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Central Administration of Inspection on Pharmaceutical Institutions

General Adminstration of Factories Inspection

Regulatory Guide for the Decree of the Chairman of the Authority No. (239) of 2026 Regarding the Procedures for Sampling and Release of Human, Herbal, and Veterinary Pharmaceutical Products, Disinfectants, Cosmetics, Pesticides, Raw Materials, Biological Products, and Medical Devices

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1. Definitions

For the application of the provisions of this Regulatory Guide, the following words and phrases shall have the meanings assigned next to each of them:

Ser	Term	Definition
1	**Bulk**	Any product that has completed all processing stages up to, but not including, final packaging.
2	**Imported Bulk Cosmetics**	Products that are imported from abroad fully manufactured, and their wrapping process takes place exclusively within the Arab Republic of Egypt.
3	**Premix**	Pre-blended raw materials.
4	**Pellets**	Raw materials in pelletized form.
5	**Reference Samples**	Representative samples of the production batch stored in the factory warehouse, provided they are sufficient to conduct two complete analyses of the product.
6	**Consignment (Shipment)**	A shipment containing one or more batches of raw materials or pharmaceutical products subjected to the same shipping and storage conditions.
7	**Reference Countries**	A group of countries determined by a binding decision issued by the Technical Committee for Drug Control.
8	**Lot Release Program**	The approved automated program of the Egyptian Drug Authority (EDA) responsible for regulating the batch release process for biological products in preparation for their marketing in the local

Ser	Term	Definition
		market.
9	**Parallel Sampling**	The withdrawal of samples from a batch for analysis at the Egyptian Drug Authority's laboratories while awaiting the release of the company's own analysis results and their submission to the Authority.
10	**MD (Medical Device)**	Any instrument, apparatus, appliance, software, material, or other article intended by the manufacturer to be used for human beings for specific purposes such as: • Diagnosis, prevention, monitoring, treatment, or alleviation of disease. • Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability. • Investigation, replacement, or modification of the anatomy or of a physiological process. • Control of conception.
11	**LMD**	Locally manufactured Medical Device.
12	**IVDs**	"In vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information.
13	**Non-compliance**	The issuance of a decision indicating the non-compliance of

Ser	Term	Definition
		samples drawn from a batch after their analysis by the competent analysing entity.
14	**The Bundle**	Pursuant to what is published in the Regulatory Guide for the procedures of issuing import approvals for IVDs (issued on 24/2/2025), where the reagents share the following: • Same legal manufacturer • Same risk classification • Same intended use or category or principle of operation or mode of action • Same IVD form (e.g., reagent, rapid test (test strip cassette, ...)
15	**The Family for Locally Manufactured Devices**	Medical devices that share the following: • Raw materials used in manufacturing • Processed on the same production lines • Manufacturing steps • Intended use / Category / Principle of operation / Mode of action • Sterilization method in case of sterile devices

2. Procedures for the Sampling and Analysis of Pharmaceutical Products

First: Registration Phase:

Human, veterinary, and herbal pharmaceutical products, as well as disinfectants, shall be subject, regarding the withdrawal of samples for analysis at the Central Administration of Drug Control, to the procedures stipulated in the current regulations in force and the decisions issued by the Technical Committee for Drug Control and the competent technical committees, unless otherwise explicitly provided for in this Decree.

Second: Post-Registration Phase:

1. The Inspection Divisions shall withdraw samples from the first three production or imported batches and release them after the issuance of a compliance decision from the laboratories of the Egyptian Drug Authority for each of the following cases:
    - Locally manufactured finished human, herbal, veterinary pharmaceutical products, and disinfectants.
    - Imported finished and bulk human, herbal, veterinary pharmaceutical products, and disinfectants from a non-reference country, after unpacking the contents of the shipment.
    - Imported or locally produced plant extracts.
    - Active pharmaceutical ingredients (APIs), as well as premix or pellets for the fore mentioned products, after unpacking the contents of the shipment.
2. The Inspection devisions shall withdraw samples from the first production or imported batch and release them for each of the following cases:
    - Imported finished and bulk human, herbal, veterinary pharmaceutical products, and disinfectants from a reference country, or imported from a non-reference country but marketed in a reference country, after unsealing the contents of the shipment.
3. The random sampling plan shall apply to all products and preparations subject to the provisions of this Decree once they obtain three consecutive compliance results. For inactive raw materials (excipients), random sampling shall be conducted; however, in the event that a non-compliance decision is issued, random sampling shall be suspended, and three samples shall be drawn from three different batches from the same source.
4. Random sampling of the finished product shall be carried out taking into account the following criteria:
    - The frequency of non-compliance reports issued for the same product or other products from the same factory or production line.
    - The factory's compliance with the latest Current Good Manufacturing Practices

