	2.00	5.00	8.00	0.00	2.00	11.00	3.00	3.00	2.00
	-----	-----	-----	-----	-----	-----	-----	-----	-----
	3.00	12.00	18.00	3.00	11.00	19.00	18.00	10.00	20.00
>= -7% and < -2%	0.00%	8.33%	5.56%	100.00%	27.27%	10.53%	0.00%	40.00%	5.00%
>= -2% and < 2%	33.33%	50.00%	50.00%	0.00%	54.55%	31.58%	83.33%	30.00%	85.00%
> 2% and <= 5%/7%	66.67%	41.67%	44.44%	0.00%	18.18%	57.89%	16.67%	30.00%	10.00%

13

MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 203050

SAMPLE NUMBER	Na			K			Cl Product	Citrate (calc) Product	Glucose Product
	Bulk	In-process	Product	Bulk	In-process	Product			
1	89.50	92.45	89.99	18.96	20.47	19.62	84.07	8.51	109.95
2	86.11	92.20	89.15	20.48	20.50	19.81	84.48	8.16	111.00
3	90.18	92.86	87.29	19.72	20.65	19.69	82.21	8.26	111.00
4		89.40	85.86		20.84	19.52	82.37	7.67	109.95
5		91.10	89.51		20.31	19.67	83.95	8.41	109.95
6		91.66	92.52		20.05	19.58	84.19	9.30	111.00
7		88.66	92.92		19.56	20.04	83.95	9.67	105.76
8		88.94	92.30		19.48	19.61	82.41	9.83	109.95
9		90.40	91.31		20.69	19.61	81.31	9.87	109.95
10		89.82	93.10		19.78	19.78	81.95	10.31	108.91
11		90.15	92.61		20.35	19.62	82.58	9.88	108.91
12		94.59	96.00		21.47	20.10	83.29	10.94	109.95
13		77.12	92.35		19.15	19.53	80.14	10.58	109.95
14			91.52			19.73	81.75	9.83	109.95
15			97.08			19.80	86.02	10.29	109.95
16			64.67			16.31	57.96	7.67	111.00
17			88.55			19.75	82.31	8.66	109.95
18			67.34			16.94	59.29	8.33	115.19
19			88.52			19.88	81.71	8.90	109.95
20			96.04			20.82	89.78	9.03	109.95
SPEC(MIN-MAX)	89.5(83.2-94.0)			20.1(18.7-21.5)			80.0(74.4-85.6)	9.9(9.2-10.6)	111.0(103.2-118.8)
SUM	265.79	1169.35	1778.63	59.16	263.30	389.41	1615.72	184.10	2202.17
MINIMUM	86.11	77.12	64.67	18.96	19.15	16.31	57.96	7.67	105.76
MAXIMUM	90.18	94.59	97.08	20.48	21.47	20.82	89.78	10.94	115.19
AVERAGE	88.60	89.95	88.93	19.72	20.25	19.47	80.79	9.21	110.11
STD	1.7801	4.0517	8.1570	0.6205	0.6111	0.9939	7.6493	0.9540	1.5982
RSDX	2.01%	4.50%	9.17%	3.15%	3.02%	5.10%	9.47%	10.36%	1.45%
FREQUENCY DISTRIBUTION									
>= -7% and < -2%	1.00	0.00	2.00	1.00	3.00	9.00	0.00	2.00	1.00
>= -2% and < 2%	2.00	7.00	5.00	2.00	6.00	8.00	2.00	4.00	18.00
> 2% and <= 5%/7%	0.00	4.00	8.00	0.00	4.00	1.00	14.00	3.00	1.00
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	3.00	11.00	15.00	3.00	13.00	18.00	16.00	9.00	20.00
>= -7% and < -2%	33.33%	0.00%	13.33%	33.33%	23.08%	50.00%	0.00%	22.22%	5.00%
>= -2% and < 2%	66.67%	63.64%	33.33%	66.67%	46.15%	44.44%	12.50%	44.44%	90.00%
> 2% and <= 5%/7%	0.00%	36.36%	53.33%	0.00%	30.77%	5.56%	87.50%	33.33%	5.00%

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MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 204070

SAMPLE NUMBER	Na		K		Glucose Product
	Bulk	In-process	Bulk	In-process	
1	89.50	99.84	18.98	21.63	109.96
2	89.50	88.16	19.73	19.87	109.96
3	92.17	88.54	18.70	19.89	109.96
4		89.68		20.30	109.96
5		86.78		20.36	109.96
6		86.22		20.07	108.93
7		87.64		20.20	108.93
8		88.95		20.18	109.96
9		88.84		20.47	109.96
10		88.93		20.54	109.96
11		83.84		19.88	112.04
12		90.18		20.62	109.96
13		99.27		21.72	111.00
14					109.96
15					112.04
16					113.07
17					
18					
19					
20					

SPEC(MIN-MAX)                      89.5(83.2-94.0)                      20.1(18.7-21.5)111.0(103.2-118.8)

SUM	271.17	1166.87	57.41	265.73	1765.61
MINIMUM	89.50	83.84	18.70	19.87	108.93
MAXIMUM	92.17	99.84	19.73	21.72	113.07
AVERAGE	90.39	89.76	19.14	20.44	110.35
STD	1.2587	4.4672	0.4348	0.5769	1.0922
RSD%	1.39%	4.98%	2.27%	2.82%	0.99%

FREQUENCY DISTRIBUTION

>= -7% and < -2%	0.00	4.00	2.00	0.00	0.00
>= -2% and < 2%	2.00	7.00	1.00	9.00	16.00
> 2% and <= 5%/7%	1.00	0.00	0.00	2.00	0.00
-----	-----	-----	-----	-----	-----
	3.00	11.00	3.00	11.00	16.00
>= -7% and < -2%	0.00%	36.36%	66.67%	0.00%	0.00%
>= -2% and < 2%	66.67%	63.64%	33.33%	81.82%	100.00%
> 2% and <= 5%/7%	33.33%	0.00%	0.00%	18.18%	0.00%

