



Guidelines for Drug Sampling

USP DQI Drug Quality Monitoring Program

Use of the Basic Tests at the Peripheral Level

August 2006

This publication was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement number HRN-A-00-00-00017-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

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Acknowledgements

We would like to thank all participants of the Mid-Project Review Meeting of the Antimalarial Drug Quality Monitoring Project, held in Vientiane, Laos on July 7-9, 2004, for their valuable inputs and recommendations on the first draft of this document.

We would like to express sincere thanks and gratitude to the following people for their comments and contributions in finalizing these sampling guidelines:

Dr. Z. Canglin, Division for Protozoal Diseases, Yunnan Institute of Parasitic Diseases, China Mr. T. N. Hai, Head of Pharmaceutical Unit, National Institute for Malariology Parasitology and Entomology, Vietnam, Mrs. R. Kovithvattanapho, Bureau of Drug and Narcotics, Ministry of Health, Thailand, Dr. C. Lon, National Center for Parasitology, Entomology, and Malaria Control, Cambodia, Dr. P. Newton, Coordination and Clinical Lecturer, Wellcome Trust UK, Laos, Dr. N. Nivanna, Director, Laboratory for Drug Quality Control Center, Cambodia, Mrs. A. Tongboonrawd, Deputy-Director, Bureau of Drug and Narcotics, MOH, Thailand and Dr. L. Vongsack, Director, Food and Drug Quality Control Center, Laos

Our special thanks go to Dr. E. M. Christophel, Medical Officer for Malaria Vector-borne and Other Parasitic Diseases WPRO; Dr. C. Ondari, Technical Officer, Essential Drugs and Medicines Policy Department, WHO HQ; Dr. K. Thimasarn, Medical Officer WHO RBM Mekong, Dr. R. Tsuyuoka, Scientist for Malaria Control WHO/Cambodia; Dr. T. C. Dai, Medical Officer for Malaria, Vectorborne and other Parasitic Diseases WHO/Vietnam.

We acknowledge the guidance and thoughtful contributions we received from Anthony F. Boni (Pharmaceutical Management Advisor, Office of Health, Infectious Diseases and Nutrition, U.S. Agency for International Development (USAID); Marni Sommer (Pharmaceutical Management Advisor, USAID; and Andrew Clements (Technical Advisor, Regional HIV/AIDS and Infectious Disease Program, USAID) who provide constant moral support and encouragement.

Thanks also go to USP DQI staff: Souly Phanouvong, Abdelkrim Smine and Dat Tran, for their valuable technical contributions, Nancy Blum and Catherine Wachira for their review, Marilyn Foster and Milissa McGinnis for editing this document; and Madeleine Welsch and Lisa Straker for their administrative support.

Guidelines for Drug Sampling

1. General Considerations

Currently the program aims to carry out a monitoring activity for the quality of antimalarial medicines (or other drugs, such as anti TB, ARVs and antibiotics) circulating and used in the selected sentinel site areas. Drug quality data obtained from this project will be reported to responsible authorities in the country for use in developing appropriate policies or strategies to improve the situation. Data will be also analyzed, classified, and disseminated, as appropriate, among participating countries in regional initiatives.

Sampling encompasses the operations designed to collect samples of different dosage forms, and testing them using basic tests according to USP DQI training and guidelines. It is very important to understand that this drug quality control monitoring program should not under any circumstances be utilized as the sole quality control measure in the country. This program should only be considered as a screening drug quality program and when samples of suspicious quality are found, only pharmacopeial tests using recognized monographs should be used to confirm the results of basic tests.

This program has proven to be very valuable in initiating and strengthening drug quality control in countries with limited capacities for drug quality assurance. The success of such a program will be seen only if it is adapted to the reality in the field of each sentinel site, taking into consideration the availability of human and financial resources, all the logistics required for sampling and testing drugs, and most importantly the close collaboration between health program (i.e. malaria control program), the drug regulatory authority, and the quality control laboratory. The training on basic tests should cover all aspects of the quality control monitoring program, and the last day of the training should focus on assisting the trainees design a program, taking into consideration the reality in each sentinel site.