(cGMP).
- The factory's compliance with the latest Current Good Laboratory Practices (cGLP).
- The compliance of the factory or importing companies with the latest Current Good Storage Practices (cGSP).
- Receipt of complaints that compromise the quality and safety of the product.
- Execution of a sampling or voluntary Sampling of the product due to a deviation in the production process or product quality.

Production batches withdrawn randomly shall not be allowed for release until all requirements of the Egyptian Drug Authority have been fulfilled.

In the case of dealing with a new supplier of the active raw material, the finished product manufactured from the first three batches of the raw material shall not be marketed until a compliance and validity decision is received from the Central Administration of Pharmaceutical Control, and the requirements of the Variations Division are satisfied.

In the event of non-compliance reported by the company's laboratories for active and inactive raw materials, packaging materials, and finished products, the company is obligated to notify the Factories Inspection Division of the non-compliance reports issued by the company's laboratories within a maximum of 10 days from the issuance of the non-compliance. A pledge must be obtained binding the company to take all necessary measures for the destruction process within a maximum period of 90 days from the date of the non-compliance issuance. The destruction procedures specified in the Regulatory Guide of the Chairman of the Authority's Decree No. 146 of 2022 regarding the rules of the Rapid Alert, recall, and Prohibition System for Medical and Biological Products must be followed.

3. Procedures for the Sampling and Analysis of Cosmetic Products

First: Registration Phase:

Cosmetic products and pesticides shall be subject, regarding the withdrawal of samples for analysis at the Central Administration of Drug Control, to the procedures stipulated in the current regulations in force and the decisions issued by the Technical Committee for Drug Control and

the competent technical committees, unless otherwise explicitly provided for in this Decree.

Second: Post-Registration Phase:

1. The Inspection Division shall withdraw samples from the first production or imported batch and release them for each of the following cases:
    - Locally manufactured finished products.
    - Imported products and bulk from a non-reference country, after unsealing the contents of the shipment, and release shall be granted after the issuance of a compliance decision from the laboratories of the Egyptian Drug Authority.
    - Imported products and bulk from a reference country, or imported from a non-reference country but marketed in a reference country, after unpacking the contents of the shipment.
2. The random sampling plan shall apply to all products and products subject to the provisions of this Decree once they obtain three consecutive compliance results, except for the cases illustrated below:
    - **Local and Imported Cosmetics:** Samples for analysis shall be withdrawn from registered/listed products from the first production batch or the first consignment imported from reference countries, or the first modified batch according to the notification-then-amendment system (Tell & Do). They and all batches produced or imported within three months from the date of withdrawing the first sample are permitted to be marketed, provided that the factory or importing company submits to the Inspection Division proof of delivery of the samples to the laboratories of the Central Administration of Drug Control. This period may be extended for a similar duration once only, on condition that no other batch shall be released unless at least one compliance result is issued during the prescribed period. As for the first consignment imported from non-reference countries, marketing is not permitted until a compliant analysis result is issued.
    - **Pesticides and their local and imported raw materials:** Samples for analysis shall be withdrawn in accordance with the recommendations of the competent committee

for the importation of insecticides and their raw materials.

- **Inactive raw materials (Excipients):** Random sampling shall be applied. In the event of a non-compliance decision, random sampling shall be suspended, and three samples shall be drawn from three different batches from the same source.
- **Cosmetic raw materials:** Analysis samples shall be withdrawn from a batch of the first consignment imported by the factory, and then randomly from subsequent consignments. For cosmetic raw materials imported through raw material companies (brokers), final release shall be granted from the warehouse, and samples shall be drawn randomly from the factory for analysis.