75

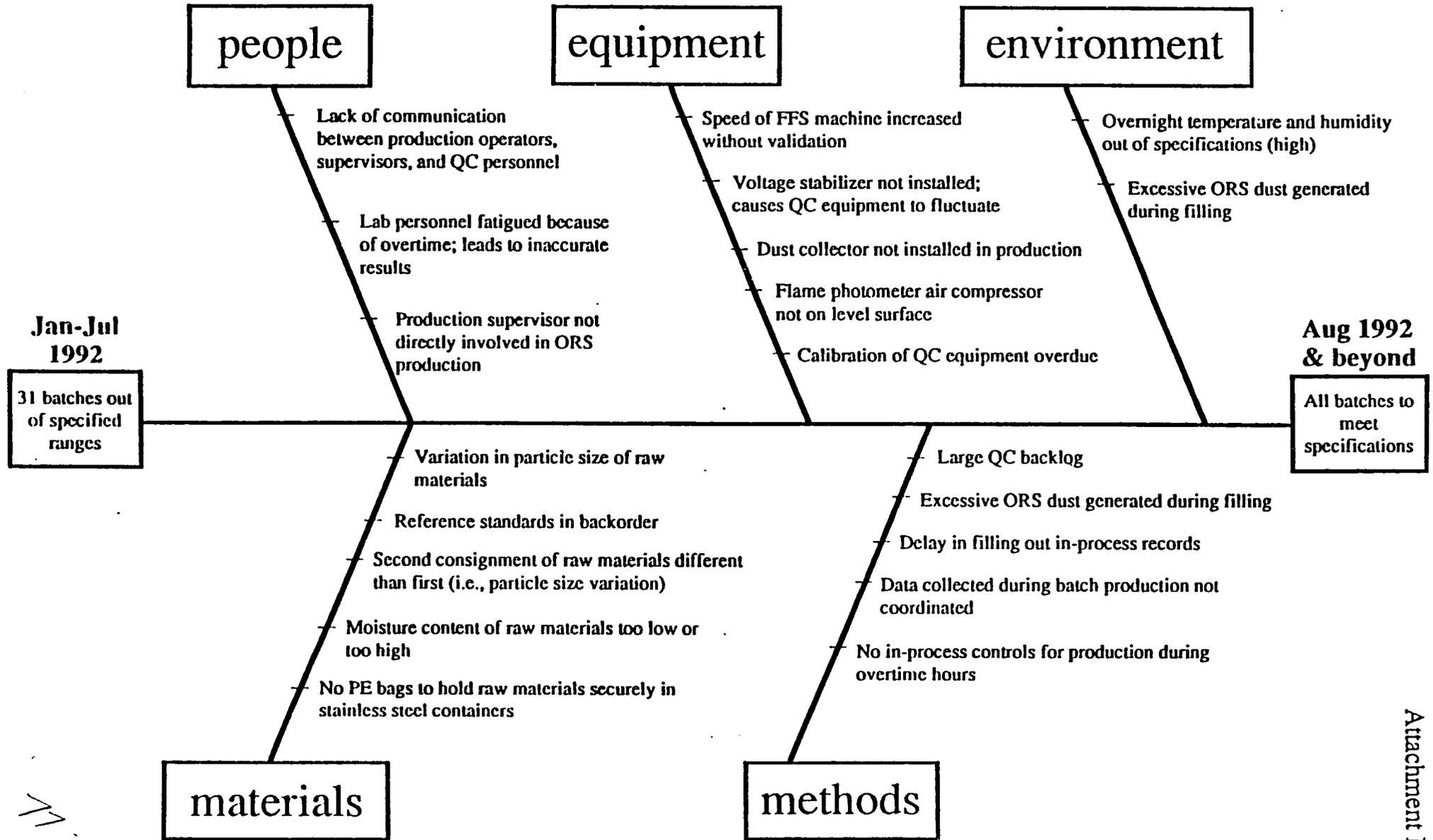
MEDIPHARM - UGANDA LAB ANALYSIS RESULTS: BATCH NO. 204078

SAMPLE NUMBER	Na	Na	K	K	Cl	Citrate (calc)	Glucose
	Bulk	Product	Bulk	Product	Product	Product	Product
1	88.81	80.94	19.71	19.37	76.37	7.98	114.14
2	94.00	94.25	20.10	21.15	90.69	8.24	109.95
3	84.64	93.60	19.71	20.79	88.55	8.61	109.95
4		91.84		20.10	84.03	9.30	105.76
5		93.08		20.45	83.62	9.97	118.33
6		93.08		20.45	84.57	9.65	108.91
7		81.17		19.00	72.32	9.28	117.28
8		97.76		21.35	92.18	8.98	108.91
9		87.00		19.89	80.79	8.70	111.00
10		97.15		20.86	90.99	9.01	105.76
11		92.71		20.00	82.30	10.14	108.91
12		97.68		21.26	87.20	10.58	115.19
13		94.64		20.74	85.65	9.91	107.86
14		90.45		19.64	81.73	9.45	113.09
15		84.66		18.36	77.67	8.45	111.00
16		88.73		19.64	82.33	8.68	115.19
17		95.63		21.10	89.84	8.96	105.76
18		93.41		21.55	85.10	9.95	111.00
19		91.43		20.69	82.33	9.93	112.05
20		78.93		19.06	65.81	10.73	105.76
SPEC(MIN-MAX)					80.0(74.4-85.6)	9.9(9.2-10.6)	111.0(103.2-118.8)
SUM	267.45	1818.14	59.52	405.45	1664.07	186.50	2215.80
MINIMUM	84.64	78.93	19.71	18.36	65.81	7.98	105.76
MAXIMUM	94.00	97.76	20.10	21.55	92.18	10.73	118.33
AVERAGE	89.15	90.91	19.84	20.27	83.20	9.33	110.79
STD	3.8288	5.4928	0.1838	0.8632	6.3514	0.7508	3.7264
RSDX	4.29%	6.04%	0.93%	4.26%	7.63%	8.05%	3.36%
FREQUENCY DISTRIBUTION							
>= -7% and < -2%	1.00	2.00	0.00	5.00	2.00	4.00	5.00
>= -2% and < 2%	1.00	2.00	3.00	5.00	1.00	4.00	10.00
> 2% and <= 5%/7%	1.00	7.00	0.00	8.00	8.00	2.00	5.00
	-----	-----	-----	-----	-----	-----	-----
	3.00	11.00	3.00	18.00	11.00	10.00	20.00
>= -7% and < -2%	33.33%	18.18%	0.00%	27.78%	18.18%	40.00%	25.00%
>= -2% and < 2%	33.33%	18.18%	100.00%	27.78%	9.09%	40.00%	50.00%
> 2% and <= 5%/7%	33.33%	63.64%	0.00%	44.44%	72.73%	20.00%	25.00%