1.1. Purpose of sampling

The purpose of this sampling is to collect random samples from various sectors and available outlets in an effort to accurately reflect what consumers use in a given sentinel site and/or geographic area. The samples collected are subjected to visual and physical inspections, simple disintegration (solid dosage forms) and Thin Layer Chromatography. Such tests will only assess the identity of the active ingredient, give an indication about the content based on what is claimed on the label, and show impurities in comparison with authentic reference standards. Visual and physical inspections of the drugs and their packages will give information about the manufacturing source and will help identify counterfeit and suspicious drugs.

1.2. Sample definition and types

A realistic sampling methodology is key in determining not only the feasibility but the overall success of the drug quality monitoring program. Samples should be collected from different lots, different locations, and from all available sectors to accurately represent the drug available and utilized by consumers. At each round, the samples

collected according to the sampling plan are tested at the sentinel site using basic tests. Portion of these samples together with all suspicious samples are sent to QC lab for verification and confirmatory tests. Sampling of more units from a specific drug could be scheduled if the QC lab decides to carry more pharmacopeial tests.

One sample of a solid oral dosage form is, at minimum, 20 units from the same lot number collected at the same location/outlet; one sample for an injectable dosage form is 10 units from the same lot number collected at the same location/outlet. In the case when fewer units are found, the sampling should also cover these drugs (i.e. in informal market). Again, more dosage units should be collected only in specific cases where further laboratory testing is required. .

After each round of sample collection and testing at the sentinel sites, approximately 10% of each drug should be retested by the designated QC lab for verification. The remaining units of tested samples should be retained for at least one year, stored according to the manufacturer's recommended storage conditions.

1.3. Sample collector

The composition of the "sampling team" should consist of, but not be limited to:

1. Drug Regulatory Authority (DRA)
2. Drug Quality Control Lab
3. Malarial Control Program

The country should select and reach a consensus on the actual composition of the sentinel site teams. This selection should be vetted and approved by the DRA. In many countries, the monitoring of drug quality using basic tests is carried out by academic or public health institutions. The close collaboration between health programs, DRA, and the QC lab is very critical to the success of the program.

2. Sampling Method and Procedures

2.1. Sampling plan and sample size

Soon after the training of sentinel site personnel, each country should formulate a Sampling Team consisting of team members described in **1.3**. The Team should then develop (in collaboration with the health authorities in the sentinel site) a plan to carry out the collection of samples. When the program is managed at the central level, it is critical to actively involve and keep health authorities at the sentinel site level well informed about all activities and share all data and findings with them, as it directly affects the sentinel site decision-making process especially if additional sample collection is required.

Sample collection frequency

Collection and testing of drugs should be carried out systematically three times a year in four-month intervals.

The Sampling Team at each sentinel site should arrange an appropriate schedule that takes into account the logistics and availability of resources. The sampling team should communicate this schedule to the verification lab (national or provincial) so the lab will be prepared to receive samples for verification testing.

Sampling techniques

The use of official protocol is required; samples collected formally may be supplemented with samples collected by “mystery” shoppers, if the country wishes to do so. The sample collection form should be completed for each sample collected whenever possible.

Sample collection special precautions

Each sample collected must have a *Sampling Form* properly filled out, and safely attached to or inserted into the sample container.

Samples must be kept and stored according to the manufacturer’s recommended storage conditions which can be found on the drug label.

The source of a sample should be traceable. The Sampling Team should make every effort to collect samples that have an “identifiable” name of the drug product and its active ingredients (APIs) and the manufacturer’s address on the label. Where possible, samples should be in their original container or package. If the sampling team knows that a particular medicine has been transferred from the original container to a smaller container (for sale or dispensing purposes) which does not have proper labeling, additional samples should be taken from the original container as well. The team must collect all information required on the *Sampling Form*, if this information is not on the label of the sample.

Sample size (number of units/sample)

- Minimum 20 units for tablet or capsule dosage forms of single drug preparation; and 10 units for injectables. When fewer units are found (i.e. in informal sector) samples with less than 20 units may also be included.

This quantity/number of sample units should be sufficient for at least two complete screening tests using basic testing methods (physical/visual inspections, disintegration and thin-layer chromatography (TLC)). More units from specific samples could be re-collected if more laboratory testing is needed.

