RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDANCE ON PRODUCT QUALITY REVIEW (PQR) REQUIREMENTS FOR GENERIC HUMAN MEDICINAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of human medicinal products in order to protect public health by increasing access and availability of essential medicines.

Considering the provisions of the technical Regulations N° CBD/TRG/010 Governing the registration of human medicinal products especially in its articles 6, 7, 8, 9, 12 and 32, and the Guidelines No DHT/GDL/001 on submission of documentation for registration of human medicinal products, the authority has to issue the Guidance N°: DAR/GDL/001E on Product Quality Review (PQR) Requirements for Generic Human Medicinal Products

Rwanda FDA adopted the Common Technical Document (CTD) Guidelines on Submission of Documentation for registration of human medicinal products. These guidelines have been developed to provide guidance to the applicants and the Authority in managing applications for registration of human medicinal products. These guidelines were developed in reference to the existing Ministry of Health (MOH) guidelines on submission of documentation for registration of Human Pharmaceutical Products which were domesticated based on Compendium of Medicines Evaluation and Registration for Medicines Regulation Harmonization in the East African Community, World Health Organization (WHO) and the International Conference on Harmonization of Technical Requirements for Registration of Medicines for Human Use (ICH) and other available literature.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

06.09.2021

Dr Emile BIENVENU
Director General

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For an established generic product, a product quality review may satisfy the requirements of sections 3.2.P.2.2.1 (a), 3.2.P.2.3 (a) and 3.2.P.3.5 of the PD and QOS-PD.
A product quality review should be submitted with the objective of verifying the consistency of the quality of the FPP and its manufacturing process.

Rejected batches should not be included in the analysis but must be reported separately together with the reports of failure investigations, as indicated below.

Reviews should be conducted with not less than 10 consecutive batches manufactured over the period of the last 12 months, or, where 10 batches were not manufactured in the last 12 months, not less than 25 consecutive batches manufactured over the period of the last 36 months and should include at least:

(a) A review of starting and primary packaging materials used in the FPP, especially those from new sources.
(b) A tabulated review and statistical analysis of quality control and in-process control results.
(c) A review of all batches that failed to meet established specification(s).
(d) A review of all critical deviations or non-conformances and related investigations.
(e) A review of all changes carried out to the processes or analytical methods.
(f) A review of the results of the stability-monitoring programme.
(g) A review of all quality-related returns, complaints and recalls, including export- only medicinal products.
(h) A review of the adequacy of previous corrective actions.
(i) A list of validated analytical and manufacturing procedures and their revalidation dates.

Notes

Reviews must include data from all batches manufactured during the review period. Data should be presented in tabular or graphical form (i.e. charts or graphs), when applicable

DOCUMENT REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change Made
25/08/2021	Rev_0	DAR/GDL/001E	First Issue

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