LAUG0089.WQ1

76

# Cause and Effect Analysis (Fishbone Diagram) Batches Outside Specified Ranges



MEDIPHARM - UGANDA LAB VALIDATION RESULTS: BATCH NO. 203034

SAMPLE NUMBER	Na	Na	K	K	Cl	Cl	Citrate (calc)	Citrate	Citrate (calc)	Glucose
	Medipharm	Ref. Lab	Medipharm	Ref. Lab	Medipharm	Ref. Lab	Medipharm	Ref. Lab	Ref. Lab	Ref. Lab
1	96.27	89.90	21.05	20.50	91.65	80.00	8.56	9.90	10.13	111.50
2	86.72	89.90	20.13	20.50	81.10	82.00	8.58	9.80	9.47	111.50
3	87.48	89.10	20.53	20.90	80.77	79.00	9.08	10.10	10.33	111.50
4	91.56	88.70	20.13	20.50	82.41	80.00	9.76	10.10	9.73	113.50
5	79.14	88.30	19.71	20.90	68.46	79.00	10.13	9.90	10.07	111.50
6	89.67	88.60	19.48	20.90	81.28	81.00	9.29	9.80	9.50	112.00
7	91.84	88.20	20.71	20.70	81.40	82.00	10.38	9.40	8.97	111.00
8	90.54	89.30	20.71	20.70	82.33	82.00	9.64	9.80	9.33	107.50
9	102.64		21.38		98.33		8.56			
10	89.79		20.31		83.63		8.82			
11	90.02		21.27		83.05		9.41			
12	89.03		20.42		84.55		8.30			
13	95.23		21.15		94.31		7.36			
14	90.09		20.46		84.56		8.66			
15	95.09		21.21		92.38		7.97			
16	88.72		20.36		84.77		8.10			
17	88.94		21.31		87.12		7.71			
18	89.24		19.67		86.19		7.57			
19	95.72		21.21		95.60		7.11			
20	92.00		20.38		86.70		8.56			
SPEC(MIN-MAX)	89.5(83.2-94.0)		20.1(18.7-21.5)		80.0(74.4-85.6)		9.9(9.2-10.6)			
SUM	1819.73	712.00	411.58	165.60	1710.59	645.00	173.55	78.80	77.53	890.00
MINIMUM	79.14	88.20	19.48	20.50	68.46	79.00	7.11	9.40	8.97	107.50
MAXIMUM	102.64	89.90	21.38	20.90	98.33	82.00	10.38	10.10	10.33	113.50
AVERAGE	90.99	89.00	20.58	20.70	85.53	80.63	8.68	9.85	9.69	111.25
STD	4.5563	0.6225	0.5668	0.1732	6.4500	1.2183	0.8827	0.2062	0.4304	1.5811
RSDX	5.01%	0.70%	2.75%	0.84%	7.54%	1.51%	10.17%	2.09%	4.44%	1.42%
FREQUENCY DISTRIBUTION										
>= -7% and < -2%	2.00	0.00	2.00	0.00	0.00	0.00	3.00	1.00	3.00	1.00
>= -2% and < 2%	9.00	8.00	8.00	3.00	4.00	5.00	1.00	5.00	2.00	6.00
> 2% and <= 5%/7%	3.00	0.00	10.00	5.00	7.00	3.00	2.00	2.00	2.00	1.00
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	14.00	8.00	20.00	8.00	11.00	8.00	6.00	8.00	7.00	8.00
>= -7% and < -2%	14.29%	0.00%	10.00%	0.00%	0.00%	0.00%	50.00%	12.50%	42.86%	12.50%
>= -2% and < 2%	64.29%	100.00%	40.00%	37.50%	36.36%	62.50%	16.67%	62.50%	28.57%	75.00%
> 2% and <= 5%/7%	21.43%	0.00%	50.00%	62.50%	63.64%	37.50%	33.33%	25.00%	28.57%	12.50%

LVUG0027.W01

18

MEDIPHARM - UGANDA LAB VALIDATION RESULTS: BATCH NO. 203051

SAMPLE NUMBER	Na	K	Cl	Citrate Citrate (calc)		Glucose
	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab
1	90.10	20.80	82.00	9.60	9.63	110.00
2	89.50	19.60	80.00	9.60	9.63	111.00
3	89.10	20.30	81.00	9.90	9.47	111.00
4	89.30	20.30	82.00	9.60	9.20	111.00
5	89.70	20.80	79.00	9.80	10.50	111.00
6	89.90	20.10	81.00	9.80	9.67	112.00
7	90.80	20.80	82.00	9.60	9.87	111.00
8	90.00	20.10	79.00	9.90	10.37	111.00
SPEC(MIN-MAX)	89.5(83.2-94.0)	20.1(18.7-21.5)	80.0(74.4-85.6)	9.9(9.2-10.6)		111.0(103.2-118.8)
SUM	718.20	162.80	646.00	77.80	78.34	888.00
MINIMUM	89.10	19.60	79.00	9.60	9.20	110.00
MAXIMUM	90.80	20.80	82.00	9.90	10.50	112.00
AVERAGE	89.78	20.35	80.75	9.73	9.79	111.00
STD	0.5166	0.4031	1.1990	0.1299	0.4128	0.5000
RSDX	0.58X	1.98X	1.48X	1.34X	4.22X	0.45X
FREQUENCY DISTRIBUTION						
>= -7X and < -2X	0.00	1.00	0.00	4.00	5.00	0.00
>= -2X and < 2X	8.00	4.00	5.00	4.00	1.00	8.00
> 2X and <= 5X/7X	0.00	3.00	3.00	0.00	2.00	0.00
	----	----	----	----	----	----
	8.00	8.00	8.00	8.00	8.00	8.00
>= -7X and < -2X	0.00X	12.50X	0.00X	50.00X	62.50X	0.00X
>= -2X and < 2X	100.00X	50.00X	62.50X	50.00X	12.50X	100.00X
> 2X and <= 5X/7X	0.00X	37.50X	37.50X	0.00X	25.00X	0.00X

LVUG0029.WQ1

17

MEDIPHARM - UGANDA LAB VALIDATION RESULTS: BATCH NO. 203062

SAMPLE NUMBER	Na	K	Cl	Citrate		Glucose
	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab	Citrate (calc) Ref. Lab	Ref. Lab
1	89.20	20.10	80.00	9.90	9.77	109.00
2	89.70	20.50	82.00	9.80	9.40	108.00
3	89.70	20.70	81.00	9.80	9.80	110.00
4	89.70	20.10	79.00	9.60	10.27	111.00
5	89.10	20.30	81.00	9.80	9.47	111.00
6	89.20	20.10	77.00	9.90	10.77	112.00
7	89.30	20.10	80.00	9.60	9.80	110.00
8	89.70	20.30	82.00	9.80	9.33	110.00
SPEC(MIN-MAX)	89.5(83.2-94.0)	20.1(18.7-21.5)	80.0(74.4-85.6)	9.9(9.2-10.6)		111.0(103.2-118.8)
SUM	715.60	162.20	642.00	78.20	78.61	881.00
MINIMUM	89.10	20.10	77.00	9.60	9.33	108.00
MAXIMUM	89.70	20.70	82.00	9.90	10.77	112.00
AVERAGE	89.45	20.28	80.25	9.78	9.83	110.13
STD	0.2550	0.2107	1.5612	0.1090	0.4537	1.1659
RSDX	0.29%	1.04%	1.95%	1.11%	4.62%	1.06%
FREQUENCY DISTRIBUTION						
>= -7% and < -2%	0.00	0.00	1.00	2.00	3.00	1.00
>= -2% and < 2%	8.00	7.00	5.00	6.00	3.00	7.00
> 2% and <= 5%/7%	0.00	1.00	2.00	0.00	1.00	0.00
----	----	----	----	----	----	----
	8.00	8.00	8.00	8.00	7.00	8.00
>= -7% and < -2%	0.00%	0.00%	12.50%	25.00%	42.86%	12.50%
>= -2% and < 2%	100.00%	87.50%	62.50%	75.00%	42.86%	87.50%
> 2% and <= 5%/7%	0.00%	12.50%	25.00%	0.00%	14.29%	0.00%