Number of samples:

Every effort should be made to collect, whenever possible, at **least five samples** for each product per sentinel site per sample collection round.

In subsequent rounds of sampling, if a specific drug product of the same lot/batch number is found at the same location, there is no need to collect this product again unless some unusual labeling, packaging, expiry date, manufacturing date or physical characteristics of the product are observed.

2.2. Sampling locations

Convenience sampling methodology is utilized in this project. In the effort to obtain geographically representative samples, sampling locations have been identified based on the following principles:

1. Sectoral coverage - sampling locations included in this project cover both the public and private sector supply and distribution systems, and both formal and informal channels;
2. Geographical coverage - both urban/suburban and rural areas of the sentinel sites selected;
3. Main route/flow of drug supply or distribution both from neighboring country (or countries) and province(s); and
4. Antimalarial drug-wise coverage – common antimalarial drugs and preparations from different brands/sources of manufacture and lots/batches are sampled

The geographical and administrative meaning of “sentinel site” can be different from one country to another. A “sentinel site” could be a province, a municipality, or a district (other sub-divisions are also used). Only municipalities, communes, and districts that belong to the selected “sentinel site” are selected during the sampling of drugs. In the planning for sample collection in each provincial site, the Sampling Team should study the geographical map of the province and identify the districts located in each province (in terms of number, surface area, port of entry/border with other province(s) or neighboring country based on the main circulation or distribution route of medicines, and physical access by car or walking).

a. Sampling localities:

Using available health and administrative information, the sampling team should divide each sentinel site into different zones (e.g. district, communes, etc.). Each round of sampling should cover new areas within the sentinel site’s limits.

b. Selection of actual sampling location level:

1. Sampling Team should make an estimate of the numbers of samples that can be collected per round and plan accordingly; the selection should cover both formal and informal channels and give priority in the following order: ports of entry, wholesalers or distributors; pharmacies; retail drug outlets; hospitals and clinics; national health program warehouses; and street vendors.

2. Once a geographical area of sampling locations is identified in a village of a district, the Team can select randomly and conveniently a site or sites taking into consideration principle 3 (above) and order of priority when arriving in the village. In addition, every attempt should be made to obtain samples from both public and private sectors (principle 1 – above).

Note: In the subsequent round of sampling, the Team is encouraged to collect samples from different lots/batches and from different manufacturers and

distributors. Efforts should be made to collect any questionable drug from any suspicious outlet at any time.

2.3. Sampling record

A written record of the sampling operations carried out is shown in [Annex 2](#). This form must be filled out and signed by all parties involved.

3. General Precautions to be Taken During Sampling Operations

All operations related to sampling should be performed with care. The “Sampling Team” should have all the tools needed to open the packages, containers, etc., at their disposal. This includes knives, pliers, sealable plastic bags, brushes to remove dust, plastic containers, and material to re-close the packages (such as sealing tape). Likewise, they will need self-adhesive labels—to indicate that a part of the contents has been removed from a package or container—and documentation tools (notebook, permanent marker, air-block dark plastic bags).

4. Packaging and Labeling of Samples

The container used to store a sample should not interact with the sampled material nor should it allow contamination. The samples should be in their original “unit” packaging and labeling, if applicable. The container should also protect the sample from light, air, moisture, etc., as required by the storage directions for the material sampled. As a general rule, the container should be sealed and tamperproof. The container must be properly labeled and contain the information described in [Annex 2](#). Drug samples should be kept in their original packaging, especially for blister pack preparations.

5. Transportation of Samples

Adequate measures have to be taken to ensure that samples are transported in good condition to where they will be tested. These measures should prevent any physical damage to the samples and should comply with the manufacturer’s recommended storage conditions found on the drug label.

Appropriate care should be taken to provide adequate packaging to protect samples during transportation, either by filling the container with cotton batting or foam, or by filling any residual space with a suitable material. All containers should be sealed and appropriately labeled.

6. Storage of Samples

Collected samples should be packed, transported, and stored in a manner that prevents any deterioration, contamination, or adulteration. Samples should be stored in accordance with the manufacturer’s recommended storage instructions for the respective drug. Closures and labels should be tamper-evident, that is, of such a type that unauthorized opening can be detected. When opening a sample container, the analyst or the person who opens it must date and initial it.

