ANNEX 1: TMDA/DLS/SOP/010

ORIGINAL

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

TMDA
Tanzania Medicines & Medical Devices Authority

DIRECTORATE OF LABORATORY SERVICES

# GUIDANCE FOR SUBMISSION OF HUMAN AND VETERNARY MEDICINES SAMPLES TO THE LABORATORY FOR TESTING

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## 1.0 Introduction

The scope of samples analyzed by the TMDA Quality Control Laboratory has been changing from time to time for various reasons which include the government's efforts to improve the quality of services delivered by the laboratory and the authority at large.

The number of sample units required for quality control testing of regulated products has been prescribed in various pharmacopoeias, manufacturers' dossiers, and internally validated analytical methods. Nevertheless, a significant portion of customers does not have access to these documents which makes it difficult for them to submit the required number of sample units and in the condition that will allow for the generation of accurate and reliable results.

These guidance document have therefore been drafted to define the minimum requirements that must be met before a sample is submitted for analysis.

### 1.1 Sample submission criteria: -

All samples submitted to TMDA Quality Control Laboratory must meet the following criteria:

a. Samples must be submitted in their original, untampered packages, which are properly sealed.

b. Samples that require storage below ambient temperatures must be delivered in appropriate temperature-controlled containers that ensure the maintenance of the cold chain.

c. Adequate number of samples (as provided in this guidance).

d. Samples must be within the shelf life.

e. Samples must be properly labeled.

### 1.2 Analysis Request

The customer shall communicate with the laboratory before submitting the sample for analysis. Internal customers shall submit the sample through the Laboratory Information Management System (LIMS) while External customers shall directly deliver the sample at the designated sample receiving office in the laboratory building; where the sample information can be entered into LIMS.

Agreement of analysis requested shall be made and signed with the respective section manager and customer in the test request form. This form is filled with information such as Reference number; Laboratory code number; Customer Details (Name and full address); Sample information (Product name; Dosage form; Description (appearance of container & contents); batch number; manufacturing and expiry date, manufacturer name and full address; Sample size (quantity in a package/pack size); Reasons for analysis; Requested parameters; and Deviation/amendment.

### 1.3 The Number of Sample Units Required

The number of medicines (human and veterinary) sample units required shall depend on the type and number of test parameters requested to be investigated. The minimum number of medicines samples units required to be submitted for analysis has been summarized in **Table 1.** In case of the non-compendial product, the sample should be submitted together with the manufacturer's validated analytical method and their respective product specifications. In a situation where several batches are submitted, each batch shall be treated as an independent sample.

Table 1: The Minimum of Sample Units required for chemical and microbiological testing

| No. | Formulation | Pack Size | Minimum units of Samples to be Submitted |
|---|---|---|---|
| 1. | Injectables (Liquid/powder) | ≤ 10 mL | 30 vials/ampoules |
| | | 10 - 100mL | 12 vials/ampoules |
| | | 100 - 2000ml | 6 bottles |
| 2. | Powders for oral preparation | 1-50g | 30 Sachets |
| | | ≥ 50g | 15 Sachets |
| 3. | Eye and Ear drops | < 10 mL | 100 bottles |
| | | > 10 mL | 50 bottles |
| 4. | Tablets/capsules | All | 100 tablets/capsules |
| 5. | Suspensions/Syrups | ≤ 10 mL | 20 bottles |
| | /Elixir/powder for reconciliation | 10 – 500 mL | 15 bottles |
| | | 500 – 2000 mL | 4 bottles |
| 6. | Transdermal Patches | 5 – 100 g | 100 sachets |
| | | > 100 g | 50 sachets |
| 7. | Sprays/Inhalers | All | 10 Packs |
| 8. | Creams, Emulsions, and Gels | < 5 g | 20 tubes |
| | | 5 – 50 g | 10 tubes |
| | | > 50 g | 5 tubes |
| 9. | Disinfectants and Sanitizers | < 50 mL | 8 bottles |
| | | 50 – 250 mL | 4 bottles |
| | | 500-1000 mL | 2 bottles |
| | | 5000 mL | 1 bottle |
| 10. | Active Pharmaceutical Ingredient (s) (API) | Solids | 5 g |
| | | Liquid | 1000 mL |

### 1.4 Shelf life limitation

All samples submitted should be within at least 60% of their shelf-life remaining at the time of receipt. In a situation where a customer request that expired sample be analyzed, such a request shall be documented in the test request form and the laboratory shall only provide the outcome of the analysis without making any conclusion as to the status of the sample.

### 1.5 Sample Analysis Timelines

All samples shall be analyzed as per timelines prescribed in the Client's Service Charter which is 30 working days for post-marketing surveillance and 20 working days for all other samples.

### 1.6 The shipping of Samples

The laboratory shall not be responsible for the shipping of the samples. The customer shall ensure that arrangements are made for the safe delivery of samples to the laboratory. The laboratory shall only contribute to the securing of importation permit in case of samples sent by customers residing outside of the United Republic of Tanzania. The customer shall also ensure provisions for samples requiring specialized storage conditions throughout the shipping duration until when the samples are delivered at the laboratory.

### 1.7 Payments and costs for sample analysis

An invoice bearing a control number shall be issued for all samples received. A customer, (except for the internal customers) shall be required to make full payment of the prescribed fee before the sample is subjected to quality control testing. Payments after analysis of the sample must be officially requested and agreed upon in advance. Cost for analysis of various of sample and parameters are stipulated in the Fees and Charges regulation (2015) available at our website (www.tmda.go.tz)

### 1.8 Certificate of Analysis (CoA)

The outcome of quality control testing of the received sample shall be reported in form of an official Certificate of Analysis (CoA) bearing the authority's prescribed security features and signatures of both the Director of the Laboratory Services and the respective Section Manager.

## 1.9 Confidentiality

The customers should communicate with either the respective section Manager or the Director of Laboratory Services for any correspondence related to the submitted sample. Communication with Analyst (s) is strictly prohibited.

## 1.10 Complaints

Any customer who happens to have any complaints against the service rendered by the laboratory shall do so by filling customer complaints form. The complaint forms can be obtained at the Director of Laboratory Services Office or be downloaded through the authority's website. The complaints shall be handled as per the timeline prescribed in the Client Service Charter.

## 2.0 Bibliography


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