



Medicines Control Authority of Zimbabwe



EVALUATIONS AND REGISTRATION DIVISION

TITLE: Standard Operating Procedure for Submission of Samples to the Laboratory			
SOP Number: EVR 07		Revision Number: 6	
		Document Level: 3	
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1.0 PURPOSE

To outline the procedures performed when registration samples are submitted to the laboratory for analysis.

2.0 SCOPE

This procedure applies to a Regulatory Officer when forwarding samples to the laboratory for analysis.

3.0 FREQUENCY

Whenever samples have to be forwarded for analysis to the laboratory.

4.0 LOCATION

- 4.1 The master copy of this standard operating procedure is kept in the Quality Office.
- 4.2 Controlled copies are kept by the Head of Evaluations & Registration Division and Evaluations & Registration Division staff.
- 4.3 Controlled copies are issued to staff at points of use in the Division.
- 4.4 Approved copies are uploaded onto SharePoint.

5.0 DEFINITIONS

- 5.1 **Sample:** A medicine of no commercial value submitted with an application for registration.
- 5.2 **EVR:** Evaluation and Registration Division.
- 5.3 **QMS:** Quality Management System.

TITLE: Standard Operating Procedure for Submission of Samples to the Medicines Control Authority of Zimbabwe		
SOP Number: EVR 07	Revision Number: 6	Page 2 of 5

- 5.4 LSD: Laboratory Services Division.
5.5 CRO: Chief Regulatory Officer

6.0 RESPONSIBILITY

- 6.1 The Samples Repository Officer and officers in the Quality Office are responsible for receiving all samples submitted to MCAZ and forwarding them to the relevant units/divisions.
- 6.2 The EVR Samples Custodian or designated Regulatory officer in the Evaluation and Registration Division is responsible for ensuring that
- shelf-life extension samples are appropriately handled
 - the client receives communication on the results of the shelf-life extension request.
- 6.3 It is the responsibility of the Chief Regulatory Officer (or designate) to assess if a particular product is eligible for shelf-life extension and will specify all tests required to determine the safety and efficacy of a product requested for shelf-life extension
- 6.4 The Head of Division has the overall responsibility of ensuring that this SOP is adhered to at all times.
- 6.5 The Quality Manager/Designate is responsible for monitoring compliance to this procedure, the Quality Management System (QMS), and international and other relevant standards.
- 6.6 The Quality Manager/Designate shall be responsible for monitoring compliance of this procedure to Quality Management Standards (QMS), International and other relevant standards.

7.0 PROCEDURE

7.1 Forwarding samples for testing after Committee's decision

- 7.1.1 The EVR Samples Custodian or designated Regulatory officer shall verify the Committee's decision regarding analysis of the sample (i.e., check Registration Minutes). If it was agreed to analyse product samples, proceed to 7.1.2.
- 7.1.2 The EVR Samples Custodian or designated Regulatory officer shall, check in the Samples Received Register (EVRB06 or EVRB11) whether sufficient samples were submitted for analysis. If samples were not submitted or are insufficient, the Regulatory Officer shall, with guidance from the laboratory, request the applicant via e-mail to submit more samples.
- 7.1.3 If enough samples were submitted, the EVR Samples Custodian or designated Regulatory officer shall retrieve the samples from the sample room using the product application number. Ensure to request the sample submission form of the product from the Samples Repository Office for the completion of the analysis request section.
- 7.1.4 The EVR Samples Custodian or designated Regulatory officer in the Evaluation and Registration shall request the Chief Regulatory Officer – Registrations or designate to indicate on the Sample Submission Form (SR 06) tests that should be done by the Laboratory Services Division (LSD).

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TITLE: Standard Operating Procedure for Submission of Samples to the Laboratory		
SOP Number: EVR 07	Revision Number: 6	Medicines Control Authority Page 2 of 5

NB: Only key tests that are considered a true representation of product quality for the given dosage form should be indicated. For pharmacopoeia methods, the CRO shall state the reference text and year of publication. For non-compendial methods the CRO shall request the volume of the finished product specifications and analytical methods of the product dossier from the Filing Clerk.

- 7.1.5 The analysis request forms shall be completed in duplicate.
- 7.1.6 The EVR Samples Custodian or designated Regulatory officer shall send the samples, analysis request forms and the file consisting of finished product specifications and analytical methods to the Samples Officer in the Samples Repository Office (SRO). The Samples Officer should comment and sign for receipt of sample submission forms and samples. The Samples Officer retains the original request form and the duplicate sent by the requisitioner to the product file.
- 7.1.7 The Samples Repository Office will in turn notify and forward the request for laboratory analysis of the samples to the Laboratory Services Division (LSD) as per Standard Operating Procedure for Receipting, Forwarding and Storage of Samples (SRO 01) procedures 7.6 (**Forwarding of Sample Submission Form to Chemistry and Microbiology Laboratories**).

