Due Diligence Visit to Vimta Labs Ltd
September 27 to October 6, 2009: Trip Report

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

Recommended Citation

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ACRONYMS

GDPA	General Directorate of Pharmaceutical Affairs
LIMS	Laboratory Information Management System
MoPH	Ministry of Public Health
MQCL	Medicines Quality Control Laboratory
MSH	Management Sciences for Health
PE	Pharmaceutical Enterprise
QA	Quality Assurance
QATF	Quality Assurance Task Force
SOW	Scope of Work
SPS	Strengthening Pharmaceutical Systems
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

Upon the request of the Mission, in February 2008 Anthony Savelli and Mark Morris of the Strengthening Pharmaceutical Systems (SPS) project of Management Sciences for Health (MSH) visited Kabul to develop a Scope of Work (SOW), initial work plan and budget to improve the use of medicines by healthcare providers and patients, and build the capacity of the Ministry of Public Health (MoPH) to manage pharmaceuticals and related services. Technical areas included Quality Assurance (QA) of pharmaceutical products, establishment of a coordinated pharmaceutical procurement and distribution system within the MoPH and design of a system for the procurement of pharmaceuticals using United States Agency for International Development (USAID) funds to succeed the system currently managed by Tech Serve.

SPS Afghanistan is currently engaged in the process of conducting medicine quality testing on 11 products. Under the direct technical supervision of the SPS Regional Technical Advisor, Inua Yusuf, the medicine sample collection exercise has been finalized by SPS staff in Afghanistan in close collaboration with the MoPH and General Directorate of Pharmaceutical Affairs (GDPA). Over the course of the sample collection process, it was noted that a significant number of medicines collected as samples were of Indian, Iranian and Pakistani origins.

Meanwhile, SPS had selected two laboratories that will carry out the actual laboratory testing of the collected samples. These were Vimta Labs Ltd in India as the primary laboratory and North West University Laboratory of South Africa as a parallel laboratory. Both were World Health Organization (WHO) prequalified, which means that "the laboratories were found to be acceptable, in principle, for use by United Nations (UN) agencies and other procurement organizations".

In spite of the fact that Vimta Labs Ltd is a reputable laboratory with WHO prequalification status, select numbers of staff of the MoPH appeared to be quite uneasy with the selection of a primary laboratory based Indian, especially as most medicines collected were from the sub-region. The basic concern of the MoPH staff appeared to be related to the general mistrust of Indian pharmaceuticals that are prevalent in Afghanistan which has in turn fueled suspicions of the quality and effectiveness of Indian laboratories.

Given the anticipated visibility of the results of the medicine quality testing and in an effort to avoid potential scrutiny and challenges from sources internal and external to the MoPH, the QA Task Force (QATF) of the MoPH/GDPA requested that SPS facilitated a field visit of select MoPH staff to India to observe firsthand testing procedures and processes of Vimta Laboratory Ltd. While SPS had full trust in the testing procedures and processes of Vimta Laboratory Ltd, SPS did believe that it would be quite advantageous to honor the request of the MoPH in this regard.

Providing the opportunity for key individuals of the MoPH to observe aspects of Vimta Labs Ltd's processes would then allow these same individuals, having had firsthand acknowledge of the quality of Vimta Labs Ltd's testing procedures, to serve as advocates for the process later when the results are generated and distributed across various stakeholders. The MoPH officials

would also be provided an opportunity to learn lessons on a functional laboratory from Vimta Laboratory Ltd.

Purpose of Trip

The purpose of this visit was to perform due diligence inspection of the Vimta Labs Ltd in India, as a primary laboratory, to assure that the facility continues to meet the WHO prequalification criteria. In accordance with this, SPS proposed to send seven persons to visit the Vimta Labs Ltd site to help assure that sample handling, data systems and quality systems were in place to support the medicine QA survey in Afghanistan.