LVUG0031.W01

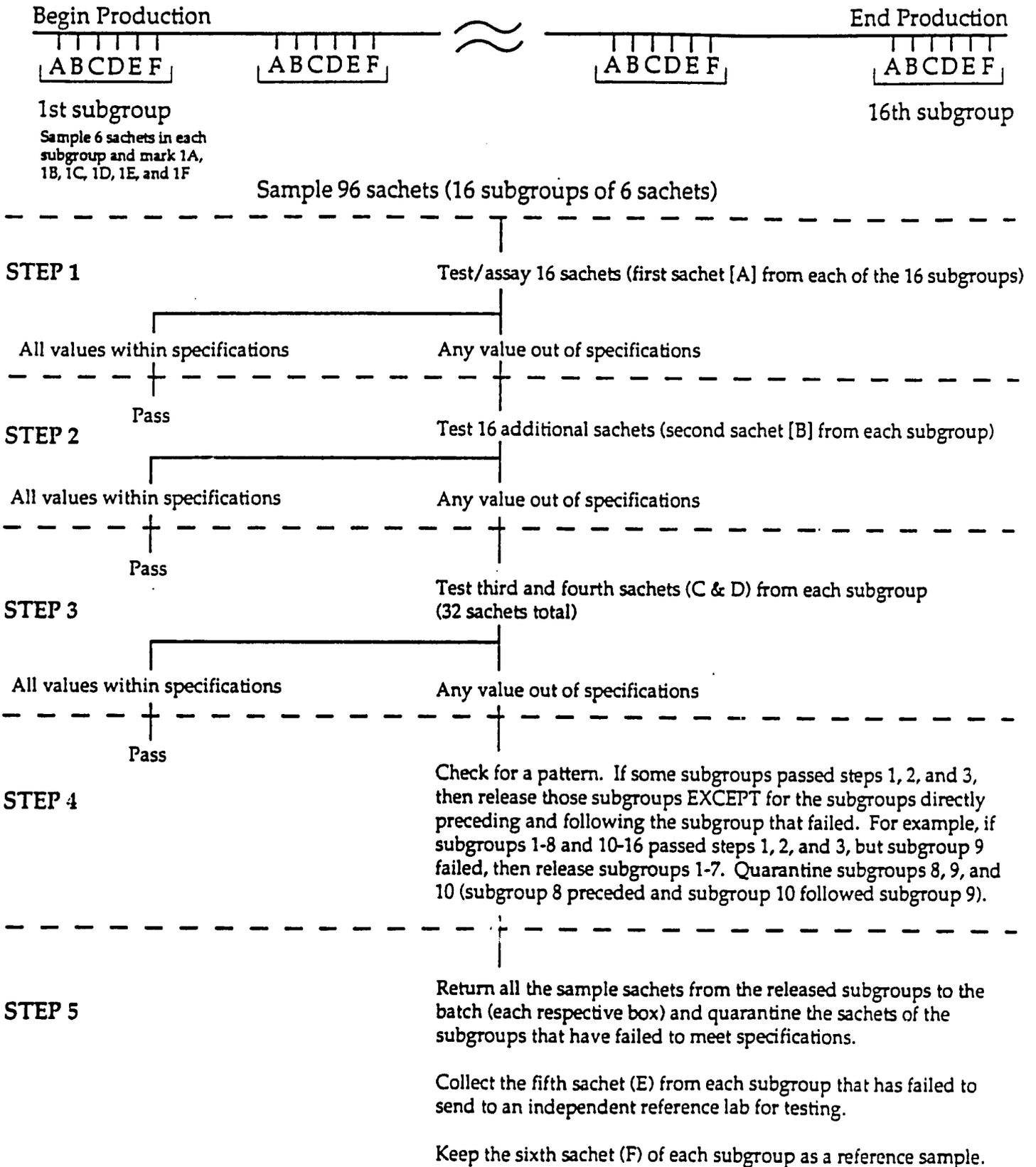
88

MEDIPHARM - UGANDA LAB VALIDATION RESULTS: BATCH NO. 203065

SAMPLE NUMBER	Na	K	Cl	Citrate	Citrate (calc)	Glucose
	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab	Ref. Lab
1	90.60	20.30	79.00	9.40	10.63	110.00
2	90.50	20.30	82.00	9.90	9.60	110.00
3	89.70	19.10	82.00	10.10	8.93	109.00
4	89.70	20.10	80.00	10.10	9.93	110.00
5	90.70	20.80	80.50	9.90	10.33	110.00
6	91.60	20.60	82.00	10.20	10.07	109.00
7	89.70	20.80	82.00	9.40	9.50	111.00
8	89.50	20.10	79.50	10.20	10.03	110.00
SPEC(MIN-MAX)	89.5(83.2-94.0)	20.1(18.7-21.5)	80.0(74.4-85.6)	9.9(9.2-10.6)		111.0(103.2-118.8)
SUM	722.00	162.10	647.00	79.20	79.02	879.00
MINIMUM	89.50	19.10	79.00	9.40	8.93	109.00
MAXIMUM	91.60	20.80	82.00	10.20	10.63	111.00
AVERAGE	90.25	20.26	80.88	9.90	9.88	109.88
STD	0.6782	0.5122	1.1924	0.3082	0.4939	0.5995
RSD%	0.75%	2.53%	1.47%	3.11%	5.00%	0.55%
FREQUENCY DISTRIBUTION						
>= -7% and < -2%	0.00	1.00	0.00	2.00	2.00	0.00
>= -2% and < 2%	7.00	4.00	4.00	2.00	3.00	8.00
> 2% and <= 5%/7%	1.00	3.00	4.00	4.00	1.00	0.00
	----	----	----	----	----	----
	8.00	8.00	8.00	8.00	6.00	8.00
>= -7% and < -2%	0.00%	12.50%	0.00%	25.00%	33.33%	0.00%
>= -2% and < 2%	87.50%	50.00%	50.00%	25.00%	50.00%	100.00%
> 2% and <= 5%/7%	12.50%	37.50%	50.00%	50.00%	16.67%	0.00%

LVUG0033.wq1

## Flowchart of Sampling Technique for Medipharm (To be used until 40 batches pass consecutively)



92

## Determination of Particle Sizes for ORS Bulk Powder

<u>Screen Size</u>	1,000 g	<u>% Retained</u>
2.006 mm	↓	0
1.650 mm	↓	0
1.250 mm	↓	0
1.016 mm	↓	0
0.180 mm	549.17 g	54.9
0.125 mm	202.19 g	20.2
Remaining Bulk	248.64 g	24.9%

### Conclusion

Particles are too fine, which tends to cause improper flow during the dosing/filling process.

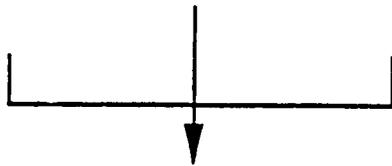
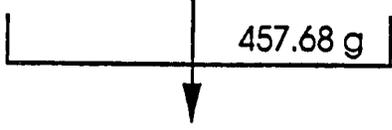
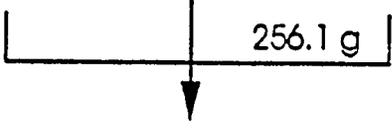
## Determination of Particle Sizes for Sodium Chloride

<u>Screen Size</u>	1,000 g	<u>% Retained</u>
1.016 mm	2.81 g	0.3
0.180 mm	940.88 g	94.1
0.125 mm	30.34 g	3.0
Remaining NaCl	25.97 g	2.6%

## Determination of Particle Sizes for Potassium Chloride

<u>Screen Size</u>	1,000 g	<u>% Retained</u>
1.016 mm	1.38 g	0.1
0.180 mm	875.03 g	87.5
0.125 mm	103.23 g	10.3
Remaining KCl	20.36 g	2.0%

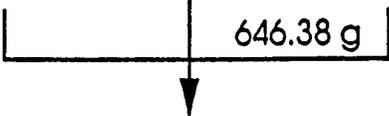
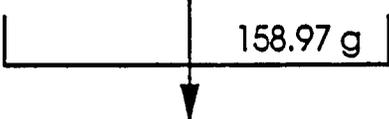
## Determination of Particle Sizes for Glucose

<u>Screen Size</u>	1,000 g	<u>% Retained</u>
1.016 mm		0
0.180 mm		45.8
0.125 mm		25.6
Remaining Glucose	286.22 g	28.6%

### Conclusion

Particles are too fine, which causes difficulty in the flow during the dosing/milling process.