7.2 Receiving and forwarding shelf-life extension samples for testing

- 7.2.1 All samples will be received and forwarded to the EVR Samples Custodian or designated Regulatory officer in accordance with the Standard Operating Procedure for Receipting, Forwarding, and Storage of Samples (SRO 01) procedures 7.1-7.5.
- 7.2.2 The Samples Repository Office shall notify the EVR Samples Custodian or designated Regulatory officer and the Chief Regulatory Officer (Registration) or designate when samples for shelf-life extension have been received from a client.
- 7.2.3 Upon receiving samples and the appropriate sample submission form (SR06) from the Samples Repository Officer, the EVR Samples Custodian or designated Regulatory officer in the Evaluation and Registration shall request the Chief Regulatory Officer – Registrations or designate to indicate on the Sample Submission Form (SR 06) tests that should be done by the Laboratory Services Division (LSD).

NB: Only key tests that are considered a true representation of product quality for the given dosage form should be indicated. For pharmacopoeia methods, the CRO shall state the reference text and year of publication. For non-compendial methods the CRO shall request the finished product specifications and analytical methods of the product dossier from the Filing Clerk.

- 7.2.4 The EVR Samples Custodian or designated Regulatory officer shall take the completed Sample Submission Form (SR 06) with the indicated tests from the Chief Regulatory Officer – Registration or designate and return it to the Samples Repository Office.

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TITLE: Standard Operating Procedure for Submission of Samples to the Laboratory Control Authority		
SOP Number: EVR 07	Revision Number: 6	Page 17 of 18

- 7.2.5 The Samples Repository Office will in turn notify and forward the request for laboratory analysis of the samples to the Laboratory Services Division (LSD) as per Standard Operating Procedure for Receipting, Forwarding and Storage of Samples (SRO 01) procedures 7.6 (**Forwarding of Sample Submission Form to Chemistry and Microbiology Laboratories**).

7.3 Analysis and results

- 7.3.1 When analysis is completed, certificates of analysis will be dispatched to the Samples Repository Office, which will acknowledge receipt of the certificate(s) of analysis.
- 7.3.2 The Samples Repository Office will notify the EVR Samples Custodian or designated Regulatory officer by email or telephone of the results of the laboratory analysis.
- 7.3.3 The Samples Repository Office will dispatch certificate(s) of analysis to the EVR Samples Custodian or designated Regulatory officer, who will also acknowledge receipt of the certificate(s) of analysis by signing in the Reports Release logbook (SRLG03) and record them in the Samples Book (EVRB06 and EVRB11).

7.4 Review and Communication

- 7.4.1 The certificate(s) of analysis will be tabled by the EVR Samples Custodian or designated Regulatory officer before the Registration Committee for consideration.
- 7.4.2 After the Registration Committee Meeting, the request for shelf-life extension and the certificate of analysis shall be communicated to the applicant. A letter shall be dispatched at the MCAZ gate reception for collection by the client by the EVR Samples Officer and an email notifying the client of the letter and results will also be sent.
- 7.4.3 Copies of the letter and certificate(s) of analysis shall be filed in the Shelf-life Extensions folder, which shall be kept in the Chief Regulatory Officer's (Registrations) office. The EVR Samples Custodian or designated Regulatory officer shall also scan the signed results and letter and upload on SharePoint in a folder designated for shelf-life extension requests.

8.0 APPENDICES/ATTACHMENTS

N/A

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TITLE: Standard Operating Procedure for Submission of Samples to the Medicines Control Authority		
SOP Number: EVR 07	Revision Number: 6	Page 5 of 5

9.0 RECORDS

Document Number	Title of Record	Retention Period
EVRB06	Samples Received Register	Infinity
N/A	Duplicate of sample request form	Infinity
EVRB11	CM-Samples Book Register-Samples Received	Infinity
SR 06	Sample Submission Form	Infinity
SR 01	Sample Receipt and Forwarding Form	Infinity
CH17	Certificates of Analysis (Chemical Analysis)	Infinity
MBF001	Certificate of Analysis (Microbiological Analysis)	infinity

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records
- 10.3 SRO 01 Receipting, Forwarding and Storage of Samples
- 10.4 SRO 02 Procedure for release of test reports to customers

11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	April 2010	Rolling review
1	January 2012	System Improvement
2	October 2014	System Improvement
3	April 2018	System Improvement
4		
5	May 2023	System improvement- including the procedure for handling shelflife extension samples, results review and communication

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