LOGISTICS FACT SHEET FOR QUALITY CONTROL OF DRUGS

GPHF-MINILAB®

BRAND AND MANUFACTURER
Sales Information
German Pharma Health Fund e.V. (GPHF)
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Tel.: +49-6171-50399-0
Fax: +49-6171-50399-20
Email: info@gphf.org
Website: www.gphf.org

Supplier
Technologie Transfer Marburg e.V. (TTM)
Auf der Kupferschmiede 1, 35091 Coelbe, Germany
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Fax: +49-6421-87373-7
Email: ttm@ttm-germany.de

For technical questions about equipment and testing procedures and references from current users:
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KIT INFORMATION
Counterfeiting of pharmaceuticals and the proliferation of substandard drugs constitute a serious health risk, especially in the developing world where drug quality control systems are not always readily available. Experts assume that currently as much as 7 percent of the world’s total pharmaceutical sales is counterfeited or of substandard quality.

The GPHF-Minilab® is a mini-laboratory used in developing countries by medical store and hospital managers, drug inspectors, and other authorities to detect counterfeit and substandard pharmaceuticals and to provide basic quality control of drugs.

* Developed by the German Pharma Health Fund (GPHF), a nonprofit organization that promotes pilot projects for the improvement of health services in developing countries.

DRUGS AND CATEGORIES

Analgesics (pain relievers)
Acetylsalicylic Acid, Metamizole, Paracetamol

Antastihamtics
Aminophylline, Salbutamol

Antibiotics
Amoxicillin, Ampicillin, Cefalexin, Chloramphenicol, Ciprofloxacin, Cloxacillin, Cotrimoxazole, Erythromycin, Metronidazole Phenoxyethylpenicillin, Tetracycline

Antidiabetic
Glibenclamide

Antifungal
Griseofulvin

Antihelmintic
Mebendazole

Antimalarias
Amodiaquine, Artemether, Artesunate, Lumefantrine, Chloroquine, Mefloquine, Primaquine, Quinine, Sulfadoxine/Pyrimethamine

Antiretrovirals (ARVs)*
Didanosine, Indinavir, Lamivudine, Nevirapine, Stavudine, Zidovudine

* On special request only and at additional cost

Antituberculosis
Ethambutol, Isoniazid, Pyrazinamide, Rifampicin

Diuretic
Furosemide

Steroid
Prednisolone
CURRENTLY USED IN

Latin America & the Caribbean
- Bolivia • Brazil
- Colombia • Ecuador
- Grenada • Guyana
- St. Lucia • Surinam
- Venezuela

Africa
- Cameroon • Congo
- Eritrea • Gabon
- Ghana • Guinea
- Kenya • Liberia
- Mali • Mozambique
- Niger • Nigeria
- Senegal • Sierra Leone
- Sudan • Tanzania
- Togo • Zimbabwe

Asia
- Afghanistan • Bangladesh
- Cambodia • China
- Georgia • India
- Indonesia • Myanmar
- Nepal • Laos
- Pakistan • Philippines
- Sri Lanka • Thailand
- Vietnam

Middle East
- Palestine

TESTING PROCEDURES

Visual Inspection Test
A comparison of solid dosage forms, including the packaging material, in order to rapidly reject crudely presented formulations. The test includes a search for deficiencies in the labeling, packaging, and dosage forms in comparison with the descriptions given in the GPHF-Minilab® manual included in the start-up package.

Disintegration Test
This test requires that all instantly soluble tablets and capsules disintegrate in water at a certain temperature within a designated timeframe, as specified in the main manual. This is a simple test for preliminary assessments of deficiencies related to drug solubility and availability. All instantly soluble tablets and capsules must pass the Disintegration Test. The manual included in the GPHF-Minilab® start-up package provides a detailed description of this test.

Color Reaction Test
A simplified test for a quick color check of any drug present against a standard in order to verify the drug’s identity. A sample of the drug is crushed and mixed with the appropriate reagents to create a color reaction. The color is verified using the reference standards given in the GPHF-Minilab® manual on color reactions. If the drug fails this step, it is recommended to reject the drug and conserve resources by not conducting the TLC testing below.

