GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHADH BHABAN
MOHAKHALI, DHAKA, BANGLADESH
www.dgda.gov.bd

Ref. WHO TRS 999, 2016, ANNEX-2

Date: 01/04/2020

Guidelines on Good Manufacturing Practices for Biological Products

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.

MA holder should follow the GMP practices for biological products as per the instructions of this guideline.

To practice GMP activities properly and effectively guidelines are needed. In this purpose WHO Guidelines on Good Manufacturing Practices for Biological products is very extensive guidelines which also covered all the aspect and issues of GMP for Biological products.

So here this is to certify that WHO Guidelines on Good manufacturing practices for biological products WHO TRS 999, 2016, Annex-2 is adopted for the purpose of GMP in DGDA from the date given below and valid up to next office order.

Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)