

LIST OF UPDATES ON GOOD DISTRIBUTION PRACTICE GUIDELINE
2nd Edition 2013
National Pharmaceutical Control Bureau, Ministry of Health

No.	GDP Guideline (1 st / 2 nd version)	Chapter/ Clause	Details	Note (Deleted/ Amended/ New)
1	GDP 1 st edition	3.16	Certain materials and/or products and/or cosmetics in suitable containers may be stored outdoors, provided that identifying labels remain legible and containers are appropriately cleaned before opening and use	Deleted
2	GDP 2 nd Edition	3.20	Where storage condition stated on the label means the following- Dry Place No more than 75±5% relative humidity in normal storage conditions; to be provided to the user in a moisture-resistant container	Amended
3	GDP 2 nd Edition	6.3.3	For Manufactures/importers, each hologram label should be recorded according to its usage in a logbook. Any hologram labeling activity that is done by a third party, delivery/ distribution record of the hologram should be recorded in a log book for traceability purpose.	New
4	GDP 2 nd Edition	8.1.4	Materials and/or products and/or cosmetics in transit must be accompanied by the appropriate documentation. For each importation, the Certificate of Analysis (CoA) for each batch of product and/or cosmetic must be kept by the importer.	Amended
5	GDP 2 nd Edition	10	Product/ Cosmetic Recall	Amended
6	GDP 2 nd Edition	Chapter 15 15.1 - 15.24	MANAGEMENT OF COLD CHAIN PRODUCTS/ MATERIALS	New
7	GDP 2 nd Edition		References	New
8	GDP 2 nd Edition		Control of Drugs and Cosmetics Regulations 1984 (Revised 2009)	Amended