Thin Layer Chromatography (TLC) Test
A semi-quantitative test against a standard to check the amount of active ingredient present to verify a drug’s potency. This test requires one whole unit of an oral solid dosage to be dissolved in a known volume of extraction solution. The sample solution is applied to a thin layer chromatoplate (supplied in the GPHF-Minilab® start-up package), allowed to develop for 15 minutes in a solvent, dried using a hot plate, analysed using an ultra-violet (UV) lamp, and finally stained with iodine to detect any spots failing to appear in the UV detection. Detailed instructions for the analysis of each drug are given in the GPHF-Mini-
## Supply Chain Implications

<table>
<thead>
<tr>
<th><strong>Equipment Included in Kit</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>rulers, thermometer, timer, labeling tape and pen, hot plate, sample preparation equipment (test tubes, test tube rack, mixing beakers, scalpel/blade, spatula, filter paper, tweezers, scissors, pestle, funnel, pipettes, pipette rack)*</td>
<td>universal pH indicator testing paper, dropping bottle and sealer cap, glass stirring rod, measuring cylinders, glass bottles with closures, transfer pipettes, microspoon, adapter plug, alcohol lamp, methylated spirit (alcohol) - 1 L, safety spectacle, test-tube brush</td>
<td>aluminum foil, glass bottles with closures, pumppette, pencil, pencil sharpener, Merck TLC aluminum plates, TLC developing chamber, iodine staining chamber, battery-powered UV lamps of various preset wavelengths with replacement batteries, authentic secondary reference standards (ARV secondary reference standards supplied on request)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Reagents and Solvents Included in Start-up Package</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>acetone (1 L); glacial acetate acid (1 L); methanol (1 L); ninhydrin (10 g); sulfuric acid 96% (1 L)*</td>
<td>ammonia solution 25-26% (50 mL)</td>
<td>disodium or tripotassium edetate (50 g)</td>
</tr>
<tr>
<td>copper (II) acetate, monohydrate (100 g)</td>
<td>ethylacetate (1 L)</td>
<td>ferric (II) chloride tetrahydrate (50 g)</td>
</tr>
<tr>
<td>4-(dimethylamino)-benzaldehyde (25 g)</td>
<td>ferric (III) chloride solution 10% (0.25 L)</td>
<td>fast red TR salt (10 g)</td>
</tr>
<tr>
<td>fast red TR salt (10 g)</td>
<td>formaldehyde 37% (50 mL)</td>
<td>formaldehyde 37% (50 mL)</td>
</tr>
<tr>
<td>ferric (II) chloride tetrahydrate (50 g)</td>
<td>hydrochloric acid solution 36% (1 L)</td>
<td>hydrochloric acid solution 36% (1 L)</td>
</tr>
<tr>
<td>ferric (III) chloride solution 10% (0.25 L)</td>
<td>formaldehyde 37% (50 mL)</td>
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<tr>
<td>formaldehyde 37% (50 mL)</td>
<td>hydrogen peroxide solution 30% (1 L)</td>
<td>hydrogen peroxide solution 30% (1 L)</td>
</tr>
<tr>
<td>hydrogen peroxide solution 30% (1 L)</td>
<td>potassium dichromate (50 g)</td>
<td>potassium dichromate (50 g)</td>
</tr>
<tr>
<td>potassium dichromate (50 g)</td>
<td>sodium hydroxide pellets (500 g)</td>
<td>sodium hydroxide pellets (500 g)</td>
</tr>
<tr>
<td>sodium hydroxide pellets (500 g)</td>
<td>Capacity sufficient for 3,000 color reaction runs</td>
<td>Capacity sufficient for 1,000 TLC runs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Packaging and Shipping Information</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 protective case (black with pre-formed dividers/pockets)</td>
<td>1 protective case (black with pre-formed dividers/pockets, wheels and extension handle)</td>
<td>1 protective case (black with pre-formed dividers/pockets)</td>
</tr>
<tr>
<td>62 x 50 x 22 cm</td>
<td>83 x 52 x 29 cm</td>
<td>83 x 52 x 29 cm</td>
</tr>
<tr>
<td>14 kg</td>
<td>23 kg</td>
<td>23 kg</td>
</tr>
<tr>
<td>Start-up package: reagents and solvents 20–22 boxes (approx. 50 kg)</td>
<td>Approximately 90 kg as ready-packed palette for worldwide delivery by air (40 kg for suitcases and 50 kg for reagents)</td>
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</tr>
<tr>
<td>Order will be shipped within 3 weeks from when order is received and the invoice is settled.</td>
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<tr>
<th><strong>Shelf Life</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>5 years for reagents and solvents in their original packaging.</td>
<td>Capacity sufficient for 3,000 color reaction runs</td>
<td>Capacity sufficient for 1,000 TLC runs</td>
</tr>
<tr>
<td>• 2 years for authentic secondary reference standards.</td>
<td></td>
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</tr>
<tr>
<td>• Less than 2 years for authentic secondary reference standards for ARVs.</td>
<td></td>
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<tr>
<th><strong>Storage Conditions</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Store at room temperature, avoiding direct sunlight.</td>
<td></td>
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</tr>
<tr>
<td>• No special storage required for the quantities of chemicals supplied.</td>
<td></td>
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</tbody>
</table>