Annex 1: Testing Methods, Procedures and Testing Data Reporting

1. Testing methods and reference materials, substances and/or standards

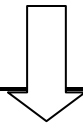
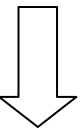
- Basic testing at the sentinel site level: Testing methods and procedures described in the USP DQI Training Manual and the reference substances/product provided by USP DQI, including those provided with the GPHF-Minilab kits should be used. The tests cover:
 - Physical/visual inspection/examination
 - Simple disintegration
 - TLC (see [Appendix 2](#) for General rules TLC result interpretation)
- Verification and confirmation tests: These tests should be performed by the designated QC lab. Testing procedures and assay methods should be carried out according to the current official monographs in established pharmacopeias, including International Pharmacopoeia (IP), USP, BP or EP, or if available national pharmacopeias.

2. Testing costs

- Cost for collecting and testing samples should be budgeted according to the prices agreed upon between USP DQI and local partners.
- All costs associated with the sentinel sites activities should be available and planned for before purchasing the Minilabs. The quality control program at the periphery level should be carried out in regular basis for at least three years to make the investment in the Minilabs worthwhile.

3. Testing levels

Tests will be performed at least at two levels: the sentinel site and a drug quality control lab. When a drug quality monitoring program is established as a regional initiative, a reference lab to support regional QC work should be designated as well.

| Activity and requirements | Level of testing | Quantity/number of samples |
|---|--|---|
| Sample collection Basic testing: visual, disintegration and TLC | Sentinel site  | Test: 100% of samples collected. Send: <ul style="list-style-type: none"> ▪ 100% doubtful samples to NDQC or designated Lab for verification ▪ 100% of failed samples ▪ 5-10% of passed samples |
| Verification: Validated methods or Pharmacopeial specifications Confirmation: When no QC lab is available or when a result need to be confirmed. Pharmacopeial specifications | NDQC or designated Lab  Reference Lab | Test: 100% samples received from sentinel sites. Send: <ul style="list-style-type: none"> ▪ 100% doubtful samples to reference lab for confirmation ▪ 100% of failed samples, where possible ▪ 5-10% of passed samples Test: all samples received |

5. Testing data reporting

- In-country reporting:
Regular reporting (every four months) – Each sentinel site sends a report covering the previous four (4) months’ activity and performance to the designated focal point of the program depending on the setup of each country.

The Report from Drug Quality Control Lab to DRA and key stakeholders should include a copy of the completed *Sentinel Site Drug Sample Collection and Testing Report Form* ([Annex 2](#)) and a copy of the *National Laboratory Testing Report Form* ([Annex 3](#)). All results (passed and failed) should be sent simultaneously to DRA and other stakeholders of the program.

Emergency reporting– For any critical questions about substandard or counterfeit drugs, all involved parties should work together to collect and test samples to respond to urgent concerns. Malaria control program, Drug quality control lab and the Drug regulatory authorities should collaborate in investigating problems, documenting evidences and taking appropriate actions.

- USP DQI technical support
USP DQI requires that the country data (including data of testing at sentinel site and national or provincial lab levels) are sent quarterly to USP DQI for analysis. USP DQI staff will work closely with the collaborating partners and provide feedbacks about the quality of data and the analysis of testing. The countries retain ownership of data; however, USP DQI will share these data with USAID and present such data in meetings and conferences as needed.

6. Supervision

A designated professional from the appointed lab (National Drug Quality Testing Lab or Provincial Lab) plus one supervisory staff member from the National Malaria Program or Provincial center will actively supervise the sentinel site through periodic visits. The supervisory visits will provide continued technical support and will ensure that standard procedures in sample collection, testing, and drug quality data documentation and reporting are being properly followed by the sentinel site staff.

- Supervisory visits should be scheduled as follows:
 - ⇒ First time, the first or second (1-2) month after operations begin;
 - ⇒ Thereafter, every four months.

