Guidelines for Good Manufacturing Practice

In the "Drug Ordinance 1982" section 15 is mentioned that "Every manufacturer of drugs shall follow the good practices in the manufacture and quality control of drugs recommended by the World Health Organization (WHO) and If any manufacturer does not follow such good practices his manufactured license may be cancelled or suspended." So, the all good practice guideline recommended by WHO is the official guideline for Bangladesh.

This circular is to adopt the WHO Guidelines for all good practice mentioned below:

1. Quality System requirements for National Good Manufacturing Inspectorates: WHO Technical Report Series No. 902,2002 (Annex-8)
2. Good Manufacturing Practice (GMP): WHO Technical Report Series No. 986, 2014 (Annex -2)
3. Good Laboratory Practice (GLP): WHO Technical Report Series No. 957, 2010 (Annex -1)
4. Good Distribution Practice (GDP): WHO Technical Report Series No. 957, 2010 (Annex -5)
5. Good Cold Chain Management Practices (GCCMP): WHO Technical Report Series No. 961, 2011 (Annex -9)
6. Good Storage Practice (GSP): WHO Technical Report Series No. 908, 2003 (Annex -9)
7. Good Documentation Practice (GDocP): WHO Technical Report Series No. 996, 2016 (Annex -5)
8. Quality Risk Management Practice : WHO Technical Report Series No. 981, 2013

The manufacturer and importer of Bangladesh should comply with the principles set forth in the above guidelines.

14 MAY 2018

Major General Md. Mustafizur Rahman
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Guidelines for Good Practice (GxP)

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This circular is to adopt the WHO Guidelines for all good practice mentioned below:

1. Good Manufacturing Practices for active pharmaceutical ingredients: WHO Technical Report Series No. 957, 2010 (Annex 2)
2. Good Manufacturing Practices for sterile pharmaceutical products: WHO Technical Report Series No. 961, 2011 (Annex 6)
3. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products: WHO Technical Report Series No.953, 2009 (Annex 2)
4. Good Manufacturing Practices: water for pharmaceutical use :WHO Technical Report Series No. 961, 2011 (Annex 2)
5. General Guidance on hold-time studies: WHO Technical Report Series No. 992, 2015 (Annex 4)
6. Supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems(HVAC) for non-sterile pharmaceutical dosage forms: : WHO Technical Report Series No.961, 2011 (Annex 5)
7. Supplementary Guidelines on good manufacturing practices: validation, WHO Technical Report Series No. 937, 2006 (Annex 4)
8. Guidelines for sampling of pharmaceutical products and related materials: WHO Technical Report Series No. 929, 2005 (Annex 4)
9. WHO good manufacturing practices for biological products: WHO Technical Report Series No. 996, 2016 (Annex 3)

10. Guidance on good manufacturing practices: inspection report: WHO Technical Report Series No. 996, 2016 (Annex 4)
11. Guideline for drafting a site master file: WHO Technical Report Series No. 961, 2011 (Annex 14)

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27.06.16

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