3. Random sampling of the finished product shall be carried out taking into account the following criteria:

- The frequency of non-compliance reports issued for the same product or other products from the same factory or production line.
- The factory's compliance with the latest Current Good Manufacturing Practices (cGMP).
- The factory's compliance with the latest Current Good Laboratory Practices (cGLP).
- The compliance of the factory or importing companies with the latest Current Good Storage Practices (cGSP).
- Receipt of complaints that compromise the quality and safety of the product.
- Execution of a Sampling or voluntary sampling of the product due to a deviation in the production process or product quality.

Production batches withdrawn randomly shall not be allowed for release until all requirements of the Egyptian Drug Authority have been fulfilled. In the case of products imported from non-reference countries, the batch shall be released after the compliance decision is issued by the laboratories of the Egyptian Drug Authority.

In the event of non-compliance reported by the company's laboratories for active and inactive raw materials, packaging materials, and finished products, the company is obligated to notify the Factories Inspection Division of the non-compliance reports issued by the company's laboratories within a maximum of 10 days from the issuance of the non-compliance. A pledge must be obtained binding the company to take all necessary measures for the destruction process within a maximum

period of 90 days from the date of the non-compliance issuance. The destruction procedures specified in the Regulatory Guide of the Chairman of the Authority's Decree No. 146 of 2022 regarding the rules of the Rapid Alert, Recall, and Prohibition System for Medical and Biological Products must be followed.

4. Regarding the Procedures for the Sampling and Analysis of Biological Products

First: Registration Phase - Biological Products

Within the framework of registering new biological products, the system of withdrawing samples for evaluation shall be applied in accordance with the provisions of Decree No. 343 of 2021 regulating the registration of biological products, according to the following procedures:

- The Biological Products Registration Administration at the Central Administration of Biological and Innovative Products shall refer an official correspondence to the Biological Products Inspection Administration specifying the required number of samples necessary to perform the analysis.
- The Biological Products Inspection Administration shall undertake the withdrawal of the required samples in accordance with the approved standard operating procedures of the Central Administration of Inspection of Pharmaceutical Institutions.
- The sealed and stamped sample packages of the product under evaluation shall be delivered to the Registration Administration to complete the prescribed procedures.

Second: Post-Registration Phase - Biological Products

The follow-up of biological products post-registration shall be managed in accordance with the batch release policy stipulated in the Egyptian Drug Authority Chairman's Decree No. 425 of 2022. The sampling plan includes the following axes:

1. **Routine Sampling of Produced and Imported Batches:** It is based on the risk assessment of each product according to the approved batch release policy. This assessment leads either to suffices with reviewing the production or importation documents and verifying their

fulfilment, or to making a decision to withdraw samples for laboratory analysis.

2. **Sampling Mechanism for Analysis:** If a decision is issued to withdraw samples, reference shall be made to the Regulatory Guide issued pursuant to the Chairman of the Authority's Decree No. 425 of 2022 regarding the policy and rules for the release of biological products batches.
3. **Periodic Follow-up of Production inside Local Factories:** Inspectors of the Biological Products Inspection Administration shall conduct regular periodic visits to local factories to verify compliance with Good Manufacturing Practices requirements in accordance with international standards. The inspector has the right to withdraw random samples and refer them to the Batch Release Administration at the Central Administration of Biological Products, Innovative Products, and Clinical Studies to perform the necessary analysis, following prior coordination between the two concerned administrations.
4. **Periodic Follow-up of Warehouses and Importing Companies:** Imported finished biological products shall be subject to regular inspection visit by the inspectors of the Biological Products Inspection Administration in licensed warehouses, with the aim of confirming the application of Good Storage and Distribution Practices requirements and maintaining the required cold chain within the procedures of sampling or permitting the circulation of products. The inspector has the right to withdraw random samples of these products, whether before being placed on the market or after commercial circulation, whenever the need arises. Prior coordination shall be carried out between the Biological Products Inspection Administration and the Batch Release Administration to receive the samples and take the necessary actions according to jurisdiction.