Constitution of Team

A team of officials from some agencies of the MoPH of Afghanistan and consultants from MSH/SPS was put together. The officials from the MoPH were selected by the MoPH. Agencies represented were the GDPA, Medicines Quality Control Laboratory (MQCL) and Pharmaceutical Enterprise (PE). The overall team consisted of a total of seven individuals as follows:

- Mr. Zakria Fatehizada - Pharmaceutical Supervision and Evaluation Manager and QATF Chairperson
- Ms. Kamila Sultani - Director, Medicines & Food QC Laboratory
- Mr. Mirza Muhammad Ayubi- Deputy Director for Pharmaceutical Enterprise
- Mr. Khaklil Khakzad - Coordinator for GDPA and MSH/SPS
- Zafar Omari - MSH Afghanistan In-Country Lead
- Mark Morris - MSH Afghanistan Country Project Manager
- Inua Yusuf - MSH Regional Technical Advisor

Scope of Work

The team of officials from the MoPH and consultants from MSH/SPS were to:

- Ascertain the physical existence of Vimta Labs Ltd in India;
- Conduct arrival and departure meetings with the management of Vimta Labs as required;
- Observe sample receiving and control areas, and chain-of-custody procedures;
- Explain the coding of medicines to management of Vimta Labs Ltd, for clarity of reporting without disclosing details (first digit is a letter, second digit is a number, third, fourth & fifth digits are letters);
- Familiarize with the work processes in the laboratory;
- Form an impression about the work environment and internal processes:
    - Receipt bay
    - Temporary storage
    - Test area
    - Test equipment
    - Test process

    - Data management
    - Human resource
- Review selected balance calibration data, HPLC calibration data, dissolution apparatus calibration data;
- Observe sterility test suite and endotoxin test procedures;
- Review an in-compliance and an out-of-compliance pharmaceutical analytical worksheet to observe the due diligence procedural follow up on the out-of-compliance product;
- Interact with staff of Vimta Labs Ltd and form an impression about their capacity to conduct the testing of selected medicines;
- Submit a trip report to USAID within two weeks of the end of the visit.

ACTIVITIES

Preparations for Visit

In preparation towards the trip to India, several contacts were made amongst the team members. The SOW was discussed amongst members, to ensure that all the necessary details were considered for a successful visit. The total number of days needed for a meaningful visit was discussed. This was then communicated to Vimta Labs Ltd for consideration. Vimta Labs Ltd indicated that a total of 5 days was sufficient for the team to gain an understanding and appreciation for its policies, system and procedures.

Physical Existence

The team ascertained the physical existence of Vimta Labs Ltd, located at Vimta Labs Life Sciences Facility Plot 5, S. P. Biotech Park, Genome Valley, Hyderabad - 500078, India.

The team was given a copy of a cover letter (attached) for the WHO Prequalification of Medicines Programme Inspection of Quality Control Laboratory, dated August 7, 2008. Also provided was the WHO prequalification inspection report (attached) dated August 6, 2008 which considered the laboratory to be operating at an acceptable level of compliance with WHO Good Practice for National Pharmaceutical Control Laboratories.

Arrival Meeting with Vimta Labs Ltd Management Team

A joint meeting of high level management team of Vimta Labs Ltd and our team was held on Tuesday, September 29, 2009. The main purpose of the meeting was to introduce ourselves and agree on the agenda for the visit.

After all members of both teams briefly introduced themselves, Mark stated the purpose of the visit. He also gave a background of MSH/SPS. Mark stated the corporate objectives of MSH/SPS, the organizational structure of MSH and the key result areas of SPS. A summary of QA related activities in Afghanistan was also provided. He requested Vimta Labs Ltd to consider the possibilities of supporting capacity building in Afghanistan. On behalf of the team, Mark expressed his appreciation for the opportunity to see and learn from Vimta Labs Ltd.

Zakria expressed the appreciation and gratitude of the MoPH and Government of Afghanistan for the opportunity to learn from Vimta Labs Ltd for the benefit of both the public and private sectors in Afghanistan. He listed of challenges in the pharmaceutical sector in Afghanistan, and stated the commitment of the Afghanistan Government to reverse the trend through an objective assessment of the situation and implementation of the appropriate interventions. Zakria said the visit was therefore most appropriate as it would serve as an opportunity to see the systems and processes for testing medicines for possible adoption. He stated that the QA process will benefit a lot from the timely release of the results of the laboratory testing.