## Determination of Particle Sizes for Sodium Citrate

<u>Screen Size</u>	1,000 g	<u>% Retained</u>
1.016 mm		0.02
0.180 mm		64.6
0.125 mm		15.9
Remaining Citrate	194.48 g	19.5%



Program for Appropriate Technology in Health

Attachment D  
4 Nickerson Street  
Seattle, WA 98109  
Tel: (206) 285-3500  
Fax: (206) 285-6619  
Telx: 4740049PATH UI

684.03V

July 13, 1992

Mr. David M. Puckett  
USAID/Kampala  
42 Nakasero Road  
Kampala  
UGANDA

Dear Mr. Puckett:

Upon return from their May 24-June 5 visit to Uganda, Fletcher Catron and Khalid Mahmood conveyed to us your interest in having PATH revise the March 4, 1992, proposal for additional technical assistance to Medipharm beyond June 1992. In order to provide additional assistance to Medipharm so that production would be well established and viable beyond the end of USAID/Kampala assistance, we have revised our proposal according to the guidelines mentioned in your conversation with Fletcher Catron and Khalid Mahmood on Friday, May 29. The attached document outlines the recommended technical assistance in such critical areas as plant management, inventory, and marketing. Assistance in these areas will strengthen Medipharm's ability to become self-sufficient by June 30, 1993.

Medipharm is at a critical time of product introduction, and full implementation of our recommendations will be crucial to its successful production, marketing, and distribution of ORS over the long term. The support from USAID/Kampala, UNICEF, and other key parties has been vital to Medipharm's overall development thus far. Further assistance from USAID/Kampala to Medipharm will be a key factor in focusing Medipharm on its goal of independent operation.

Our recommended activities will be carried out by PATH staff in Kampala and Seattle through June 30, 1993. Per your request, trips have been combined to reduce costs, and our overall level of effort has been reduced from the March proposal by eliminating technical assistance in the areas of financial management, personnel, and computer systems. Therefore, the revised budget for our proposed activities is \$208,037. In order not to delay this letter, under a separate cover we will fax you our estimation of the cost of one year's supply of raw materials purchased and shipped by PATH to Medipharm.



Mr. David M. Puckett  
July 13, 1992  
Page 2

Please let us know if you need additional information relating to this proposal. We appreciate your support and this opportunity for us to extend our assistance to Medipharm.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Walker", followed by a horizontal line extending to the right.

Eric G. Walker  
Vice President, Finance

EW:cs  
Enclosure  
cc: Sjoerd Postma, PRITECH/Uganda  
EWL01014

Recommended Technical Assistance  
to Medipharm  
Kampala, Uganda

(July 1, 1992 - June 30, 1993)

**BACKGROUND**

Medipharm, a Ugandan pharmaceutical manufacturer, commenced local production of "ORS," its public sector oral rehydration salts (ORS) product, in January 1991 during a nationally and internationally publicized plant inauguration attended by Ugandan President Yoweri Museveni, A.I.D. Administrator Dr. Ronald Roskens, and U.S. Secretary of Health and Human Services Dr. Louis Sullivan. Production of the manufacturer's private sector product, "ORADEx," began in July 1991.

During the highly visible inauguration ceremony, key comments regarding the expectations of this project were made by President Museveni, Dr. Roskens, and Dr. Sullivan. President Museveni thanked A.I.D. for the assistance given to Uganda to manufacture the ORS and noted that, for the project to be sustainable, meaningful aid should provide a catalyst for activities that continue after donor assistance. Dr. Sullivan noted that key elements--adequate food; medicines; health practices; and skilled, motivated, and disciplined health care professionals--must be woven into a sustainable system which meets the social, cultural, and financial requirements of Uganda. Dr. Roskens noted that, while Medipharm had acquired the technology and equipment to produce ORS, it must train a competent staff to use and maintain the equipment, and produce and market ORS that meets the highest international standards. These comments underscore the need to extend the provision of technical assistance beyond equipment and technology to the development and implementation of systems and know-how required for sustainable operation.

During Medipharm's first year of production in 1991, it produced 1.12 million sachets, exceeding the production goal of 1.08 million sachets. Medipharm's production challenges in 1992 will focus on its ability to

20

(1) meet a production goal of 2 million sachets (a 79 percent increase over 1991) and (2) produce ORS sachets in a cost-effective manner, allowing Medipharm to realize the profit required for sustained production. This profit will support the manufacturing infrastructure for both the public and private sector ORS products. Medipharm can reach these goals if it produces ORS sachets with no wastage of materials or rework and at an overall machine efficiency factor of 70 percent or better, and if it establishes systems to efficiently manage its finances, inventory, and sales efforts.

In addition to its emphasis on pharmaceutical production, Medipharm launched "ORADEX," its private sector ORS product, in October 1991. Medipharm has progressed tremendously toward developing marketing and promotion skills and is gaining knowledge and experience in its first collaborative effort with a local pharmaceutical distribution firm, ARMTRADES.

Because "ORADEX" is new to the market in Uganda, Medipharm is at a critical stage of product introduction and will require oversight and guidance during the coming year to develop its promotion, sales, and distribution capabilities. In addition, PATH proposes to continue to assist Medipharm to collaborate with other nongovernmental organizations, such as UNICEF and the Danish Red Cross Essential Drug Programme, to supply locally manufactured ORS.

Successful sales of "ORADEX" in the private sector will sustain Medipharm's production of ORS for both public and private sectors, thereby resulting in the elimination of continued donor assistance.

The demonstrated capacity and quality of local ORS production at Medipharm can result in a decrease in importation of ORS into Uganda and a strengthening of Ugandan private sector manufacturing for other essential drugs.

## RECOMMENDATIONS

PATH recommends technical assistance in the following areas to help Medipharm achieve sustainability after June 30, 1993:

- A. Production and plant management systems
- B. Production planning and inventory controls
- C. Reduced sampling plan for quality control (QC)
- D. Quality assurance (QA) audit
- E. Master plan for five years' growth
- F. Contingency plans
- G. Sales and distributor management systems
- H. Forecasting
- I. Pro forma profit and loss (P&L) statements for "ORADEx" product line
- J. Professional sales techniques
- K. Advertising
- L. Coordination of public and private sector ORS
- M. Raw material purchases

This proposed technical assistance will be provided by PATH in Seattle and in Kampala. A total of five technical assistance visits will be carried out during the remainder of 1992 and 1993: four visits for production and one for marketing. The exact timing of these visits will be determined once the activities are approved.

