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MCA Technical Working Group

Guideline for Bioanalytical Method Validation

This Guideline (GL) is an adaptation of the Guideline on bioanalytical method validation, EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2**, whereby region, country, and national medicines regulatory authorities (NMRA) specific requirements as well as improvements of certain aspects that differ from the adopted GL are specified by Medicines Control Agency (MCA) annotations in the following document.

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End of consultation (deadline for comments)	20 March 2025
Agreed by MCA Technical Working Group	21 March 2025
Approved by Executive Director	08 April 2025
Date of coming into effect	09 April 2025

This is a new guideline.

Comments should be provided by using the template (MCA-F-021/03) for Submission of Comments and sent to info@mca.gm

Keywords	validation, bioanalytical method, analyses

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162 Serekunda
Telephone +220 4380632
Send a question via our website www.MCA.gm or info@mca.gm
An agency of The Gambia

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Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January / February 2020 by GHPP-PharmTrain Project team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone), and The Gambia (MCA, Medicines Control Agency).

This document has been discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-PharmTrain project team from February 2022 to May 2022. Version 1 of the Guideline on Bioanalytical Method Validation for the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia was finalised on 02 December 2022 for annotation in the MCA guideline.

This document should be read in conjunction with the relevant sections of the MCA *Guideline for Marketing Authorisation (Registration) of Medicines*, MCA *Guideline for the Investigation of Bioequivalence* and other applicable guidance.

Information on the parent guideline

Title: Guideline on bioanalytical method validation

Author(s): European Medicines Agencies (EMA), Committee for Medicinal Products for Human Use (CHMP)

Document No: Doc. Ref.: EMEA/CHMP/EWP/192217/2009 Rev. 1 Corr. 2** superseded by the by the ICH guideline M10 on bioanalytical method validation and study sample analysis, following its finalisation in July 2022

Version No: (Not applicable)

Date of issue: 21 July 2011

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(Accessed May 2024, February and April 2025)

1 General aspects and terms deviating from parent guideline

1.1. For the purpose of consistency with other MCA guidelines, the terms of the parent guideline (left column) shall read as synonymous to the following terms (right column):

Parent guideline term	Synonymous term
Medicinal product	Medicine
Drug	Medicine

2 MCA annotations on the adopted Guideline on bioanalytical method validation

2.1 Concerning Section 3 Legal Basis

Annotation:

Replacement of the EMA legal requirement with the MCA specific legal requirements Medicines and Related Products Act, 2014 and Medicines and Related Products Regulations, 2020. This amendment includes all references to "Directive 2001/83/EC" in the guideline.

Rationale:

Since The Gambia is not a member state of the European Union, the EMA legal requirements; Part I and II of the Annex I to Directive 2001/83 as amended, Regulation (EC) No. 726/2004 and any other EMA legal requirement are not applicable.

References

- Guideline on Guidelines V1, February 2021 developed by the joint working group of Food and Drugs Authority (FDA, Ghana), Liberia Medicines & Health Products Regulatory Authority (LMHRA, Liberia), Medicines Control Agency (MCA, The Gambia), Pharmacy Board of Sierra Leone (PBSL, Sierra Leone), and the Global Health Protection Programme (GHPP) PharmTrain-Project of the Federal Institute for Drugs and Medical Devices (BfArM, Germany).