Notice to applicant

Central Administration of Operation
General Administration For Factories Inspection
Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants

Adopted list of WHO norms and standards for Medicinal Products

Year 2023

Code: EDREX:NP.CAO.004/2023
Version No: 1/0
Issue Date: 26/09/2023

Guidelines and guidance texts adopted by General Administration for Factories Inspection -

Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants; As recommended by World Health Organization (WHO)

As per Law No. 151 of 2019 issued for the establishment and regulation of the Egyptian Drug Authority (" EDA ")

The list of WHO norms and standards for medicines, quality assurance and regulatory guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations and published in the WHO Technical Report Series (TRS) has been drawn up as follows.

The guidelines are published in English as the primary language.

Category	Guideline	TRS	Annex	Year
Production	WHO good manufacturing practices for pharmaceutical products: main principles	986	2	2014
Production	WHO good manufacturing practices for active pharmaceutical ingredients	957	2	2010
Production	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients	885	5	1999
Production	WHO good manufacturing practices for sterile pharmaceutical products	961	6	2011
Production	WHO good manufacturing practices for pharmaceutical products containing hazardous substances	957	3	2010
Production	Guidelines on good manufacturing practices for the manufacture of herbal medicines	1010	2	2018
Production	WHO guidelines on good herbal processing practices for herbal medicines	1010	1	2018

Distribution	Points to consider for setting the remaining shelf-life of medical products upon delivery	1025	8	2020
Distribution	Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products	961	9	2011
Distribution	Technical supplements to Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products	992	5	2015
Distribution	Technical supplements to WHO Technical Report Series No. 961, 2011: introduction to the technical supplements	992	5	2015
Distribution	*Supplement 1:* Selecting sites for storage facilities	992	5	2015
Distribution	*Supplement 2:* Design and procurement of storage facilities	992	5	2015
Distribution	*Supplement 3:* Estimating the capacity of storage facilities	992	5	2015
Distribution	*Supplement 4:* Building security and fire protection	992	5	2015
Distribution	*Supplement 5:* Maintenance of storage facilities	992	5	2015
Distribution	*Supplement 6:* Temperature and humidity monitoring systems for fixed storage areas	992	5	2015
Distribution	*Supplement 7:* Qualification of temperature-controlled storage areas	992	5	2015
Distribution	*Supplement 8:* Temperature mapping of storage areas	992	5	2015
Distribution	*Supplement 9:* Maintenance of refrigeration equipment	992	5	2015
Distribution	*Supplement 10:* Checking the accuracy of temperature control and monitoring devices	992	5	2015
Distribution	*Supplement 11:* Qualification of refrigerated road vehicles	992	5	2015
Distribution	*Supplement 12:* Temperature-controlled transport operations by road and by air	992	5	2015
Distribution	*Supplement 13:* Qualification of shipping containers	992	5	2015

Distribution	*Supplement 14:* Transport route profiling qualification	992	5	2015
Distribution	*Supplement 15:* Temperature and humidity monitoring systems for transport operations	992	5	2015
Distribution	*Supplement 16:* Environmental management of refrigeration equipment	992	5	2015
Inspection	Guidance on good manufacturing practices: inspection report	996	4	2016
Inspection	Quality management system requirements for national inspectorates	1025	5	2020
Inspection	Guidelines on pre-approval inspections	902	7	2002
Inspection	Provisional guidelines on the inspection of pharmaceutical manufacturers	823	2	1992
Inspection	Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions	1010	9	2018
Production	General guidance on hold-time studies	992	4	2015
Production	WHO guidelines for drafting a site master file	961	14	2011
Production/ regulatory standards	International Atomic Energy Agency and World Health Organization guideline on good manufacturing practices for radiopharmaceutical products	1025	2	2020
Production	Good manufacturing practices: water for pharmaceutical use	1033	3	2021
Production	Production of water for injection by means other than distillation	1025	3	2020
Production	Guidelines on heating, ventilation, and air-conditioning systems for non-sterile pharmaceutical products [Part1]	1010	8	2015
Production	Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of guideline	1019	Annex 2	2019

Production/ distribution	Guideline on data integrity	1033	Annex 4	2021
Production	WHO guidelines on transfer of technology in pharmaceutical manufacturing	961	Annex 7	2011
Production/ regulatory standards	WHO guidelines on quality risk management 2013	981	Annex 2	2013
Production/ inspection	Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance	1025	Annex 6	2020
Production	Good manufacturing practices: guidelines on validation	1019	Annex 3	2019
Production	Points to consider when including health-based exposure limits (HBELs) in cleaning validation	1033	Annex 2	2021