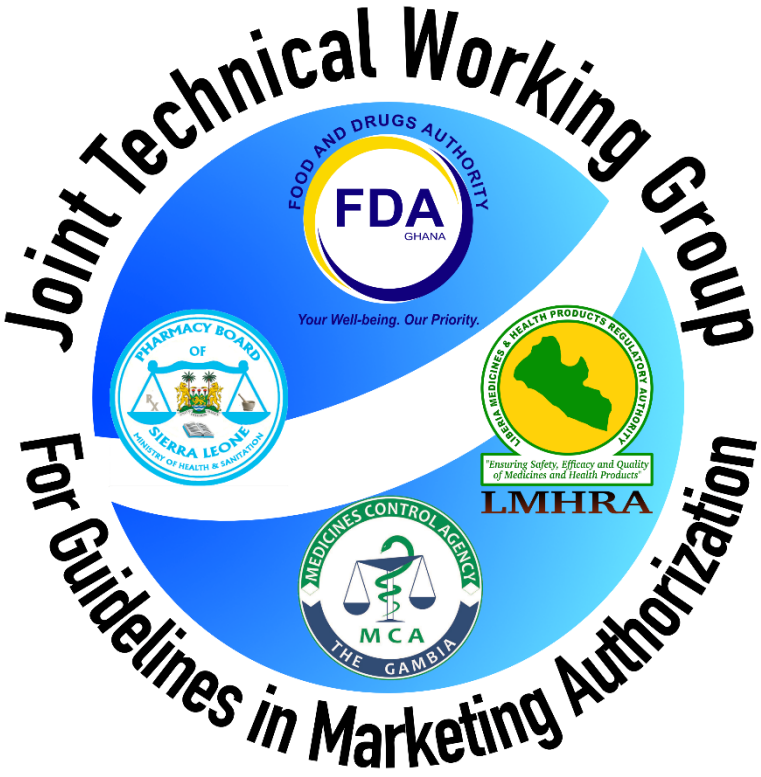

Guideline on Stability Testing

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

Updated December 2, 2022

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<02 December 2022>
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The Guideline on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Version 1.0, Updated December 2, 2022

This Guideline (GL) is an adaptation of the Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical products, WHO Technical Report Series, No. 1010, 2018 (including appendix 1, 2, and 3), 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 of annotation written by <FDA Ghana/MCA Gambia>	April 2022
Draft annotations reviewed and agreed by TWG-MAG: LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	10th September 2022
Updated by LMHRA, MCA The Gambia, PBSL, FDA Ghana, GHPP PharmTrain	02 December 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]

[1]Last day of relevant Committee meeting.
[2]Date of publication on the NRA 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 months after adoption.

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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	stability studies, long term, accelerated, active pharmaceutical ingredients (API), finished pharmaceutical ingredients (FPP)

Guideline on Stability Testing of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products, Version 1.0, Updated December 2, 2022

Table of contents

Style notes for this draft version:

[ ] Comments to be removed after finalization

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

Executive summary

The development of this guideline (GL) is based on the outcomes and consensus of the meetings convened in January/February 2020 and additional online meetings in 2021-2022 including a hybrid workshop in November 2021 by the 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 Ghana (FDA, Food and Drugs Authority), 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 should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance>.

Information on the adopted Guideline

Title: Annex 10 Stability Testing Of Active Pharmaceutical Ingredients and Finished Pharmaceutical Products

Title(s) of Annexes/Appendixes:

APPENDIX I- Examples of testing parameters

APPENDIX II- Recommended labelling statements

APPENDIX III- Interpretation of storage statements for products approved in climatic zone II when the products are to be distributed in zone IV

Author(s): World Health Organization (WHO)

Document No: WHO Technical Report Series, No. 1010, 2018

Version No:

Date of issue: 2018

Source (e.g. website link): https://extranet.who.int/pqweb/news/publication-updated-who-stability-guideline-trs-1010-annex-10-2018

1. <NMRA> annotations on the adopted WHO Annex 10 Stability testing of active pharmaceutical ingredients and finished pharmaceutical products

1.1. Concerning Section 1.2 SCOPE

Annotation: Replacement of the following sentence:

"These guidelines apply to new and existing APIs and address information to be submitted in original and subsequent applications for marketing authorization of their related FPP for human use"

by the following sentence "*The guideline addresses the information to be submitted in registration applications for a new and existing molecular entity and associated finished pharmaceutical products*."

Rationale: The aim is to limit the scope of this guideline to medicinal products.

1.2. Concerning section 2.1.7 STORAGE CONDITIONS

Annotation: The sentence

"*Additional data accumulated during the assessment period of the registration application should be submitted to the authorities upon request*."

is amended by the deletion of "upon request" as follows:

“Any additional data accumulated during the assessment period of the registration application should be submitted immediately to the authorities.”

Rationale: It is the applicant’s responsibility to submit any additional data during the assessment period of the registration application and not the NMRAs to request for it.

1.3. Concerning Section 2.2.7.3 FPPS PACKAGED IN SEMI-PERMEABLE CONTAINERS

Annotation: Deletion of all sections linked to long-term studies done at 25 °C ± 2 °C/40% RH ± 5% RH and intermediate studies at 30 °C ± 2 °C/35% RH ± 5% RH.

Rationale: The above storage conditions are not applicable to WHO Zone IV b climatic conditions which are present in <country>.

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).