

Recommendations on the content of a Survey protocol

Survey of the Quality of Antimalarial Medicines

A Survey protocol may follow chapters as suggested below or may be appropriately modified.

Explanatory notes are in italics.

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1. Introduction and background

Provide information about situation in the territory, where the monitoring is planned. It is a basis for setting objectives of the survey.

2. Glossary of terms and abbreviations

ACT	Artemisinin-based combination therapy products
API	Active pharmaceutical ingredient
BP	British Pharmacopeia
FDC:	Fixed dose combination
INN	International Non-proprietary Name
NDRA	National Drug Regulatory Authority
Ph.Int.	International Pharmacopoeia
QCL	Quality control laboratory
USP	United States Pharmacopoeia
WHO	World Health Organization

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3. Objectives

It is very important to set detailed objectives in the beginning of planning because all the activities and requirements for the survey are derived from the objectives. Clearly defined objectives are essential for setting up conditions for sampling and testing, which are reflected in the protocol of the survey. Objectives for a quality survey should be formulated in a way, which makes possible to identify the following :

- *Products to be surveyed - it is possible to characterize them e.g.*
 - *By active ingredients (e.g. ACTs, sulfadoxine/pyrimethamine, ...), or*
 - *By manufacturer (specific manufacturer, if he poses some problems, or domestically produced medicines or imported medicines focusing on selected manufacturers, ...), or*
 - *By specific programme under which they are supplied (The Global Fund grant, national programme, ...), or*
 - *As widely used (then a pre-survey of medicines on the market may be necessary before the survey can be planned);*
- *Types of sample collection sites - which may be specified as e.g.*
 - *Close to patients - covering manufacturing quality as well as possible influence of distribution and storage conditions on medicines quality, or*
 - *At points of entry to the market - excluding possible influence of distribution and storage conditions on medicines quality, or*
 - *At a specific manufacturer, if he poses some problems;*
- *Countries in which the survey will be performed should be identified*
 - *Conduct in more countries in the region according to the same survey protocol can bring broader picture of quality of medicines in the region and enable comparison.*

Examples:

- To evaluate pharmaceutical quality of ACT medicines close to patients in selected countries with the aim to assess exposure of patients to substandard medicines and plan appropriate actions.
- To monitor pharmaceutical quality of selected antimalarial medicines supplied under The Global Fund grant as required by the Global Fund Quality assurance policy.
- To compare pharmaceutical quality of domestically produced medicines with imported ones in order to adopt appropriate regulatory actions and adjust pharmaceutical policy in the country.
- To identify possible causes of inferior quality of ACT medicines to which patients are exposed. To propose possible strategies and implementation plans to address the problems identified by the survey.
 - *Close cooperation with national drug regulatory authorities is normally necessary to address these two questions.*
- Test quality of ACT medicines in order to support regulatory authority in identification of manufacturers non-compliant with quality standards and in adoption of regulatory measures.
- To evaluate content of the information accompanying collected products on labelling and/or in package leaflets.
 - *If products from various suppliers are collected, it may be useful to evaluate if package leaflets are available and evaluate the quality and completeness of essential information in the following parts of package leaflets*
 - *Indications*
 - *Dosage and administration*
 - *Contraindications*
 - *Other important warnings (which may be under various headings, e.g. Special warnings and precautions for use, Interactions, Pregnancy and lactation)*
 - *Undesirable effects (to look at e.g. 5 most important adverse reactions)*

Questions to be addressed in the survey should be clearly formulated. E.g.:

- What proportion of samples fails quality testing?
- What proportion of samples at different points of the regulated and informal distribution chain fails quality testing?
- What proportion of samples at different geographical regions fails quality testing?
- What proportions of sampled domestically produced and imported products fail quality testing?
- Which specific quality tests do the samples fail?
- Are any of the deficiencies critical, i.e. could they substantially affect treatment efficiency and/or cause harm to the patient?
- What is the registration status of sampled products and what proportions of registered and non-registered products fail quality testing?
- What is the WHO Prequalification status of sampled products and what proportions of registered and non-registered products fail quality testing?

4. Survey management

Responsibilities and tasks of persons having key roles in survey organization (e.g. survey coordinator, focal persons in individual countries) should be identified and should include also responsibility for monitoring of conduct of the survey, for processing results, preparation of report. Communication lines and means should be agreed in advance.

It is necessary to plan the financial resources expected for the whole survey in the beginning.