### A. Production and plant management systems

Effective production and plant management systems require:

- (1) in-process monitoring and control;
- (2) cause and effect analysis;
- (3) QC statistical review;
- (4) preventive maintenance; and
- (5) QA policies and guidelines.

### In-process monitoring and control:

In-process monitoring is an effective and proven tool widely used to increase productivity and improve product quality. The maximum benefit of this system is derived when the data collected are accurate, are coordinated in a timely manner, and are adapted to the particular process and organization.

While producing pharmaceuticals since 1984, Medipharm was first exposed to in-process monitoring and control in January 1991 when ORS production started. Even with PATH's continuous efforts to familiarize Medipharm's managers and supervisors with this statistical and managerial tool, the actual results are still to be achieved. In-process monitoring and control at Medipharm needs to be reviewed and reinforced.

Medipharm completes documentation for all batches, but it is not extracting information for immediate action to prevent the repetition of delays; loss of materials; improper setting of machines; improper analysis of process trends; and improper usage of support services, such as power, compressed air, dust extractor, etc.

While in country, PATH proposes to work with machine operators, managers, and supervisors on actual collecting, plotting, and analysis of data and trends. By using this on-the-job training reinforcement, being present to answer questions, and providing reading materials, PATH will provide Medipharm with all the necessary tools and support to completely utilize this important tool.

A comprehensive implementation of in-process monitoring will lessen Medipharm's machine hours per batch, thereby reducing direct and indirect costs per unit produced. The result will be a higher margin per unit sold. Further, implementation will result in more

efficient and higher utilization of available capital; thus, Medipharm will be less dependent upon loans.

#### **Cause and effect analysis:**

Cause and effect analysis is a method of searching for the causes of quality and productivity problems in the areas where causes are most likely to occur. Mastering this managerial technique is key to reaching sustainability. Its value is proven for any kind of industry, in any country, in any segment of the industry, business, or other organizational activity. Medipharm was formally introduced to this technique in February 1992. Like in-process monitoring, follow-up is the only assurance for continuous use.

PATH staff will spend approximately two days during each technical assistance visit to assist the Medipharm managers, supervisors, operators, technicians, and analysts in identifying the causes of low quality or low productivity and in improving the process.

Medipharm's mastering of the cause and effect technique will prevent the undesirable repetition of the March/April 1992 incident when batches continued to be produced even though 12 batches had not met specifications. Had Medipharm mastered the technique of cause and effect analysis, its managers would have stopped production after the first rejected batch and rectified the problem.

#### **QC statistical review:**

Statistical analysis of production and QC data is a scientific method to anticipate problems, identify causes, and eliminate them before a batch has to be rejected. The success of a manufacturing company can be short-lived if attention is only given to producing products within the specifications.

PATH prepared a user-friendly system for Medipharm to plot QC results. The analysis of these results indicates trends that lead to process/methods improvement.

Medipharm has the basic capability to compute and perform the QC statistical review. At this second phase of implementation, Medipharm needs to apply the QC statistical review to production results in a more timely manner and coordinate it with production and QC personnel with the objective of recognizing a negative trend and stopping it before the trend progresses into batch rejections.

PATH will train the QC manager and supervisors in QC statistical review while in country. This technique will provide Medipharm with the skills to interpret the spread or variation in assay results, monitor and reverse negative trends of product quality in a timely manner, and ensure production within specifications.

#### **Preventive maintenance:**

In order to reach sustainability, a company must stretch the life of fixed assets beyond their fiscal depreciation. ORS is a low margin product, particularly when major clients are in the public sector. ORS is also a very corrosive product, which can have devastating effects on driers, scales, mixers, form-fill-seal machines, warehouse equipment, air conditioning systems, and metal building structures.

Most of the spare parts for machines will need to be imported, thereby requiring hard currency. It is PATH's objective for Medipharm to locally develop, fabricate, and procure as many spare parts as possible.

PATH designed a basic preventive maintenance program for major production equipment and systems of any ORS plant. This system services and maintains machines before they break down, and thus

extends the life of parts. This system also maintains the minimum number of spares necessary to keep the machines producing all the time. This system was first introduced to Medipharm in January 1991 when production started. Personnel turnover, troubles with utilities supplies, the learning curve process, and other factors have contributed to low adherence to the proposed plan.

Medipharm's maintenance department was organized in March 1992 after PATH urged Medipharm to allocate a full-time technician to this function and also hire an electrician. The system is now at a crucial stage of implementation.

While in country PATH proposes to assist the Medipharm maintenance team for one full day each trip to execute preventive maintenance, organize and control parts inventory, and develop a list of local companies that can help in future emergencies with either spare equipment or parts.

Preventive maintenance will provide Medipharm with a spare parts inventory and asset protection program and will reduce operating costs due to the following: less wear on spare parts, extended equipment life, reduced machine "down time," increased utilization of labor hours, and lower material wastage.

#### **QA policies and guidelines:**

PATH developed a comprehensive set of policies and guidelines applicable to any company engaged in manufacturing, packing, storing, distributing, and/or selling pharmaceutical products.

The QA policies and guidelines manual was presented to Medipharm in October 1991. While some of these policies have been implemented, most were not implemented because of scarce cash resources and the lack of management's concentration on QA (due to production of the first year's supply and the product launch of "ORADEx"). As the

production volume increases, so do the problems and challenges of applications; it is imperative that these policies be implemented.

PATH proposes to help Medipharm's management, supervisory, and clerical staff implement the Project SUPPORT proposed QA policies and guidelines. Policies will be clarified, benefits explained, and any problematic areas will be discussed. PATH proposes that technical assistance be allocated to this activity for two four-hour sessions during each technical assistance visit.

Complete implementation of QA policies and guidelines, yet to be achieved by Medipharm, will provide the QA systems necessary to institutionalize and ensure the implementation of good manufacturing practice (GMP). Further, this action will promote product quality, pride in workmanship, and productivity.

B. Production planning and inventory controls

Production planning and inventory controls are tools that systematically plan production for future months and specify quantities of raw materials, packaging foil, and cash required on a month-by-month basis for a period of 24 months or longer.

By February 1992 Medipharm had established a formal materials management department and trained the staff to coordinate, plan, and compute production planning and inventory control. However, during the May 1992 visit, PATH found that even though Medipharm staff understand the basic concepts of this system, specific production data for inventory planning and control are not being used and analyzed.

Medipharm needs guidance to implement this extremely useful system of computation and monitoring. This system requires management planning and resource allocation to provide accurate information.

Prior to each technical assistance visit, Medipharm will send PATH its production planning and control work sheets for review. During each visit, actual on-the-spot inventory checks will be made, and future periods will be planned in coordination with the marketing and production departments. This entire activity will take at least one full day during each visit.

Successful implementation will result in reduced capital costs, reflected in lower indirect costs, and optimized cash flow, resulting in lower interest expense and exposure to debt and foreign exchange losses. Ultimately, it is expected that these controls will enable Medipharm to manage the purchase of the raw materials heretofore provided by UNICEF.