The team showed a video on corporate Vimta Labs Ltd. This emphasized quality as a mind set at Vimta Labs Ltd. It was made clear that the organization was guided by quality which is not only about how it is delivered, but also about how it is done.

The team was informed that Vimta Labs Ltd had been in operation for the past 25 years, and has over 700 professional staff, with over 450 scientists. Vimta Labs Ltd is the only WHO accredited laboratory in India, and the first to be accredited in Asia.

The meeting discussed the SOW in detail, to ensure that every item was well understood. This facilitated the process of logistics mobilization and scheduling of resource persons.

Progress on the transportation of samples was provided. Vimta Labs Ltd informed the team that an application for a test license had been filed, to facilitate the entry of the samples into India. The purchase order (PO) was also receiving attention. While awaiting finalization of these, Vimta Labs Ltd agreed to issue a letter of intent for MoPH to expedite action on permission to send the samples out of Afghanistan.

Coding of Samples in Afghanistan

For clarity of reporting, Inua explained the coding system used for the samples to be sent to the laboratory for testing. This was done during the introductory meeting with the management of Vimta Labs Ltd. He explained that the tablets and capsules had been removed from their original foil and blister packs and repackaged in zip loc plastic carriers, for the purpose of blinding. He further stated that all the samples had been coded. The codes were clearly written on each sample pack in a uniform handwriting, to ensure consistency. In addition to the codes, the complete names and dosage forms of the samples were stated on the packages.

Inua informed the team that each code consisted of five digits: the first digit was a letter, representing the zone; the second digit was a number, representing the type of facility; and the third, fourth and fifth digits were letters, representing the first three letters of each medicine. He drew attention to possible confusion of letters and numbers, for which it was necessary to take note of their positions in the codes. The management of Vimta Labs Ltd confirmed that the information provided was adequate and appropriate for their testing process.

Chain of Custody Procedures

The team took a tour of the receipt area for samples at the point of entry into the laboratory. The samples were first received and temporarily held in the space under roof. There was an adjourning mails/documents room which was used for the documentations that accompanied the samples. Products were then sent to a sample separation room for sample registration into the Laboratory Information Management System (LIMS). This followed a systematic verification process. A unique registration code is given to each sample before dispatch to the various areas for the appropriate testing.

Using the LIMS, there was demonstration on data on the arrival, receipt and internal processes of the samples, as well as basic information on the supplying clients which were being kept. The

team satisfied itself that the LIMS could accommodate the coding system for the samples collected in Afghanistan.

Samples were then sent and duly received in their respective rooms for testing. At the points of testing, the scientists retrieved the necessary information on the samples from the LIMS. A determination of which sample to test was made at this point.

The atmospheric conditions (temperature and humidity) in the sample retention rooms were strictly controlled.

Internal Work Processes

The team was led through the various sections of the laboratory. At each point, the scientist in-charge led the tour, which was extremely interactive. These included areas for:

- Dissolution and disintegration testing
- Bioavailability and bioequivalence testing
- Stability testing
- Spectrophotometric analysis (IR and UV)
- Chromatographic methods (HPLC and GC)
- Sterility and endotoxin testing
- Instrumental analysis
- Microbiology analysis
- Biological testing
- Biomedical testing
- Conventional chemical analysis
- Clinical trials
- Immunological testing
- Clinical pathology and Histopathology

The team saw several equipment used for the various laboratory testing. The processes of sample preparations, recoding and labeling were also observed. Equipment were calibrated regularly and duly recorded by internal and external experts.

The archives storage room was also visited. Reports were being stored under lock in a strictly limited access area. Entry in this area by any person(s) was duly authorized and well documented. All reports were retained in accordance with regulatory requirements.

The team also saw areas for cold storage, separate store rooms for reagents, glassware and stationery. Security for the laboratory complex, waste management, and housekeeping were subcontracted to other companies.

A standby generator with uninterrupted power supply system was available to maintain continuous alternative power supply. A central monitoring and control room for tracking alarm systems was also visited. Facilitates for detecting accidents and potential dangers at point locations were available. Systems were in place to disengage all doors in case of fire outbreak. Water sprinklers were found at vantage points.