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<thead>
<tr>
<th><strong>Installation and Use</strong></th>
<th><strong>Color Reaction Kit</strong></th>
<th><strong>TLC Kit</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Can be used outdoors and indoors.</td>
<td></td>
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</tr>
<tr>
<td>• Can be mounted on a bench top or office table.</td>
<td></td>
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</tr>
<tr>
<td>• Fits all electrical sockets and voltages.</td>
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</tr>
<tr>
<td>• Sufficient air ventilation needed, e.g., fan and open window, when using indoors.</td>
<td></td>
<td>• Sufficient air ventilation needed, e.g., fan and open window, when using indoors.</td>
</tr>
<tr>
<td>• Requires access to running water for cleaning equipment.</td>
<td></td>
<td>• Requires access to running water for cleaning equipment.</td>
</tr>
</tbody>
</table>

* Included in both the Color Reaction Kit and the TLC Kit.
## ESTIMATED PRICE

**Minilab Start-up Package** 1
- 3,100 €
- U.S.$3,760 without optional features

**Transport to Country** 2
- 800 ± 100 €
- U.S.$970 ± U.S.$120

**Transport in Country**
- 120 €
- U.S.$145

**Duties**
- 1000 €
- U.S.$1,213

**Total**
- 4,750 € (about 5 €/assay)
- U.S.$5,760 about U.S.$6/assay

**One Week Training**
- 450 €/person
- U.S.$546/person

**Travel Expenses** 3
- 2,500 €
- U.S.$3,032

**Resupply of Reagents & Solvents** 4
- Minimum order: 10 €
- U.S.$12

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2 U.S.$ value as of June 23, 2005.

3 Price of transport and duties varies by destination.

4 Price lists are available from the supplier.

## OPTIONAL FEATURES

(with minimal increase in weight and volume)

- Authentic secondary reference standards for ARVs. Cost: approximately 7 € (U.S.$8.50) for each ARV secondary reference standard.

  Note: As of May 2004, there is a donated stock of these materials, so this cost is only for additional packaging and handling fees for each tube (containing 20 samples of authentic reference tablets/capsules). Cost for stock falling below a shelf life of 6 months is negotiable. If this donated stock is not available, the actual market value of the ARV drug will be applicable.

- Small battery-driven pocket balance with a precision of 0.01 g for testing the quality of bulk drug substances, uniformity of tablet and capsule mass, and easy preparation of test solutions. Cost: 160 € (U.S.$194).

## LIMITATIONS

- Reagents are supplied separately and need an adequate amount of storage space, although there are no special storage requirements for the chemicals.

## TRAINING

Training on the Minilab’s operational procedures is offered locally, or in Germany by the:

- Medical Mission Institute Würzburg, mi-appro@mailuni-wuerzburg.de
- German Medical Aid Organization action medeor, info@medeor.org
- GPHF-Minilab® Project Manager, info@gphf.org

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The author’s views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.