The survey period with key milestones and organizations/persons responsible for individual parts should be pre-defined together with estimated timeframe.

Timeframe and responsible officers for the survey (*as an example*)

Activity	Timeframe	Responsible officers
Selection of countries and medicines to be surveyed		
Agreement with countries		
Selection of testing laboratory/ies		
Preparation of testing protocol in agreement with testing laboratory/ies		
Meeting held with focal points from countries to explain the survey protocol		
Preparation of detailed national sampling plans		
Collection of samples and transport to testing laboratory/ies		
Testing of samples		
Compilation of results		
Meeting held with the participating countries to discuss the results and the actions needed		
Report finalization		

5. Methodology

5.1 Participating countries

Each involved country (Ministry of Health/ National Drug Regulatory Authority) should agree with the participation before the survey commences. Issues like utilization of results and their public availability should be clearly understood by responsible authorities and all the parties involved in the survey.

5.2 Medicines surveyed

Based on the objectives of the survey, medicines to be sampled (active ingredient/s, dosage form, strength) should be listed. It is reasonable to formulate the objectives and organize the survey in a way to focus on medicines

- *For which inferior quality has documented serious implications for the health of patients*
- *Used in large volumes*
- *Susceptible to quality deterioration (unstable active ingredients, liquid dosage forms, ...)*
- *For which quality problems were already experienced.*

Not more than 5 different types of products (identified by active ingredient/s and dosage form) should be included in one survey, otherwise the project would be difficult to manage.

5.3 Selection of sample collection sites

Based on the objectives of the survey, the types of sample collection sites should be identified. E.g.:

- *If samples should be collected close to patients and manufacturing quality as well as possible influence of distribution and storage conditions on medicines quality should be covered, then:*
 - *Sampling should be performed in hospitals, clinics, treatment centres, pharmacies, retailers, dispensing facilities, ... (depending on the distribution system for given medicines in the particular country) - both public and private sector should be included - as well as at "informal market" (i.e. outside the approved distribution chain), if exists in the country.*
 - *For estimation of possible influence of distribution and storage conditions on medicines quality, approx. 10-15% proportion of samples should be collected also at points of entry to the market, i.e. at domestic manufacturers, importers and central medical stores.*
- *If samples should be collected at points of entry to the market, excluding (from reasons defined in objectives of the survey) possible influence of distribution and storage on medicines quality, then*
 - *Sampling should be performed at domestic manufacturers, importers and central medical stores, i.e. the first level of the distribution chain.*

It is advantageous to organize a meeting with participation of focal persons involved in sample collection to explain the project, survey protocol and provide detailed instructions.

A detailed national sampling plan will be prepared for collection of samples in each participating country in cooperation with the respective NDRA.

Definition of a sample - for the purposes of the survey, a sample means an item collected from each presentation at the same collection site. All units of one sample must be of the same batch. That means, that an identical product (the same name, content of APIs, the same dosage form, same strength, same batch and produced by the same manufacturer) collected in two different sites represents two samples.

National sampling plan will identify:

- Names and addresses of the sites, where samples shall be collected
 - *The risk analysis should be applied when selecting sample collection sites to assure that sites, where quality deterioration can occur, are involved. It should consider way of product distribution to the site, transport conditions, storage conditions and handling products in the site, experience of the NDRA with the distribution chain and sites.*
 - *Different geographical areas, preferably those of high malaria prevalence, should be involved. Samples should not be collected in the capital city only, as situation in other areas often differs.*
 - *To obtain a better picture of quality of medicines available on the market (if required by objectives of the survey), samples produced by as many manufacturers as possible*

should be collected at sampling sites. In order to collect samples from more manufacturers it may be necessary to visit more sampling sites.

- Identification of medicines to be collected (active ingredients by INNs, dosage form, strength, number of batches from one manufacturer to be collected in each site and number of units to be collected per batch of each medicine)
 - Number of dosage units or multidose packages of selected medicines to be collected should allow for:
 - conducting the agreed tests,
 - possible confirmative testing due to out-of-specification investigations, and
 - retention samples.