The Vimta Labs Ltd had a program for in-service training of its professionals and scientists. The team was informed that in-service training was compulsory for staff. Newly recruited employees were trained before commencement of work. These were usually tested for proper placement. Transportation was available for staff to commute to and from town. Lunch was also provided for all staff on the laboratory compound. A special area was designated for visitors.

In-Compliance and Out-of-Compliance

Some in-compliance and out-of-compliance pharmaceutical analytical worksheets were reviewed to observe the due diligence procedural follow ups on the out-of-compliance products. Copies of forms (attached) used for these processes were retrieved.

Interaction with Staff

The team had first-hand and direct interacts with staff of Vimta Labs Ltd during the tour. These included professionals and scientists, who were found to be very attentive. Questions put to them were very well answered. Formal presentations were made on the various subjects in a highly professional manner. Explanations on procedures and processes were provided in a manner that demonstrated in-depth knowledge of the subject matter.

Visit Review Meetings

The team held review meetings to adopt strategies aimed at optimizing the time during the visit. The meetings were used to review compliance with the SOW and need for any documents required for further action. Observations and impressions by team members were shared.

Departure Meeting with Vimta Labs Ltd Management Team

A departure meeting was held at the laboratory complex to discuss the tour. Kamila spoke on behalf of the visiting team. She stated that the visit was very useful and successful. The set objectives were achieved and some very useful lessons were learnt. She expressed the gratitude of the team to the management of Vimta Labs Ltd for opportunity and attention provided.

Kamila noted that the laboratory complex was found to be very comprehensive and well kept. Furthermore, the management and staff of Vimta Labs Ltd were very receptive and open minded. The profound level of knowledge and professionalism demonstrated by the technical staff during the visit were highly commendable.

On their side, the management of Vimta Labs Ltd expressed their appreciation for the choice of laboratory made by the Government of Afghanistan. They reassured the team of their corporate desire for quality. Management of Vimta Labs Ltd further stated that questions and observations made by the MoPH and SPS team during the visit had been noted for further improvement in their services.

Collaborators and Partners

The following officials were contacted during the visit:

- Dr. N. V. Rama Rao - President, Life Sciences, Vimta Labs Ltd
- Dr. Jyothi Ganti - Vice President, Analytical, Vimta Labs Ltd
- Dr. Vinod Srivastava - Associate Vice President, Vimta Labs Ltd
- Rakesh Sablock - Associate Vice President, Business Development, Vimta Labs Ltd
- Harita Vasireddi - Director, Quality, Vimta Labs Ltd
- V. Harriman - Director, Technical, Vimta Labs Ltd
- V. Anuradha - Manager, Quality Assurance, Vimta Labs Ltd

Adjustments to Planned Activities and/or Additional Activities

Mark and Inua arrived as scheduled in Hyderabad, India. However, the Kabul team delayed in arriving as a result of flight availability. There was also a public holiday during the week. This inevitably led to some changes in the visit agenda. Vimta Labs Ltd gracefully agreed to the proposed changes, which also included receiving the ream during the weekend.

NEXT STEPS

Follow up activities include:

- Complete contractual agreements with Vimta Labs Ltd and North West University Laboratory;
- Send collected samples to the selected laboratories;
- Receive results from laboratories;
- Write report;
- Carry out the Afghanistan medicines quality assurance rapid assessment survey.

World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Tel. direct: +41 22 791 3743
Fax direct: +41 22 791 4730
E-mail : streipai@who.int

In reply please refer to: P5-447-3/IS/SC/I

Your reference:

Dr N. V. Ramarao
President - Life Sciences
Vimta Labs
Life Sciences Facility, Plot No. 5
S.P. Biotech Park, Genome Valley
Hyderabad 500 078
Inde

7 August 2008

Dear Dr Ramarao,

WHO Prequalification of Medicines Programme
Inspection of Quality Control Laboratory
Vimta Labs, Hyderabad, India, from 14 to 15 April 2008

Referring to the above-mentioned inspection, please find enclosed the World Health Organization (WHO) Final Conclusion.