C. Reduced sampling plan for quality control (QC)

Medipharm currently samples and tests 16 sachets per batch, which is the "normal" sampling plan. Medipharm's lab has not yet been validated because QC test results indicate considerable variation between ORS batches produced at Medipharm.

The first step toward validation is to bring Medipharm's process "in control." For a process to be deemed "in control," it is expected that all of the units produced will follow certain statistical distribution. The larger the variation, the less "control" of the process.

Medipharm production received a setback this year when 18 batches failed to meet specifications when tested by its QC lab. While Medipharm's final products are within physical and chemical specifications, with the exception of the rejected batches, there are indications that its process can be improved to eliminate potential rejections.

Assay results for the five components (sodium, potassium, chloride, citrate, and glucose) show widely distributed individual results and high standard deviations. In order for Medipharm to reduce the number of samples required for testing, it must first pass 40 consecutive batches and then improve the process results for both physical and chemical characteristics: (1) within batches Medipharm must reduce the variation in assay results, and (2) the results from batch to batch must consistently fall within a specified range.

Once Medipharm's process is "in control," its QC lab can be validated by an independent, or reference, lab. During each technical assistance visit, ten samples from five batches will be collected and sent to an independent lab for validation. The assay results from the reference lab will be compared statistically with the assay results of the Medipharm lab in order to validate the Medipharm lab. Lab validation of Medipharm's batches will take place on three separate occasions.

Once the Medipharm QC lab is validated, the number of samples tested per batch will be reduced from 16 sachets per batch to 11 sachets per batch. This reduced sampling plan will result in a cost savings of US\$90 per batch. For 2 million sachets (or 267 batches), Medipharm could realize an annual savings of US\$24,000 in reagents, labor, and samples required for its QC tests.

#### D. Quality assurance (QA) audit

A QA audit consists of an in-depth technical and managerial evaluation of a company. Key elements reviewed during a QA audit include organization and personnel; building and equipment; material, product, production, and processing controls; holding and distribution; laboratory controls; records and reports; and returned and salvaged products. It is recommended that a formal QA audit be conducted annually. Internal QA audits can be conducted by a manufacturer as a self-regulatory mechanism.

PATH proposes to conduct a QA audit during its first technical assistance visit in 1993 to assess to what extent Medipharm has implemented the recommendations from PATH's July 1991 audit and the additional suggestions that were made during the subsequent visits, and identify Medipharm's current adherence to applicable policies and procedures. A QA audit will take two days to complete. One half-day will be spent in reviewing the results of the audit with the management and developing a plan for corrective actions identified in the audit. During the subsequent visit the corrective actions will be evaluated for the extent of implementation.

Findings from this audit will result in an action plan for Medipharm to use in fully implementing recommendations and GMP; eliminating deficiencies in the manufacturing, control, and operating systems and facilities; and ensuring production of a quality ORS product.

E. Master plan for five years' growth

PATH assisted Medipharm in developing and implementing a one-year manufacturing plan. Based on current projections, by the end of 1993 Medipharm's annual production goal of 3 million sachets is expected to reach 70 percent of its production capacity on a single shift.

To prepare the five-year master plan, PATH will provide the guidelines and questionnaires to Medipharm during its second visit, and Medipharm will fill out and send the questionnaires to PATH for review. During the third visit, one full day will be dedicated to converting the figures into requirements for floor space, equipment, capital, and a manufacturing strategy for the next five years.

To meet this challenge, Medipharm must begin implementation of its five-year master plan before mid-1993. Implementation of this plan will ensure production of a quality product at optimum cost in the future, a planned and systematic operation during each year of

growth, and an adequate maintenance of an ORS supply with no disruptions.

F. Contingency plans

The real world offers challenges even to the most accurate forecast. During a period of crisis it is difficult to focus and identify solutions. To refocus and maintain continuous growth, organizations must apply immediate remedies. Successful organizations have "emergency kits" called contingency plans with alternatives for facing a variety of potential problems.

PATH has developed the following contingency plans to help Medipharm solve some of the potential problems that may be encountered in the course of local ORS production:

- (1) Cost higher than expected
- (2) Volume higher than expected
- (3) Volume lower than anticipated
- (4) High turnover of permanent (contracted) employees
- (5) Quality-related problems
- (6) Good manufacturing practice problems

These theoretical plans will be reviewed with Medipharm's senior management during any of the visits. By the end of this technical assistance, Medipharm will be able to develop its own contingency plans.

G. Sales and distributor management systems

Prior to the launch of "ORADEx," Medipharm had not contracted with a distributor; nor had it had any experience in paying commission to a distributor for product sales. The commercial success of "ORADEx," and ultimately Medipharm, is dependent upon the distributor's

efforts, planning, and success. Medipharm must be able to monitor and manage the sales performance of the distributor.

Sales management is key to the success of "ORADEX." Sales management includes (1) customer profiling, which involves maintaining customer inventory cards; (2) sales profiling, which involves maintaining data on the "A" regions, districts, and customers (those that generate 70% or more of sales) and periods; (3) setting and monitoring goals for sales personnel; and (4) introducing sales incentives, such as bonuses and promotions, which are common in the private sector.

During each in-country visit PATH will accompany sales staff from Medipharm and its distributor on visits to at least two regions of the country. PATH will review, analyze, and discuss monthly data during meetings with the distributor and Medipharm. Also, creative incentive schemes, such as bonuses to shopkeepers and pharmacists, will be introduced, and their effect on sales and profits will be discussed via correspondence from Seattle and while in country.

Effective sales management will increase the demand of ORS and help "ORADEX" penetrate into new market segments and regions. It will ensure that sales are generated when utilizing minimum resources. Medipharm will be able to evaluate options of expanding distribution channels beyond ARMTRADES to other organizations or increase its own distribution capabilities.

#### H. Forecasting

Forecasting is the key to efficient planning for production, financial management, and inventory planning. Medipharm now has sales data for the past seven months for regions and customers. Medipharm must use this data to generate a forecast for the next one to four years. The forecast for the first year must be exact and should be broken down by month, region, and districts.

While in country, PATH will introduce simple and effective statistical tools for forecasting based on analyzing past data and factoring in elasticity due to resources allocated for promotion and advertising.

Forecasting will provide Medipharm with the tools to efficiently use resources and plan production, thereby ensuring uninterrupted supply of ORS. Forecasting will also help Medipharm use its available cash effectively, i.e., utilizing available inventories and avoiding accumulation of large inventories for unusually long periods of time.

I. Pro forma profit and loss (P&L) statements for "ORADEx" product line

The P&L statement is a standard marketing work sheet that calculates how much profit a product will generate on a monthly basis. The P&L should be reviewed every month, in which the previous month's figures will be entered and the next month's figures adjusted. Likewise, sales, price, cost, promotional spending, and advertising expenses, if possible, are adjusted to ensure that "ORADEx" always generates a positive return.

PATH will introduce the P&L model and computations and work with Medipharm to make monthly adjustments in the P&L variables, such as cost, exchange rate, spending, quantity sold on profits, etc. PATH will spend one half-day during each technical visit helping Medipharm adjust its figures. PATH will also review these data in Seattle.