Checklist for Sentinel Site “Drug Testing” Personnel

1. Collect samples (every 4 months) – Staff must follow the sampling procedure described in the course materials. Do not collect samples in 1 or 2 days only.
2. Complete a *Drug Sampling Receipt Form* for each sample collected and attach it to the sample container. Samples must be kept and stored according to manufacturer’s recommended storage as indicated on the labels (often in room temperature).
3. Testing – tests to be carried out by sentinel sites “drug testing” staff include:
 - physical/visual inspection,
 - simple disintegration, and
 - TLC
4. Fill out the Drug Quality Report Form (see last page of training materials) with required information, data, and test results obtained –
 - Sign, date, and keep report in a safe place; retain one sample (if possible).
 - Store the “tested” TLC plates wrapped in foil; keep with the report and sample materials.
5. Sending sample for verification/confirmation – Enclose in the shipping case/parcel a copy of the completed *Sentinel Site Drug Sample Collection and Testing Report Form (Annex 2)* together with samples to the malaria program focal point or to the drug quality control Lab. The Lab will conduct verification tests and provide feedback about the test results to the sentinel site; if further action is necessary, the Lab will coordinate with the malaria program and others to make a decision and any follow up required.

IMPORTANT NOTE:

Due to the sensitive nature of this activity and possible conflicts of interest, NO DATA or RESULT of any preliminary or initial test data obtained at the sentinel sites should be shared with or disclosed to third parties until it has been verified and discussed among the relevant authorities or agencies concerned (DRA, National Lab, and Malaria Program), and if applicable with USP DQI.

Annex 2: Sentinel Site Drug Sample Collection and Testing Report Form

Report No. -----/(province name)

| SAMPLE INFORMATION | |
|---|--|
| Sample Serial Number: _____ / _____ (Province name) | |
| Name of location/place where sample was taken | |
| Street address (with telephone and fax number, if applicable) | |
| Date of sampling | |
| Drug Name (trade or brand name) | |
| Generic or INN ¹ name | |
| Dosage form and strength | |
| Manufacturer's Batch or Lot Number | |
| Manufacturing date | |
| Expiry date | |
| Registration or licensed number (if applicable) | |
| Manufacturer name and address | |
| Number of sample units taken (minimum 20 tablets or capsules; and 10 for injectables) | |
| <input type="checkbox"/> taken in original package | <input type="checkbox"/> taken from bulk container |
| Brief physical/visual description of sample | |
| Name of collector(s)/date/sign | |
| Name of seller or representative identified of establishment where sample was taken | |
| PHYSICAL/VISUAL INSPECTION TEST | |
| Labeling (requirements) | |
| Brand Name of the drug sample (if applicable) | |
| Generic or INN name of active ingredient(s) | |
| Dosage form and strength | |
| Name of reference standard used (as claimed on label e.g. USP, BP, IP, EP) | |
| Manufacturer's Batch or Lot Number | |
| Name of manufacturer and address (with telephone and fax number if applicable) | |
| Manufacturing date | |
| Expiry date | |
| Storage conditions | |
| | |

¹ INN is the International Non-proprietary name of a drug product

| | | |
|--|---|--|
| Packaging | | |
| Material (blister pack/card, bottle, others specify) | | |
| Unit dose per blister card or container stated | | |
| Any print on the backing foil (if packed in blister pack or card) | | |
| Description of dosage form | | |
| Shape (circular, oval, flat sides, other) | | |
| Uniformity of shape | | |
| Uniformity of color | | |
| No physical damage (cracks, breaks, erosion, abrasion, sticky) | | |
| Other observations (no foreign contaminant, dirty marks, proper seal - for capsule) | | |
| DISINTEGRATION TEST | | |
| Time of complete disintegration expected (30 minutes for uncoated tablet) | Time of complete Disintegration observed | Did the drug pass disintegration test? |
| ----- | ----- | ----- |
| RESULT OF TLC TEST (see Appendix 2 for TLC result interpretation) | | |
| Rf Standard: ----- | Did the drug and the standard Spots have the same intensity? ----- | Did The sample pass quality by using the TLC Test? <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Rf Sample:- ----- | Was there any contaminant spot on TLC? ----- | |
| FINAL COMMENTS | | |
| <input type="checkbox"/> The sample passes basic testing | | |
| <input type="checkbox"/> The sample failed basic quality testing (Reason:.....) | | |
| <input type="checkbox"/> The sample is doubtful for its basic quality testing (Reason:.....) | | |
| REPORT PREPARED BY: | | REPORT REVIEWED BY: |
| Date: | | Date : |
| Name:..... | | Name: |
| Signature: | | Signature :..... |
| ACTION TO BE TAKEN BY THE PROVINCIAL SENTINEL SITE² | | |
| Report the result to malaria program | Send the remaining sample units together with this Form to malaria program or to the National Lab for further testing | |
| Date of report | Date.....Signature..... | |
| Signature..... | | |
| Reasons given for the chosen action: ----- ----- | | |