The following general rules can be used, if not justified otherwise:

Dosage form	Packaging (typical)	Number of dosage units or multidose packs per batch
Tablets & capsules (immediate/modified release, chew, dispersible, etc.)	Blisters, co-blisters, bottles, securitainers	Approx. 100 units (e.g. 5 packs of 20 units 3 packs of 30 units 3 packs of 40 units 2 packs of 60 units 1 pack of 90 units and above) In case of co-packaged products approx. 100 units shall be collected from each medicine.
Multidose oral solutions/suspensions, powder for oral solution/suspension & injections or powders for injections	Multidose bottles and vials	6 containers of 60 ml / 100 ml 3 containers of 240 ml
Single dose powders for oral solution/suspension & single dose injections or powders for injections	Sachets and single dose bottles, vials & ampoules	Unless otherwise specified, 15 units (20 units if dose is below 50 mg)

- *The collection of sufficient number of units per sample is very important for proper testing and successful conduct of the survey. It should be remembered that sampling cannot lead to the shortage of medicines available for patients.*
- Maximum number of samples collected per country
 - *Testing of approximately 300 samples per survey is manageable (not taking into account financial resources, which may be another limiting factor). Therefore the maximum number of samples to be collected should be set before sample collection starts. If more countries are involved, maximum number of samples should be set for each country.*

For the example of a national sampling plan see Annex 1.

The focal person will arrange for training of collectors to be familiar with the project, survey protocol, national sampling plan and instructions for collection of samples.

5.4 Sample collection

Samples should be collected by the NDRA's staff (preferably inspectors or staff trained for sampling of medicines). Cooperation with the WHO country offices staff in the respective country is useful.

The following instructions for sample collection shall be applied:

- The time period, within which samples should be collected in the countries and the deadline for sending the last sample to the testing laboratory, should be clearly indicated and followed.
- The number of units per sample and number of batches to be collected from each collection site for each selected medicine as indicated in the national sampling plan shall be followed. There should not be a mix-up with batches; all units of one sample must be of the same batch. In the case that in a collection site the required number of packages of the same batch is not available, sample of that particular medicine is not collected.
- Only intact unopened original packages shall be collected.
- The medicine samples should not be taken out of the original primary packaging and outer containers (though removal from large secondary packs is appropriate). Containers such as bottles and vials should not be opened.
- Samples collected should have at least six months remaining to expiry.
- The medicine labels and package leaflets should not be removed or damaged.
- Sampling will be recorded using the Sample Collection Form individually for each sample (Annex 2). Whenever the required information is not available, it should be indicated in the appropriate space on the Sample Collection Form, where also any abnormalities should be recorded.
- In order to avoid confusion, each sample will be identified by a unique Sample Code (coding system shall be defined in the Sample Collection Form template) specified in the Sample Collection Form as well as on all the original packages belonging to the respective sample. Packages belonging to one sample and Sample Collection Form will be kept together (e.g. blisters inserted in a dedicated envelope marked with the appropriate sample code and trade name of the product).
- Manufacturer's batch certificates of analysis will be collected with samples, if available, and kept with the Sample Collection Form.
- The samples should be collected and kept under controlled conditions, as per label requirement. The cold chain should be maintained, where required.

If needed, the appropriate arrangements shall be made with treatment centres to ensure that there is no shortage due to collection of samples (e.g. requesting for replacements of medicines).

5.5 Storage and transport of samples

Storage and transport of the sample should be done according to the requirements set out in paragraph 2.3 of WHO Guidelines for Sampling of Pharmaceutical Products and related materials¹:

- The samples should be kept in original packaging and under storage conditions specified on the label.
- For transport all samples should be packaged adequately and transported in such a way as to avoid breakage and contamination during transport. Any residual space in the container should be filled with a suitable material. Where required, the cold chain should be retained during storage and transport.
- A covering letter, the copies of Sample Collection Form and, if available, copies of Manufacturer's batch certificate of analysis should accompany the samples.

¹ World Health Organization. WHO Technical Report Series, No. 929 (2005). Annex 4: WHO guidelines for sampling of pharmaceutical products and related materials. http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf#page68

- Samples with the accompanying documents should be sent straightforward to the assigned testing laboratory by a courier service. For each shipment it should be clearly indicated that samples are sent for laboratory testing purposes only, will not be used on humans or animals, have no commercial value and will not be placed on the market. Low price just for customs purposes should be indicated to avoid problems with the customs clearance.
- The laboratory should be informed about the shipment and the tracking number as provided by the courier service to be able to follow the shipment and pick it up as soon as possible.
- Copies of Sample Collection Forms and, if available, copies of Manufacturer's batch certificates of analysis should be sent also to survey coordinator/person preparing the report on the survey.