- Regarding biological products, the produced or imported batches shall remain impounded (sequestered) and their marketing is prohibited until a clearance and circulation report is drafted by the Biological Products Inspection Administration.
- In the event of non-compliance reported by the company's laboratories for active and inactive raw materials, packaging materials, and finished products, the company is obligated to notify the Biological Product Inspection Administration of the non-compliance reports issued by the company's laboratories within a maximum of 10 days from the issuance of the non-compliance. A pledge must be obtained binding the company to take all necessary measures

for the destruction process within a maximum period of 90 days from the date of the non-compliance issuance. The destruction procedures specified in the Regulatory Guide of the Chairman of the Authority's Decree No. 146 of 2022 regarding the rules of the Rapid Alert, Recall, and Prohibition System for Medical and Biological Products must be followed.

- Regarding active raw materials, they shall remain impounded until the contents of the imported shipment are unpacked so that the factory can commence using them for production.
- In the event of the arrival of an unregistered biological product from non-reference countries in the following cases (emergencies, donations, shortages, and requests of entities and individuals), it shall be dealt with according to the Regulatory Guide for the Chairman of the Authority's Decree No. 444 of 2023.

5. Procedures for the Sampling and Analysis of Medical Devices and IVDs

First: Registration Phase for Imported / Local Medical Devices:

The Medical Devices Registration Division at the Central Administration of Medical Devices shall address the Inspection Division with a request to withdraw samples of the medical device submitted for registration or re-registration. The request shall be transferred to the competent unit (Imported Medical Devices Inspection Unit / Local Medical Devices Inspection Unit).

The inspector of the competent unit at the Inspection Division for Medical Devices and IVDs shall withdraw the required samples for analysis in the laboratories of the Central Administration of Drug Control, one of the faculties of engineering, or any entity deemed appropriate by the competent committee for analysis.

Upon receipt of the laboratories' decision by the Inspection Division for Medical Devices and IVDs, the Central Administration of Medical Devices shall be addressed according to the standard operating procedure (QP:QA.005.03.) attached with the original decision.

Second: Post-Registration Phase for Imported Medical Devices:

Sampling for imported medical devices shall be carried out taking into account the following criteria:

- Company History

- Manufacturer History
- Legal manufacturer / actual manufacturer
- Professional / non-Professional use
- Quality certificates obtained by the imported medical device
- Product History
- Effective Sampling system
- Warehouse compliance

Third: Post-Registration Phase for Local Medical Devices:

1. Sampling shall be conducted using the "Family System": meaning that a sample is drawn from one medical device, and the analysis result shall cover the remaining devices within the same family.
2. An identical duplicate sample (counter-sample) shall be drawn and remain at the factory throughout the shelf-life period of the device.
3. Sampling shall be conducted in the following cases:
   The first 3 production batches after the initial registration from 3 different sterilization cycles, while keeping the batches under impoundment until a compliance and validity decision is issued by the Central Administration of Drug Control, taking into account that the number of batches from which samples are drawn shall be reduced as follows:
   - In the event that the factory laboratory obtains ISO 17025 accreditation for all tests it performs on devices, sampling shall be drawn from the first batch produced after obtaining the notification without impoundment.
   - Sampling shall be conducted either from the first production batch after the new registration or the first two batches from two different sterilization cycles in case of factory compliance with the following (according to the compliance rating): (Good Manufacturing Practices rules - Laboratory - presence of process validation - tracking and market sampling system - quality certificates obtained by the factory - market history).
4. Batches on which a validation study was conducted after licensing the sterilization unit for the first time.
5. Random sampling from produced batches while keeping the batches under impoundment

until a compliance and validity decision is issued by the laboratories in certain cases. Samples shall be drawn from all existing batches, including but not limited to:

- Cases of deviation in cleanroom readings / monitoring of critical non-compliances in the cleanroom that affect production safety.
- Completion of the evaluation study for the sterilization room.
- Failure to follow Good Storage Practices conditions.
- Monitoring of violations in the factory laboratory that affect analysis results.
- Following the issuance of a non-compliance decision for one of the batches by the Central Administration of Pharmaceutical Control.