² Action to be taken and communication between key agencies in the country should be dependent on individual country setting.

Annex 3: National Laboratory Testing Report Form

Report no. _____/[name of the lab]

| SAMPLE INFORMATION <i>(This section should be refilled out when receiving the incoming sample or the report should be attached with the Sentinel Site Sample Collection and Testing Report Form, in which case only discrepancies should be marked)</i> | |
|--|--|
| Sample Serial Number or Code (use the same number appeared in the Sentinel Site Sample Collection and Testing Report Form) | |
| Drug Name (trade or brand name) | |
| Generic or INN ³ name | |
| Dosage form and strength | |
| Manufacturer's Batch or Lot Number | |
| Manufacturing date | |
| Expiry date | |
| Registration or licensed number (if applicable) | |
| Manufacturer name and address | |
| Name and address (with telephone and fax number, if applicable) of location/place where sample was collected | |
| Date when the Lab receives sample | |
| Name of test requester or sender of the sample/date/sign | |
| PHYSICAL/VISUAL INSPECTION TEST | |
| Labeling (requirements) | |
| Brand Name of the drug sample (if applicable) | |
| Generic or INN name of active ingredient(s) | |
| Dosage form and strength | |
| Name of reference standard used (as claimed on label e.g. USP, BP, IP, EP) | |
| Manufacturer's Batch or Lot Number | |
| Name of manufacturer and address (with telephone and fax number if applicable) | |
| Manufacturing date | |
| Expiry date | |
| Storage conditions | |
| Expiry date or manufacturing date | |
| Storage conditions | |
| Packaging | |
| Material (blister pack/card, bottle, others specify) | |
| Unit dose per blister card or container stated | |
| Any print on the backing foil (if packed in blister pack or card) | |
| Description of dosage form | |
| Shape (circular, oval, flat sides, other) | |
| Uniformity of shape | |

³ INN is the International Non-proprietary name of a drug product

| | | | |
|---|--|--|---------|
| Uniformity of color | | | |
| No physical damage (cracks, breaks, erosion, abrasion, sticky) | | | |
| Other observations (no foreign contaminant, dirty marks, proper seal - for capsule) | | | |
| DISINTEGRATION TEST (IF TESTED) | | | |
| Time of complete Disintegration expected | Time of complete Disintegration observed | Did the drug pass Disintegration test? | |
| 30 min | ----- | ----- | |
| RESULT OF TLC TEST (IF TESTED) (see Appendix 2 for TLC result interpretation) | | | |
| Rf Standard: ----- Rf Sample: ----- | Did the drug and the standard Spots have the same intensity? ----- Was there any contaminant spot on TLC plate? ----- | Did The sample pass quality by using the TLC Test? <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| DISSOLUTION TEST (IF TESTED, SPECIFY METHOD OR PROCEDURE AND ACCPETANCE CRITERIA.....) | | | |
| Result: ----- <input type="checkbox"/> Passed <input type="checkbox"/> Failed | | | |
| OTHER TEST USED FOR VERIFICATION OF IDENTIFICATION AND CONTENT OF ACTIVE INGREDIENT (API) | | | |
| Specify the test method(s) and reference to a pharmacopeial monograph e.g. IP 3 rd ed., USP26 | | | |
| Identification | Name of API(s) | Results | |
| | 1. | <input type="checkbox"/> Present <input type="checkbox"/> Not present | |
| | 2. | <input type="checkbox"/> Present <input type="checkbox"/> Not present | |
| Assay for content | Name of API(s) | Acceptance criteria | Results |
| | 1. | | |
| | 2. | | |
| FINAL COMMENTS | | | |
| <input type="checkbox"/> The sample meets standards <input type="checkbox"/> The sample does not meet standards (Reason:.....) <input type="checkbox"/> The sample is doubtful for its quality testing (Reason:..... and further testing is needed at a reference lab) | | | |
| REPORT PREPARED BY: | | REPORT REVIEWED BY: | |
| Date: | | Date : | |
| Name:..... | | Name: | |
| Signature: | | Signature :..... | |

