

Screening Medicines with the GPHF-Minilab™

Medicines quality is critical to patients' health: in addition to straining a country's financial resources and health care system, substandard and falsified medicines may contribute to drug resistance development and can lead to treatment failure, adverse effects, prolonged illness, and even death. The Promoting the Quality of Medicines (PQM) program, supported by the U.S. Agency for International Development (USAID) and implemented by USP, helps low- and middle-income countries to strengthen their quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health.

Assessing Medicines Quality in the Field

PQM helps develop risk-based country- and context-specific protocols for medicine sampling and testing and trains field personnel to test collected medicines.

The first step in assessing the quality of a medicine is the physical inspection of the dosage form and packaging materials. Following this, the dosage forms are submitted to additional tests to evaluate other quality attributes.

In field settings, the Global Pharma Health Fund (GPHF)-Minilab™ includes tools that support the physical inspection of the dosage form, as well as the following tests:

- Simple disintegration tests assess whether solid oral dosage forms disintegrate within predetermined timeframes. Disintegration is not a measure of active ingredient dissolution, but it is required for proper dissolution to occur.
- Easy-to-use thin-layer chromatography tests provide a quick check of the identity of the active pharmaceutical ingredient (API) and a semi-quantitative assessment of its content, to verify label claims about identity and potency.

Limitations of GPHF-Minilab™ Testing

The tests included in the GPHF-Minilab™ are intended for screening medicines in the field. They are not as comprehensive, accurate, or precise as compendial analysis, nor are they intended to replace laboratory testing of registration specifications. Some of Minilab's™ limitations are:

- API content determination is limited to a visual assessment within an 80%–120% range. This procedure cannot replace compendial analyses with more sophisticated and precise methods.
- Critical quality attributes, such as dissolution rate or uniformity of dosage forms, cannot be determined using the GPHF-Minilab™.

- Limited qualitative information about certain impurities can be obtained, but impurity levels are not quantifiable with the methodologies included.
- In most countries, data on products failing Minilab™ testing cannot be used for regulatory actions.
- Confirmation of Minilab™ data using comprehensive compendial procedures for failed samples and subsets of passing samples is required and recommended.

GPHF-Minilab™ Product Profile*

Description:

- Simple, low-cost screening methods assembled as a self-contained kit ready-packed for worldwide delivery.
- Helps detect poor-quality medicines without APIs, containing the wrong APIs, or with API content below or above acceptable levels.
- Can be utilized outside of a laboratory environment by properly trained personnel without extensive background on analytical chemistry.
- Includes basic laboratory ware, starter kit of chemicals, and manuals with testing methodologies.
- A customized set of secondary reference standards for tests included in the manuals can be purchased.
- Streamlines and enhances medicines testing capacity.

Drugs covered: 90 unique products can be tested, including medicines prevailing in low- and middle-income countries for priority diseases, such as vital antimicrobials, anthelmintics, antiretrovirals, antimalarials, and tuberculosis medicines. The most relevant fixed-dose combinations of these products can also be tested. The list of covered drugs is expanded annually.

Equipment: 1 protective case including manuals and collection of authentic secondary reference standards (83 x 52 x 29 cm, 25 kg, black with preformed dividers/pockets, wheels and extension handle).

Costs: Approximately \$4,000 USD, including laboratory ware, manuals with method inventory on drug compounds plus solvents, and other consumables to run approximately 1000 test runs.

* Some of this information was extracted from GPHF-Minilab™ Fact Sheet, accessed on September 25, 2017, at <http://www.gphf.org/en/minilab/factsheet.htm>

LEARN MORE about PQM at www.usp-pqm.org, or contact us at pqm@usp.org or +1-301-881-0666.