



GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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Ref. WHO TRS, NO.822, 1992, ANNEX-2

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The Guideline on Quality Assurance for Biological Products

In Bangladesh DGDA is functioning as National Regulatory Authority.

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

In General Biological products are distinguished from other drugs by being derived from living organisms (ranging from normal or genetically modified microorganisms to humans), and frequently have a complex molecular structure.

They require special quality considerations because of the biological nature of a) the starting material, and/or b) the manufacturing process, and/or c) the test methods needed to characterize batch to batches of the product.

So guidelines are needed to review the submitted documents/ dossier of Biological product properly and effectively.

In these purpose WHO TRS, No. 822, 1992 Annex-2, on "Guidelines for national authorities on quality assurance for biological products" is very extensive guidelines which covered all the aspect and issues of reviewing application and documentation of marketing authorization.

So this guidelines (page: 31-46) is adopted for the purpose of review in DGDA from the date give below and valid up to next office order.

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