ACTION TO BE TAKEN BY THE QC LAB*

| | | |
|---|---|--|
| 1. Report to responsible authorities | Report in writing to e.g. MOH Drug Regulatory Authority and the Malaria Program Date and sign..... | |
| 2. Send samples to the Reference Lab for confirmatory testing. They should always be accompanied by a Request Form (Appendix 1) | Send to | <input type="checkbox"/> Bureau of Drug and Narcotics Lab in Thailand |
| | | <input type="checkbox"/> National Institute for Drug Quality Control in Viet Nam |
| | | <input type="checkbox"/> USP Lab |
| Date:..... | | |
| Signature:..... | | |

* Action to be taken and communication between key agencies in the country should be dependent on individual country setting.

Appendix 1: Test Request Form

| | |
|---|--|
| Request submitter: | For National Lab Use Only |
| Contact details: Telephone: Fax: Email: Street address: | Project or Receipt Number: Receiving Officer: Date:..... |
| Date of request:..... | |
| Type of request: (check where applied) | |
| <input type="checkbox"/> Verification testing <input type="checkbox"/> Confirmation testing <input type="checkbox"/> Others (specify)..... | |
| Tests request for: (check where applied) <input type="checkbox"/> Identification of active ingredient(s) (API)(s) <input type="checkbox"/> Dissolution <input type="checkbox"/> Assay for content of active ingredient(s) (API)(s) <input type="checkbox"/> Others (specify)..... | |
| Suggested Method to be used (check where applied) <input type="checkbox"/> International Pharmacopeia (specify Edition number or Year) <input type="checkbox"/> U.S. Pharmacopeia (specify Edition number or Year) <input type="checkbox"/> Other (specify)..... | |
| Desired Completion Date:..... Provide reasons for the date:..... | |
| Attachments and/or materials provided with this Request Form: <input type="checkbox"/> Samples (if more than one sample, attach a separate list of the samples with names and other details e.g. sample code) <input type="checkbox"/> Sentinel Site Drug Sample Collection and Testing Report Form <input type="checkbox"/> Others (specify)..... | |
| Please send invoice/bill of testing charge to:..... Telephone:Fax: Email: Street address: | |

Appendix 2: General Rules for Interpreting TLC Results

This simple guideline uses the percent **R_f error**, defined below, to determine the fate of a sample based on simple TLC.

$$\mathbf{R_f \text{ Sample Error} = \{|R_f(\text{standard}) - R_f(\text{sample})| / R_f(\text{standard})\} \times 100\%}$$

Example

From multiple TLC experiments, the following R_f values were obtained:

$$R_f(\text{standard}) = 0.55$$

$$R_f(\text{sample}) = 0.53$$

$$\text{Then, } R_f \text{ Sample Error} = \{(0.55 - 0.53)/0.55\} \times 100\% = 3.6 \%$$

Interpretation of TLC Results

Based on the typical R_f values, broadness of TLC spots and simple error analysis⁴, some broad rules can be applied to interpret TLC results. It is important to note that these rules should only be considered semi-quantitative and not absolute.

1. When R_f Sample Error is **5% or less**, the sample can be considered **“Pass”**
2. When R_f Sample Error is **10% or more**, the sample can be considered **“Fail”**
3. When R_f Sample Error is **between 5% and 10%**, the sample can be considered **“Doubtful”**

Note:

1. If the TLC chamber and plates were not well saturated, or if the saturation has been disturbed the spots may not be horizontal and this could give high R_f sample error.
2. Always make TLC in duplicate and compare the R_f of both runs.
3. When R_f sample error is more than 5%, always make another duplicate run under optimal conditions to double check the doubt.

⁴ *Quantitative Chemical Analysis*, 6th Edition. Daniel C. Harris, W. H. Freeman, New York, 2003.