



Medicines Control Authority of Zimbabwe

MCAZ/EVR/GL-15

GUIDELINE ON BIOANALYTICAL METHOD VALIDATION AND STUDY SAMPLE ANALYSIS

EFFECTIVE DATE: 08/04/2026

Medicines Control Authority of Zimbabwe

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Approved by:
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08/4/2026
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Date

1.0 APPLICATION

This guideline applies to all pharmaceutical manufacturers and applicants involved in bioanalytical method validation and study sample analysis, and to regulatory assessors involved in the scientific review of bioanalytical validation and study data.

2.0 PURPOSE

The purpose of this document is to formalize MCAZ's adoption and implementation of the Annex 6: WHO Guideline on bioanalytical method validation and study sample analysis (WHO Technical Report Series, No. 1060, 2025). It informs applicants and assessors of the standards to be applied during product registration and post approval changes (variations).

3.0 ADOPTION STATEMENT

MCAZ formally adopts Annex 6: WHO Guideline on bioanalytical method validation and study sample analysis (WHO Technical Report Series, No. 1060, 2025).

The source guideline is accessible at:

https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/annex-6_guideline-on-bioanalytical-method-validation-and-study-sample-analysis.pdf

4.0 RATIONALE FOR ADOPTION

To ensure that the MCAZ standards are aligned with international standards and state-of-the-art scientific practices. Adopting international standards such as WHO or ICH reduces duplication of studies, promotes information exchange among the regulators, including reliance, more efficient assessment, aligns the region with global standards, and ultimately increases the availability of medicines to the public. The intended benefits of adopting the Annex 6: WHO TRS 1060, 2025 are in line with the MCAZ agenda.

5.0 SCOPE

This guideline describes the validation of bioanalytical methods and study sample analysis that are expected to support regulatory decisions. The guideline is applicable to the bioanalytical methods used to measure concentrations of chemical and biological drugs

and their metabolites in biological samples (for example, blood, plasma, serum, or other body fluids or tissues) obtained in non-clinical toxicokinetic studies conducted according to the principles of good laboratory practice, non-clinical pharmacokinetic studies conducted as surrogates for clinical studies, and all phases of clinical trials, including comparative bioavailability/bioequivalence (BA/BE) studies, in regulatory submissions.

It represents the MCAZ's current thinking on the conduct of bioanalytical method validation and study sample analysis.

6.0 VALIDITY

This document is effective from the date of adoption and shall be reviewed as required, but not later than three (3) years from the effective date. In case of revision or updates to the source guideline, the latest version automatically applies, unless a specific transition period is specified by MCAZ.

7.0 ANNOTATIONS/NOTES

Additional references

For further information applicants may consult the ICH M10 Question and Answer document accessible at:

https://database.ich.org/sites/default/files/M10_Guideline_FAQs_2022_0616_0.pdf

8.0 DISCLAIMER

All guidelines adopted/adapted by MCAZ from international organizations such as WHO, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) must be read in conjunction with the current, applicable MCAZ guidelines.

MCAZ reserves the right to request additional information in keeping with the knowledge current at the time of evaluation. It is not intended as an exclusive approach as alternative approaches may be used but should be scientifically and technically justified.

9.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments

N/A	N/A	None-New Document
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