5.6 Testing laboratory

An appropriate laboratory has to be selected for testing. Preferably a prequalified laboratory should be used (see the list of WHO-prequalified laboratories at www.who.int/prequal). Should such a laboratory not be available or should it not have sufficient capacity, then another laboratory, for which evidence of reliability is available, should be chosen.

The appropriate arrangement with the laboratory has to be made in advance to give the laboratory time to be ready for testing (find the appropriate time slots, purchase necessary materials and standards, ...). The request for testing should be in line with WHO guideline: Considerations for requesting analysis of drug samples² and no sample will be sent before such an arrangement is made. A contract with the laboratory should be concluded in advance to allow the laboratory to prepare for testing.

Detailed address of the laboratory selected for the survey shall be provided to sampling organization. If there are more laboratories involved, clearly specify products which should be sent to each laboratory.

Name of the laboratory	Detailed address, incl. name of contact person, phone number and e-mail	Products to be tested

The laboratory normally starts testing only when all the samples are received. Therefore it is important to set and adhere to the deadline for sending to the testing laboratory.

5.7 Tests conducted

Laboratory testing of all collected samples will be performed according to the testing protocol, which is a part of the survey protocol and has to be agreed with the testing laboratory/ies.

- *Tests to be conducted depend again on the objectives of the respective survey. For example of testing protocol see Annex 3.*

² World Health Organization. WHO Technical Report Series (TRS), No. 902 (2002). Annex 4: Considerations for requesting analysis of drug samples. http://whqlibdoc.who.int/trs/WHO_TRS_902.pdf#page69

In principle the following tests should be included in quality surveys of products on the market:

- Appearance
- Identity
- Assay
- Related substances test
- Dissolution or Disintegration and Uniformity of mass for (solid dosage forms, e.g. tablets, capsules)
- pH value for liquid dosage forms (e.g. oral solutions, injections, powders for injection)

Some tests, such as Uniformity of content for single dose dosage forms or sterility and bacterial endotoxins for parenteral products are not normally included in quality surveys of products on the market, unless there is a specific reason to include them. These tests are costly and to assure these parameters there are other more efficient tools in medicines regulation, namely inspections and enforcement of compliance to good manufacturing practices (GMP).

To monitor pharmaceutical quality of medicines, it is recommended to perform testing in QC laboratory as described above and not only screening using some basic tests and simple methods (such as GPHF-Minilab). Screening methods do not provide full picture of quality of medicines and, as shown in QAMSA study, often underestimate non-compliant findings in comparison with laboratory testing. Basic tests and simple screening methods are more suitable for screening of large number of samples in the field, e.g. to search for counterfeits.

5.8 Test methods and specifications

Test methods and specifications are in general selected according to the following rules:

- Preferably Ph.Int. monographs should be used, if available.
- If no monograph exists in the Ph.Int., then BP or USP can be used.
- If there is no pharmacopoeial monograph or the existing monographs do not provide for desired tests, a validated method of the laboratory or manufacturer's method, if available, should be used.

For the example of testing protocol used in QAMSA study for ACTs and Sulfadoxine/Pyrimethamine see Annex 3.

In general, when samples from different manufacturers are collected within a quality survey, all samples containing the same combination of active ingredients are tested according to the same specification to enable comparison of samples from different manufacturers. This specification is then used to decide on compliance or non-compliance of tested samples for the purposes of this survey. It should be noted that individual manufacturers may use different specifications and different methods for testing of their products and these specifications and methods may be approved by regulatory authorities in individual countries. Non-compliance with the specification selected for the survey does not necessarily imply non-compliance with the specifications approved in the country. But it indicates the need to look at the product and conditions of regulatory approval more closely and further actions should be considered by the respective NDRA.

5.9 Receipt and testing of samples by a testing laboratory

When samples received, the testing laboratory will:

- Inspect each sample to ensure that the labelling is in conformance with the information contained in the Sample Collection Form or test request.
- Store the samples according to the respective medicine requirements. If appropriate, ensure compliance with the cold chain.
- Conduct quality testing in line with the testing protocol and in compliance with WHO standards recommended for quality control laboratories³.
- Complete an Analytical Test Report (Annex 4). In the case that non-compliant results are found and confirmed after application of a laboratory out-of-specification procedure, they have to be reported immediately to the contact point⁴.
- Keep records of each sample, accompanying document/s and retention samples for at least six months if the sample complied with the analytical test requirements, or for at least one year or until the expiry date (whichever is longer) if it did not comply.
- An electronic databank (e.g. photos of medicine such as tablets, packaging, package leaflet) is recommended.

