

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd



Ref. WHO TRS 992, 2015, ANNEX-9

Date:.....

The Guideline on Good Review Practices (GRevP)

DGDA,

As a competent medicine regulatory authority gives marketing authorization of a new pharmaceutical product for the purpose of marketing or distribution after evaluation of its safety, efficacy and quality.

For getting marketing authorization applicant submit required documents/dossier to DGDA. Guidelines are needed to review the submitted documents/dossier properly and effectively.

In these purpose WHO Guidelines on "Good review practices: guidelines for national and regional regulatory authorities" is very extensive guidelines which covered all the aspect and issues of reviewing application and documentation of marketing authorization.

So this guidelines (page: 191-202) is adopted for the purpose of review in DGDA from the date give below and valid up to next office order.

Major General Md. Mustafizur Rahman

Director General

Directorate General of Drug Administration

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Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh