Notice to applicant

Egyptian Drug Authority
Central Administration of Inspection on Pharmaceutical Institutions
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 2026

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1. Purpose

A regulatory system is not defined by the number of texts it issues. It is defined by the coherence of the standards against which it inspects, decides, and holds itself accountable.

This document is issued to establish that coherence in explicit terms.

The purpose of this publication is to formally declare the list of norms, standards, guidelines, and guidance texts recommended by the World Health Organization (WHO) that are adopted by the General Administration for Factories Inspection, through the Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants, as the reference basis for the conduct of inspection activities and for the assessment of compliance by pharmaceutical establishments falling within its scope of oversight.

The adoption is made in the service of an objective: to safeguard the quality, safety, and efficacy of medicinal products placed on the Egyptian market, to protect the patient who has no visibility of the process and no defense other than the regulator acting on their behalf.

2. Legal Basis

This adoption is issued pursuant to Law No. 151 of 2019 concerning the establishment and regulation of the Egyptian Drug Authority, and in accordance with the mandate conferred upon the Central Administration of Pharmaceutical Establishment Inspection to regulate and inspect pharmaceutical establishments in the Arab Republic of Egypt.

3. Scope of Application

This adopted list applies to:

1. Inspectors of the Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants, in the planning, conduct, reporting, and classification of Good Manufacturing Practice (GMP) inspections.
2. Manufacturing establishments of human medicinal products, herbal medicinal products, veterinary medicinal products, and disinfectants, licensed or applying for licensure within the Arab Republic of Egypt.

4. Basis of Selection

The list of WHO norms and standards for medicines, quality assurance, and regulatory guidance texts adopted herein is drawn from the texts adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP) and published in the WHO Technical Report Series (TRS).

5. Status of the Adopted Texts

The adopted texts constitute the technical reference standard against which compliance is assessed. They complement, and do not supersede, the requirements of Law No. 151 of 2019, its executive regulations, and the guidelines issued by the Egyptian Drug Authority. In any case of conflict between an adopted WHO text and Egyptian legislation, the national legislation prevails.

An establishment may adopt an alternative approach to that described in an adopted text, provided that the alternative is demonstrated, on the basis of objective evidence and a documented risk assessment, to achieve an equivalent or higher level of assurance of product quality and patient safety. The burden of that demonstration rests with the establishment.

6. Language

The guidelines are published in English as the primary language.

7. Statement of Alignment

The adoption of these norms and standards reflects the continuing commitment of the Egyptian Drug Authority to regulatory practice that is grounded in science, exercised on a risk basis, and aligned with WHO and internationally recommended standards. It supports the Authority's institutional objectives of regulatory maturity, reliance and work-sharing with trusted regulators, and the harmonization agenda advanced through the African Medicines Regulatory Harmonization (AMRH) initiative, in which Egypt serves as lead country for the Technical Working Group on GMP and Inspection in the North African region.

Alignment with international standards is not an act of deference. It is an act of discipline. It is what allows an inspection decision taken in Cairo to be understood, trusted, and relied upon beyond it.

8. Contact information:

For further information or clarification, please contact:

Central Administration of Pharmaceutical Establishment Inspection

General Administration for Factories Inspection

Administration of Inspection of Pharmaceutical Factories for Human, Herbal, Veterinary and Disinfectants

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The Adopted list of WHO norms and standards for Medicinal Products

Category	Guideline	TRS	Annex	Year
Production/ inspection	Quality assurance of pharmaceuticals: a compendium of guidelines and related materials,	Tenth Edition - Volume 2 Good manufacturing practices and inspection		2023
Production	WHO good manufacturing practices for pharmaceutical products: main principles	986	Annex 2	2014
Production	WHO good manufacturing practices for sterile pharmaceutical products	1044	Annex 2	2022
Production	WHO good manufacturing practices for active pharmaceutical ingredients	957	Annex 2	2010
Production	Good manufacturing practices: supplementary guidelines for the manufacture of pharmaceutical excipients	1052	Annex 2	2024
Production	WHO good manufacturing practices for excipients used in pharmaceutical products	1060	Annex 3	2025
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
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	2018
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	1044	Annex 4	2022
Production/ regulatory standards	WHO guidelines on quality risk management	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
Quality control/ inspection	WHO good practices for pharmaceutical quality control laboratories	1052	Annex 4	2044
Production/ inspection	Guidelines on packaging for pharmaceutical products	902	Annex 9	2002
Production/ inspection	WHO good manufacturing practices for investigational products	1044	Annex 7	2022
Production/ inspection	IAEA - WHO guideline on good manufacturing practices for investigational radiopharmaceutical products	1044	Annex 3	2022
Production/ inspection	WHO points to consider in continuous manufacturing of pharmaceutical products	1067	Annex 2	2026
Production/ inspection	International Atomic Energy Agency and World Health Organization guidelines on good practices for quality control of in-house radiopharmaceutical preparations	1067	Annex 3	2026
Production/ inspection	Procedure for prequalification of pharmaceutical products	1067	Annex 4	2026
Production/ inspection	WHO listing of quality control laboratories: procedure for assessing the acceptability, in principle, of quality control laboratories	1067	Annex 5	2026
Production/ inspection	WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of	1067	Annex 7	2026

	Essential Medicines immediate-release, solid oral dosage forms			
Production/ inspection	Development of pediatrics medicines: points to consider in formulation	1067	Annex 8	2026
Production/ inspection	Regulatory considerations for the life cycle of medicinal oxygen	1067	Annex 10	2026
Production/ inspection	Good storage and distribution practices for medical products	1025	Annex 7	2020
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
Production/ inspection	WHO good practice considerations for the prevention and control of nitrosamines in pharmaceutical products	1060	Annex 2	2025
Quality control/ inspection	Guideline on bioanalytical method validation and study sample analysis	1060	Annex 6	2025