6. Data management, reporting and publication

About any non-compliant result the respective NDRA will be informed as soon as possible and it should be investigated in line with regulatory practice and legislation with the respective manufacturer.

The analytical test reports of the testing laboratory/ies will be provided to all NDRA involved in the project. The outcomes of the project will be discussed by national authorities and WHO in a meeting, and corrective actions, if necessary, will be recommended. To take the relevant measures in countries lies within the responsibility of the NDRA.

Agreed outcomes and report from the survey should be reviewed and published by WHO. It should be remembered that non-compliant result not necessarily indicate sub-standard medicine and deviation from manufacturer's specifications.

³ World Health Organization. WHO Technical Report Series (TRS), No. 957 (2010). Annex 1: Good practices for pharmaceutical quality control laboratories.

http://www.who.int/prequal/info_general/documents/TRS957/GPCL_TRS957_Annex1.pdf.

⁴ *Specify the contact point.*

Annex 1

Survey of the quality of antimalarial medicines

National Sampling Plan

Country: _____

Focal Person: _____

MEDICINES TO BE COLLECTED:

- **INN(s), dosage form, strength**
-
-
-

NUMBER OF UNITS TO BE COLLECTED PER SAMPLE:

- **Approx. 100 units for tablets/capsules**
-
-

TOTAL NUMBER OF SAMPLES PER COUNTRY:

NAMES AND ADDRESSES OF THE SITES, WHERE SAMPLE SHALL BE COLLECTED:

	Facility name	Address	Facility type 1. (private/public; 2. level 1/level 2; 3. wholesaler/retailer/treatment centre/...)
1.			
2.			
3.			
4.			
5.			

INSTRUCTIONS FOR COLLECTORS:

- The amount of the selected products defined above will be sampled from the identified sites. All these samples are inclusive of the samples needed for the out-of specifications investigations and retention samples.

- An item collected from each presentation at the same collection site will be called a sample. **All units (tablets, capsules, vials) of one sample must be of the same batch**, there should not be a mix-up with batches. In the case that in a collection site the required number of packages of the same batch is not available, sample of that particular medicine is not collected.
- Samples collected shall have **at least six months remaining to expiry**. Products with shorter period remaining to expiry date are not collected.
- One batch of each product will be collected from each collection site and **only unopened original packages shall be collected**.
- The medicine **samples should not be taken out of the original primary packaging and outer containers** (though removal of blisters from large secondary packs is appropriate). Containers such as **bottles and vials should not be opened**.
- The medicine labels and package leaflets should not be removed or damaged.
- Sampling will be recorded using the Sample Collection Form. Whenever the required information is not available, it should be indicated in the appropriate space on the Sample Collection Form, where also any abnormalities should be recorded.
- In order to avoid confusion, each sample will be identified by a unique Sample Code (for coding system see the Sample Collection Form) specified in the Sample Collection Form as well as on all the original packages belonging to the respective sample. Packages belonging to one sample and Sample Collection Form will be kept together (e.g. blisters inserted in a dedicated envelope marked with the appropriate sample code and trade name of the product).
- Manufacturer's batch certificates of analysis will be collected with samples, if available, and kept with the Sample Collection Form.
- The **samples should be collected and kept under controlled conditions**, as per label requirement. The cold chain should be maintained, where required.
- Samples should be collected in all the countries involved within the period and the **deadline for sending the last sample to the testing laboratory is**

Survey of the quality of antimalarial medicines**Sample Collection Form*****Country:** _____ **Sample code:** _____

(Country code/product abbreviation/sequence number/sampling date ddmmyy)**

Name of location/place where sample was taken: _____

Address (with telephone, fax number and email address, if applicable):

Organization and names of people who took samples:

1. _____

2. _____

Product name of the sample: _____

Name of active pharmaceutical ingredient(s) (INN) with strength:

Dosage form (tablet, capsule, powder for injection, etc): _____

Package size, type and packaging material of the container: _____

Batch/lot number: _____

Date of manufacture: _____ Expiry date: _____

Regulatory status in the country, registration number, if applicable: _____
_____Name and address of the manufacturer: _____
_____Quantity collected (number of sample units or of multidose containers taken):
_____*Initialise first page:*

* This Sample Collection Form should always be kept with the sample collected. Proper sampling procedures should be followed.

** Product abbreviations: Sample code system can be extended to be appropriate for a particular country collection system.