In 1992 Medipharm will lose money because (1) it failed to anticipate and respond to the rapid change in inflation and devaluation of Uganda shillings; and (2) various restrictions prevented Medipharm from increasing the price. Medipharm can react to circumstances such as these only if it recognizes the impact

these changes may have on the many variables that affect profitability.

J. Professional sales techniques

In late 1991 Medipharm's sales staff began making sales calls to doctors, pharmacies, hospitals, and clinics. They are competing with sales staff of highly professional, organized, and well-funded companies that sell imported, expensive anti-diarrheal products. If Medipharm is to be successful, it must match some of this professionalism. In addition to this challenge, there has also been high turnover in Medipharm's sales and marketing staff.

There is tremendous consumer brand awareness of "ORADEX" in the market because of Medipharm's excellent advertising and promotional campaigns. Now, the doctors, nurses, shopkeepers, and pharmacists must be convinced that "ORADEX" is the first choice of therapy for diarrhea, and professional sales calls from sales staff will be key to increasing sales.

PATH will visit the pharmacies, shops, and hospitals with the sales staff and train them in making presentations, explain and teach product presentation techniques, explain the pharmacology of the products, and teach the professional aspects of selling to doctors, pharmacists, and clinics. Professional sales techniques will not only help increase the market share of "ORADEX" but also inform doctors, pharmacists, and health workers of the benefits of ORS in treating diarrhea.

Medipharm will apply the experience gained in materials development thus far in the project to design, contract, and supervise a 1994 promotional campaign to the public and private sectors with funds generated from 1992 and 1993 sales. This experience will position Medipharm securely in an increasingly competitive Ugandan market to design and implement marketing and sales tracking systems which

maximize product promotional efforts and allow strategic product positioning and growth throughout the 1990s and beyond.

K. Advertising

Advertising for "ORADEx" will continue to enhance product brand awareness and stimulate private sector sales. To maintain continuity with the advertising campaign that has been in effect since product introduction, PATH proposes to procure advertising materials/activities through June of 1993 which will include continuance of the current radio advertisements in three languages, a 1993 calendar for shops and pharmacies, and newspaper ads every other week in Uganda's two most circulated daily periodicals, The New Vision and Munno. PATH also proposes to help Medipharm develop a revised product information brochure as a sales tool which will address pharmacy attendant questions about product usage and basic diarrheal disease case management. These advertising activities, along with the current supply of bus posters and metal signs, will provide necessary sales incentives until "ORADEx" is firmly established as a common and necessary consumer product.

L. Coordination of public and private sector ORS

Coordination between public and private sectors in total ORS supplied is a requirement for successful sales of "ORADEx," while guaranteeing sufficient quantities of "ORS" to meet national requirements for health centers and mission hospitals, which are currently supplied by UNICEF and the Danish Red Cross. Both of these groups have expressed interest in decreasing donated quantities of "ORS" as local production helps improve private sector availability of ORS. Eventually, the Ministry of Health CDD Program will purchase sufficient quantities of "ORS" from Medipharm to fulfill public sector requirements.

Using sales projections and the figures from the stated requirements of UNICEF, the Danish Red Cross Essential Drug Programme, and the Ministry of Health CDD Program, PATH will assist Medipharm to determine at what point it will be able to independently purchase raw materials upon utilization of the UNICEF-donated raw materials and conclusion of donor assistance. Based on total projected demand for 1992 and 1993, the current supply of ORS raw materials is expected to be depleted by December 1993.

M. Raw material purchases

USAID/Kampala has specifically asked at what point Medipharm will be able to sustain raw material purchases and all production costs. This key concern of USAID/Kampala will be addressed through PATH's proposed technical assistance to Medipharm for implementation of a system which will generate a monthly cash flow projection. Since ORS revenue and expenses are known, a cash flow projection will be generated for the period 1992 through 1994 and will be verified, maintained, and updated on a monthly basis. The cash flow projection will enable Medipharm to plan cash generation and consumption for the planned purchase of raw materials at some point in 1994 before depletion of donated raw materials.

PATH

Faxed 3:00pr

4 Nickerson Street, Seattle, Washington 98109 USA  
Phone: 206-285-3500 Fax: 206-285-6619 Telex: 4740049 PATH UI

FACSIMILE MESSAGE

Date: July 21, 1992  
Fax No: 011 256 41 233 417  
To: David Puckett, USAID/Kampala  
From: Jacque Holden  
Total Pgs  
(incl. cover): 2  
Copies to: MB/HZ/KM/FC  
Reference: Budget for Procurement of Raw Materials

As discussed during your telephone conversation with Khalid Mahmood on Friday, July 17, here is the estimate for the raw materials procurement for 2.5 million sachets. This estimate is based on recent quotations from U.S. vendors.

Kind regards,

Jacque Holden

Charge Code: 684-35

File Code:

107

PROJECT: MEDIPHARM / UGANDA CONTINUATION  
 PROCUREMENT OPTION  
 FUNDER: USAID/KAMPALA  
 DATE: 07/17/92 REF: AIDCONT4

SALARIES & FRINGE		Days	
-----			
Deputy Department Director	BRIT	0.5	
Technical Director	ZARD	1.0	
Associate Technical Officer	MAHM	3.0	
Associate Admin. Officer	HOLD	0.5	
Senior Admin. Supervisor	MALO	0.5	
Associate Procurement Officer	KEND	12.0	
Program Assistants	SUPP	6.0	
		-----	-----
Total salaries		23.5	3,328
FRINGE BENEFITS @	29.5%		982
			-----
TOTAL SALARIES & FRINGE			4,310
PROCUREMENT			
-----			
Raw materials			72,006
Packaging materials			51,200
Overpackaging materials			11,400
Shipping costs			51,186
			-----
TOTAL PROCUREMENT			185,792
OTHER DIRECT COSTS			
-----			
Copying & duplicating			67
Telephone, fax, telex			166
Postage			133
Office supplies			33
Facilities			799
			-----
TOTAL OTHER DIRECT COSTS			1,198
TOTAL DIRECT COSTS			191,300
INDIRECT COSTS @	32.9%		1,812
			-----
TOTAL COSTS			\$193,112
			=====

UGANDA FOLLOW-ON TECHNICAL ASSISTANCE  
TASK ASSIGNMENT NO. SUP-228-UG

EXPENDITURE REPORT NOVEMBER 13, 1991-JULY 31, 1992

	Budgeted	EXPENDITURES 11/91 - 2/92	EXPENDITURES 3/92 - 7/92	TOTAL EXPENDITURES	AMOUNT REMAINING
Salaries	\$28,516.00	\$23,675.03	\$23,762.35	\$47,437.38	\$75,953.38
Staff Leave/Fringe	13,806.00	6,917.51	8,260.71	15,178.22	(1,372.22)
Procurement	12,000.00	10,000.00	0.00	10,000.00	2,000.00
Travel	43,967.00	15,386.52	10,810.61	26,197.13	17,769.87
Other Direct	24,243.00	6,762.66	9,918.76	16,681.42	7,561.58
Overhead	41,539.00	20,872.49	17,352.73	38,225.22	3,313.78
<b>TOTAL</b>	<b>\$164,071</b>	<b>\$83,614.21</b>	<b>\$70,105.16</b>	<b>\$153,719.37</b>	<b>\$10,351.63</b>

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8/20/92