



Annex V: Bioequivalence Trial Information (BTIF)

GENERAL INSTRUCTIONS:

Please review all the instructions thoroughly and carefully prior to completing the Bioequivalence Trial Information Form (BTIF).

Provide as much detailed, accurate and final information as possible. Note that the greyed areas are NOT to be filled in by the applicant but are for EAC use ONLY!

Please state the exact location (Annex number) of appended documents in the relevant sections of the BTIF. For example, in **section 3.4.3.1 under point b**), indicate in which Annex (number) the Certificate of Analysis can be found. This procedure must be followed throughout the entire document where location of annexed documents is requested.

Before submitting the completed BTIF, kindly check that you have provided all requested information and enclosed all requested documents. Should you have any questions regarding this Form, please contact Tanzania Medicines and Medical Devices Authority (TMDA)

A properly filled out and signed original copy of the BTIF with all its annexes (including a copy on CD-ROM) must be submitted to TMDA together with the bioequivalence part of the dossier to the address below

Director General,
Tanzania Food and Drugs Authority,
Off Mandela Road, Mabibo-External
P.O. Box 77150
Dar es Salaam
Email: medicines@tmda.go.tz