Notice to applicant

Central Administration of Operation

Adopted list of WHO norms and standards for Medicinal Products

Year 2024

Code: EDREX:NP.CAO.004/2023
Version No: 2
Issue Date: 2024

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	comment
Production	WHO good manufacturing practices for pharmaceutical products: main principles	986	2	2014	OK
Production	WHO good manufacturing practices for active pharmaceutical ingredients	957	2	2010	OK
Production	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients	885	5	1999	UNDER REVISION
Production	WHO good manufacturing practices for sterile pharmaceutical products	961	6	2011	REPLACED BY TRS 1044 ANNEX 2 2022
Production	WHO good manufacturing practices for pharmaceutical products containing hazardous substances	957	3	2010	OK
Production	Guidelines on good manufacturing practices for the manufacture of herbal medicines	1010	2	2018	OK
Production	WHO guidelines on good herbal processing practices for herbal medicines	1010	1	2018	OK

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

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

Production/ distribution	Guideline on data integrity	1033	Annex 4	2021	OK
Production	WHO guidelines on transfer of technology in pharmaceutical manufacturing	961	Annex 7	2011	REPLACED BY TRS 1044 ANNEX 4 2022
Production/ regulatory standards	WHO guidelines on quality risk management 2013	981	Annex 2	2013	OK
Production/ inspection	Points to consider for manufacturers and inspectors: environmental aspects of manufacturing for the prevention of antimicrobial resistance	1025	Annex 6	2020	OK
Production	Good manufacturing practices: guidelines on validation	1019	Annex 3	2019	OK
Production	Points to consider when including health-based exposure limits (HBELs) in cleaning validation	1033	Annex 2	2021	OK
Production/ inspection	Quality assurance of pharmaceuticals: a compendium of guidelines and related materials,	1044	Annex 4	2023	THE COMPENDIUM CONTAIN ALL UPDATED GUIDELINES
BIOLOGICAL					
Production/ inspection	WHO guidelines on good manufacturing practices for blood establishments	961	Annex 4	2011	OK
Production/ inspection	WHO good manufacturing practices for biological products	996	Annex 3	2016	OK
Production/ inspection	Guidelines on packaging for pharmaceutical products	902	Annex 9	2002	OK

Production/ inspection	WHO good manufacturing practices for investigational products	1044	Annex 7	2022	OK
Production/ inspection	IAEA - WHO guideline on good manufacturing practices for investigational radiopharmaceutical products	1044	Annex 3	2022	OK
Production/ inspection	Good storage and distribution practices for medical products	1025	Annex 7	2020	OK
Production/ inspection	WHO good manufacturing practices for biological products	999	Annex 2	2016	