Product name: _____

Sample code: _____

Storage/climatic conditions at sampling site/point (temperature and humidity, indication of conditions during daytime only is acceptable, comments on suitability of premises where products are stored at the particular site for the NDRA information):

Abnormalities, remarks or observations that may be considered relevant, if any:

Date:

Signature of person(s) taking
samples

Signature of representative of the
establishment where sample(s) was
taken (optional)

1.

.....

2.

Note: Samples collected must remain in their original containers, intact and unopened

Survey of the quality of antimalarial medicines

Testing Protocol

Product	Tests to be performed and specifications for testing
Artemether/ Lumefantrine tablets FDC	International Pharmacopoeia monograph
	<ul style="list-style-type: none"> • Appearance - general requirements of Ph.Int. for tablets • Uniformity of mass - PhInt • Identity - HPLC as for assay • Assay - PhInt - HPLC • Artemether related substances - PhInt - TLC • Dissolution - laboratory validated method similar to the method used for Lumefantrine and Artemether tablets in USP Non-US Monograph (authorized 1.3.2009); Requirements: lumefantrine - not less than 60% (Q) in 45 min, artemether - not less than 40% (Q) in 1 hour and not less than 60% (Q) in 3 hours.
Artesunate / Amodiaquine tablets Co-blistered	<u>Artesunate tablets:</u> International Pharmacopoeia monograph
	<ul style="list-style-type: none"> • Appearance - general requirements of Ph.Int. for tablets • Uniformity of mass - PhInt • Identity - HPLC as for assay • Assay - PhInt - HPLC • Artesunate related substances - PhInt - HPLC • Dissolution - Ph.Int.
	<u>Amodiaquine tablets:</u> US Pharmacopoeia monograph
	<ul style="list-style-type: none"> • Appearance - general requirements of Ph.Int. for tablets • Uniformity of mass - PhInt • Identity - USP • Assay - USP - UV spectrophotometry • Dissolution - USP
Artesunate / Amodiaquine tablets FDC	Laboratory validated methods
	<ul style="list-style-type: none"> • Appearance - general requirements of Ph.Int. for tablets • Uniformity of mass - PhInt • Identity - HPLC as for assay • Assay - HPLC; 90-110% • Artesunate related substances - tested without specifications • Dissolution - not less than 75% of each API at 30 minutes
Sulfadoxine/ Pyrimethamine tablets FDC	US Pharmacopoeia monograph
	<ul style="list-style-type: none"> • Appearance - general requirements of Ph.Int. for tablets • Uniformity of mass - PhInt • Identity - HPLC • Assay - USP - HPLC • Dissolution - USP
Sulfamethoxypyrazine/ Pyrimethamine tablets	Manufacturer validated methods

FDC	<ul style="list-style-type: none"> • Appearance - package leaflet • Uniformity of mass - PhInt • Identity - HPLC as for assay • Assay - HPLC - 90-110 % • Dissolution - not less than 80% (Q) in 30 min
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Annex 4

Content of the Analytical Test Report

Analytical test report[♦]

An analytical test report usually includes a description of the test procedure(s) employed, results of the analysis, discussion and conclusions and/or recommendations for one or more samples submitted for testing.

The Analytical Test Report shall in accordance with the Good practices for pharmaceutical quality control laboratories provide the following information:

1. Name and address of the laboratory performing the sample testing,
2. Number/code of the Analytical Test Report,
3. Name and address of the originator of the request for testing,
4. Laboratory registration number of the sample,
5. Sample code from the Sample Collection Form,
6. Date on which the sample was received,
7. Name of the country where the sample was collected,
8. Sample product name, dosage form, active ingredients, strength, package size, type and packaging material of primary container,
9. Description of the sample (both product and container),
10. Batch number of the sample, expiry date and manufacturing date, if available,
11. Name and address of the manufacturer,
12. Reference to the specifications used for testing the sample, including the limits,
13. Reference to the reference standards used for quantitative determinations,
14. Detailed results of all the tests performed (numerical results, if applicable), including any observations made during analysis,
15. Conclusion whether or not the sample was found to be within the limits of the specifications used,
16. Discussion of the results obtained,
17. Date on which the test was completed, and
18. Signature of the head of the laboratory or authorized person.

[♦] World Health Organization. WHO Technical Report Series (TRS), No. 957 (2010). Annex 1: Good practices for pharmaceutical quality control laboratories.
http://www.who.int/prequal/info_general/documents/TRS957/GPCL_TRS957_Annex1.pdf.