We should like to take this opportunity to thank you for your collaboration.

Yours sincerely,

Dr Raul Kiivet
Manager
Prequalification Programme
Quality Assurance and Safety: Medicines

ENCL. (1)

Director Quality / President LS
2008/08/14

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WHO FINAL CONCLUSION OF THE INSPECTION of the QC Laboratory

The report is the property of the organization responsible for performing the inspection.

Part 1: General information about the inspection

Name of laboratory	**VIMTA LABS LTD**
Physical address	LIFE SCIENCES FACILITY PLOT NO.5, S.P.BIOTECH PARK, GENOME VALLEY HYDERABAD - 500078, INDIA
Postal address	As above
Telephone number	+91 40 3984 84 84
Fax number	+91 40 3984 77 76
Summary of all the activities performed by the manufacturer	The company was involved in: • Conventional chemical analysis • Instrumental analysis • Microbiological analysis • Biological testing • Stability testing • Clinical trials
Scope of inspection	Prequalification inspection of QC laboratory
Focus of inspection	• Quality system of the Quality Control Laboratory • Conventional chemical analysis • Spectrophotometric analysis (IR, UV) • Chromatographic methods (HPLC, GC) • Dissolution and Disintegration testing • Microbiological analysis
Contact person(s)	Dr.N.V.Ramarao President - Life Sciences Ph.: 91-40-39848484 (Extn: 2101) Mobile: 9885574604 Email: ramarao.nittala@vimta.com

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Quality Assurance	Ms. V. Anuradha - Manager QA
Other staff present	Dr S P Vasireddi - Chairman & Managing Director Mr. V Harriman - Director-Technical Dr. N V Rama Rao - President-Life Sciences Dr. Y L Paruchuri - AVP-Micro Biology Mr. P Srinivas - Dy. Manager-QA Mr. Y Sudhakar - AVP-TAL Mr. Satyanarayana - Dy. Manager-Drug Lab Mr. Ankaiah - Group Leader-Drug Lab Mr. Mujeeb - Group Leader-Drug - Lab Ms. P Janaki - Group Leader-Drug Lab Mr. Jayapal Reddy - Group Leader-Contract Lab 3 Ms. T Naga Radhika - Quality Auditor Ms. S Madhavi - Quality Auditor Ms.N.Susmitha - Quality Auditor
Inspector	Mrs. Iveta Streipa (WHO)
Date of inspection	14, 15, April 2008
Programme	Prequalification Programme: Priority Essential Medicines.

2. Company response to the inspection report

We acknowledge receipt of your response to the World Health Organization (WHO) report related to the Quality Control Laboratory inspection mentioned above.

3. Assessment of the corrective action proposed

Actions taken or proposed to be taken in relation to the observations listed in the WHO inspection report have been outlined in the company's correspondence.

WHO inspector Iveta Streipa have reviewed the corrective action plan, actions and information provided by the laboratory in relation to the observations.

The non-compliances with the guidelines listed in the full inspection report have been addressed by the laboratory and verified through evaluation of the documentation regarding the corrective actions (planned and implemented) submitted. The corrective actions

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taken and proposed were found to be acceptable. No more correspondence is needed related to this inspection.

4. Final Conclusion

Conclusion of the Inspection report and final conclusion, August 2008:

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection (reflected in the observations listed in the inspection report) and the laboratory corrective actions, VIMTA LABS LIFE SCIENCES FACILITY PLOT NO.5, S.P.BIOTECH PARK, GENOME VALLEY HYDERABAD - 500078, INDIA, was considered to be operating at an acceptable level of compliance with WHO Good Practices for National Pharmaceutical Control Laboratories (GPCL).

