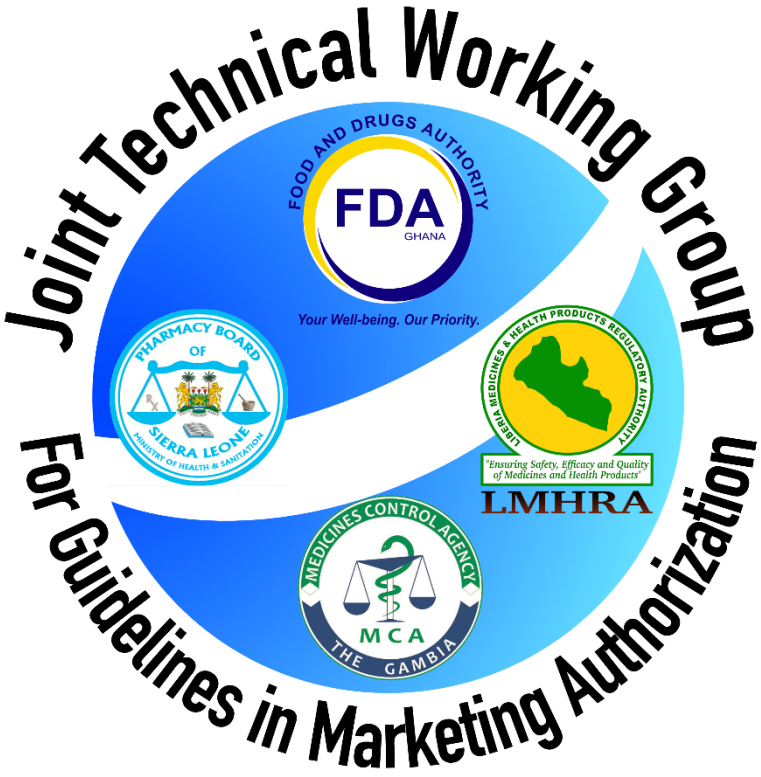

Guideline on

Bioanalytical Method Validation

For the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia

Updated December 2, 2022

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NMRAs are welcome to download and use the following guideline if credit is given to the authors - all members of the Joint Technical Working Group for Development of Guidelines in Marketing Authorization (TWG-MAG):

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<02 December 2022>
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Guideline on bioanalytical method validation, Version 1, May 10, 2022

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 <NMRA> annotations in the following document.

Draft written by FDA Ghana and MCA The Gambia	26th February 2022
Draft annotations reviewed and agreed by TWG-MAG: LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	10th May 2022
Adopted by <Committee/Board> for release for consultation	<DD Month YYYY>[1]
Start of public consultation	<DD Month YYYY>[2]
End of consultation (deadline for comments)	<DD Month YYYY>[3]
Agreed by <Working group(s)/Departments>	<Month YYYY>
Adopted by <Committee/Board>	<DD Month YYYY>
Date of coming into effect	<DD Month YYYY>[4]

Comments should be provided using the template for submission of comments. The completed comments form should be sent to <as appropriate (NMRA's Email)>.

Keywords	*bioequivalence, pharmacokinetics, biowaiver, in vitro dissolution, generic*

[1]Last day of relevant Committee meeting.
[2]Date of publication on the NMRA public website/1st day of the month following adoption of the guideline.
[3]Last day of the month concerned.
[4]First day of coming into effect. Latest 3 month after adoption.

Guideline on bioanalytical method validation, Version 1.0, May 10, 2022

Table of contents

Style notes for this draft version:

[ ] Comments to be removed with finalization

< > Placeholder to be filled with specific information or to be decided if kept or deleted.

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.

From January 2022 the Joint Technical Working Group for Guidelines in Marketing Authorization (TWG-MAG), with the above-mentioned members, was established to continue the successful development of regulatory guidelines.

<This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance, such as the <BE GL>, <NMRA specific GLs (e.g. Clinical trial department GLs may also cover some aspects of BA)>.

Information on the adopted Guideline on bioanalytical method validation

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**

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1 <NMRA> annotations on the adopted Guideline on bioanalytical method validation

1.1 Concerning Section 3 Legal Basis

Annotation: Replacement of the EMA legal requirement with the <NMRA> specific legal requirement <quote title of regulation/ national medicines Act if applicable>. This amendment includes all references to “Directive 2001/83/EC” in the guideline.

Rationale: Since <NMRAs> are not member states 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

This guideline template is based on the structure of the adoption approach of the 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).