WHO inspector
Mrs I. Streipa

6.08.2008
Date

VIMTA LABS
Determining Quality

Laboratory Investigation Report

Form 02/64-OOX-I
May 2009
Page 01 of 05

Initiation : Investigator(s)'s Signature/Date:_____

1. Description of OOX Results **OOX No:**

OOX type : ☐ OOS ☐ OOT (atypical) ☐ OOG

Date: _____ VLL Regn. No./Sample ID/Study ID_____

Sample Particulars	
Test Parameter and Method	
OOS/OOG/OOT results	
Specifications / Guidelines	
Analyst name and Notebook / Worksheet Reference	

2. Customer Notification

Notified to (name/s)	
Date & mode of notification	
Notified by	
Customer comments received, if any	
Date on which the investigation report is sent to the customer*	

** Only this particular information is filled after the investigation has been completed and the report is sent to the customer. Rest of the information shall be filled as and when the customer is notified.*

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Laboratory Investigation - Phase Ia:

A. Analyst and Test Method

Test method review / problems or deviations:

Analyst training and appropriate knowledge of technique:

Comparison of method performance against typical performance or validation data:

B. Material, Reagents and Standards

Standard preparation & correct weight(s) documentation:

Preparation of reagents and solutions:

Glassware or contamination issues:

C. Documentation and Raw Data Review

Raw data discrepancies and data transcription:

Calculation errors and review:

D. Equipment and Instrumentation

Correct instrumentation, equipment and accessories:

Current instrument calibration or performance qualifications:

Appropriate operating parameters or setting:

Mechanical or electrical failures:

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E. Chromatograms & Spectra

Programmed method and sample set:

Baseline noise and consistency throughout the sequence:

Performance characteristics (resolution, efficiency, system suitability):

Interferences, chromatographic anomalies and extra peaks:

F. Product or material history or trend analysis

Agreement or consistency with other results:

Agreement or consistency with the test results from typical product or similar samples:

G. Sample Handling

Sample transport, handling and storage:

H. Sampling

Sample records, procedural deviations:

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I. Additional Information (if any)

Summary of Phase Ia Investigation

Did the Phase-Ia investigation reveal a determinate cause for the OOS/ OOT / OOG result(s)? - Tick below.

☐ Yes - Invalidate the original data and reanalyze the original sample at the same level of replication, or reanalyze the original sample preparations.

Investigator's sign & date	HOD's signature & date	QA's signature & date

☐ No -Proceed to confirmation test, additional investigation test, or retest.

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Laboratory Investigation - Phase Ib:

Confirmation Test Plan

_____

_____

_____

_____

_____

_____

Investigator's signature & date: _____

_____ _____

HOD's Approval Signature & Date QA's Approval Signature & Date

Confirmation Test Results

_____

_____

_____

_____

_____

_____

Did the results from confirmation test confirm the original result(s)?

☐ Yes - Report the all results or proceed to retest or additional investigation test.

☐ No - Proceed for Laboratory Investigation -Phase II

Was the cause of the discrepancy between the original and confirmation test results identified?

☐ Yes - Invalidate the original data and reanalyze the sample, repeat the test at the original replicate level or repeat the analyses using fresh sample preparations at same level of replication or report the confirmation test results.

_____ _____

HOD's Approval Signature & Date QA's Approval Signature & Date

☐ No - Proceed to retest or additional investigation test.

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Laboratory Investigation - Phase II **OOX No:**_____

Additional Investigation Test Plan

_____

_____

_____

_____

_____

_____

_____

Investigator's signature & date: _____

_____ _____

HOD's Approval Signature & Date QA's Approval Signature & Date

Additional Investigation Test Results (Reference the worksheet/notebook no.)

_____

_____

_____

_____

_____

_____

Did the additional investigation reveal the root cause for the OOX result?

☐ Yes - Invalidate the original data and reanalyze the sample, repeat the test at the original replicate level, or report the results from the additional investigation test.

_____ _____

HOD's Approval Signature & Date QA's Approval Signature & Date

☐ No - Proceed to retest.

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Retest Plan

Investigator's signature & date:

HOD's Approval Signature & Date

QA's Approval Signature & Date

Re-sample Justification

Customer consent (reference)	HOD Approval Signature & Date	Manager-QA Approval Signature & Date

Retest Results

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Laboratory Investigation Conclusion **OOX No:**_____

Summary of Reported Results

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Investigation Timeline Extension

_____

_____

_____

_____ _____

HOD's Approval Signature & Date QA's Approval Signature & Date

Confirmed OOS Result(s): ☐ Yes or ☐ No

Further investigation required: ☐ Yes or ☐ No

Corrective & Preventive Action Reference Numbers (if applicable)

_____

Designation	Name	Signature & Date
Investigator		
HOD		
Manager-QA		

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Annex 3: Test Report

[illegible], Prescience Facility 5, 5 F Biotech Park, Genome Valley
Hyderabad 500 078, RR District, India
91-40-[illegible] Fax 91-40-27263657, Email : quality@vimta.com

TEST REPORT

Form 39 See rule 150-E[f] [Under the Drugs & Cosmetics Act 1940 and the Drugs & Cosmetics rules 1945thereunder]

Report Number	:	06141/09/VLL/000/01
Issue Date	:	11-Sep-2009
Your Ref	:	PO.NO AP9229
and Date	:	26-Jun-2009

Analytical Report of	Emtricitabine 200mg + Tenofovir DF 300mg Tablets		
Batch Number	1018253		
Manufacturer			
Pack Size	30 Tablets		
Mfg Date	06/2009	Exp Date	05/2011
IDA Protocol No	A-3131-MTR	Rev.No	00
IDA Method of Analysis No	L-440	Rev.No	00
Sample Registration Date	2009-08-24		
Date Of Analysis	2009-08-27	Date of completion	2009-09-09

EXECUTIVE SUMMARY

The aim of this study is to prove compliance of a routine batch sample analyzed by VIMTA LABS LTD.with the applicable IDA product specification.

All the Tests have been performed on calibrated equipment and results are reported in the following document section.

C215255

VIMTA LABS
Determining Quality
Analytical Division, Lifesciences facility : 5, S P Biotech Park, Genome Valley,
Hyderabad - 500 078, RR District, India
☎ : 91-40-3984 8484, Fax : 91-40-27263657, Email : quality@vimta.com

TEST REPORT

CONTINUATION SHEET :

Report Number : **06141/09/VLL/000/01**

TEST RESULTS

Sr.No	Test parameters	Method	Specification	Results
1	Characteristics	Visual	Blue coloured,oval shaped, film coated tablet debossed with 'M117'on one side and plain on the other side	Complies
2	Identification	L-440	ret.times correspond to those of standards of emtricitabine and tenofovir disoproxil	Complies
3	Average Weight	---	For information only	1035.2mg
4	Uniformity of weight	BP	NMT 2 units > 5% none >10%	Complies RSD:1.10%
5	Dissolution Test (900 ml 0.01M HCl,37°c, paddle 50 rpm.)	L-440		--
6	Emtricitabine	---	NLT 80%(Q) in 30 minutes	Min:96.84% Max:104.70 Avg:101.78%
7	Tenofovir disoproxil fumarate	---	NLT 80%(Q) in 30 minutes	Min:96.87% Max:105.01% Avg:101.98%
8	Related Substances	L-440	-----	--
9	S-oxide impurity	---	NMT 0.6%	0.15%
10	Monoester impurity	---	NMT 3.5%	0.65%
11	Tenofovir disoproxil dimer impurity	---	NMT 0.75%	0.07%
12	Mono POC dimer	---	NMT 0.75%	Not detected
13	Mix dimer impurity	---	NMT 0.75%	0.02%
14	Any other individual unknown imp.	---	NMT 0.2%	0.09%
15	Total(known+unknown)	---	NMT 6.0%	1.18%
16	Assay	L-440	---------	--
17	Emtricitabine	L-440	90-110%	1)204.49 mg(102.24%) 2)203.96 mg(101.98%) Avg:204.23 mg(102.11%)
18	Tenofovir disoproxil fumarate	L-440	90-110%	1)311.07 mg(103.69%) 2)309.33 mg(103.11%) Avg:310.20 mg(103.40%)

2.CONCLUSION

Based on above findings the submitted sample complies with the criteria defined in IDA protocol.

	Name	Signature	Designation	Date
Author	T. Trinath	T. Prof	Group leader	2009-09-11
VIMTA LABS Approval	Vinod	Vinod	AVP. Ops	24/09/09/11

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AUTHORISED SIGNATORY

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