6. **Routine Sampling:** A random sampling performed according to the internal plan of the Administration.
7. Sampling based on the factory's request or a correspondence from another division, or in the case of a complaint received regarding the medical device after its marketing. In this case, the remaining batches shall not be impounded, and the factory shall supply the product without waiting for the analysis results, provided that a tracking system for the medical device is in place.

Fourth: Locally Manufactured IVDs:

1. IVDs Inspection Unit shall withdraw samples from the first production batches and release them upon the issuance of a compliance notification letter from the Central Administration of Drug Control.
2. Random sampling of locally finished IVDs shall be conducted taking into account the following criteria:

- The factory's compliance with the latest Current Good Manufacturing Practices (cGMP).
- The factory's compliance with the latest Current Good Laboratory Practices (cGLP).
- The factory's compliance with ISO 13485 quality systems.
- Receipt of complaints that compromise the quality and safety of the reagent.
- The frequency of non-compliance reports issued for the same laboratory reagent or another laboratory reagent from the same factory or production line.

- Execution of a sampling or voluntary sampling of the IVD due to a deviation in the production process or reagent quality.

Fifth: Imported IVDs:

In case registration has not been applied for:

Each item mentioned in the invoice released under impoundment shall be treated as a separate item.

In case registration has been applied for / Registered (Marketing Authorization issued):

The "Bundle System" shall be applied (all items submitted in the same marketing authorization are considered a single item) when implementing the random sampling decree, based on the files submitted for issuing the marketing registration license.
The Inspection Division shall withdraw samples from the first imported shipment of the IVD, provided that the rest of the shipment is impounded until a compliance notification letter is issued by the Central Administration of Drug Control. IVDs used in a closed system and IVDs with a short shelf life shall be exempted from impoundment.
Random sampling of imported IVDs shall be conducted under the Bundle System without impoundment after being included in the random sampling system, taking into account the following criteria:

- Compliance / Risk
- Company History
- Manufacturer History
- Product History
- Effective Sampling system
- Warehouse compliance

Part Three: Cases of Non-Compliance

First: Procedures Followed in Cases of Non-Compliance for Local and Imported Pharmaceutical Products, Cosmetics, Medical Devices, Laboratory Reagents, and Biological Products

1. In case the quantities have not been distributed (marketed):

- The non-compliant quantities shall be impounded in the company's warehouses by the inspector of the Central Administration of Inspection on Pharmaceutical Institutions. A pledge shall be taken binding the company to take all necessary measures for the destruction process within a maximum of 90 days from the date of the non-compliance issuance, provided that the destruction procedures specified in the Regulatory Guide of the Chairman of the Authority's Decree No. 146 of 2022 regarding the rules of the Rapid Alert, Recall, and Prohibition System for Medical and Biological Products are followed.
- The company is obligated to submit a comprehensive investigation into the root causes of the non-compliance within 10 working days, accompanied by a corrective action plan (CAPA) for those causes. In the case of biological products, these documents shall be uploaded to the electronic platform dedicated to the release of biological product batches for evaluation by the competent divisions and to make the final decision regarding them for evaluation by the Related administrations and to make the final decision regarding them.
- In the event of repeated non-compliance results for an imported biological product, reference shall be made to the Regulatory Guide for the Chairman of the Authority's Decree No. 343 of 2021.

2. In case the quantities have been distributed (marketed):

- A Detention and Seizure Order for the quantities shall be issued by the General Administration of Market Control, taking into account the classification of non-compliance and the Sampling class according to the severity of the defect, as provided for in the Chairman of the Authority's Decree No. 146 of 2022 regarding the rules of the Rapid Alert, Recall, and Prohibition System for Medical and Biological Products.

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- Samples for analysis shall be withdrawn from the first three incoming or produced batches after the issuance of the non-compliance decision for pharmaceutical products, cosmetics, medical devices, and IVDs.
- Each batch shall be released after the issuance of a compliant analysis result from the Central Administration of Pharmaceutical Control. No other batches of the product shall be released unless at least one batch out of the three sampled batches is found to be compliant.

6. References

1. Law on the Practice of the Pharmacy Profession No. (127) of 1955.
2. Egyptian Drug Authority Law No. (151) of 2019.
3. Presidential Decree No. (18) of 2024 forming the Board of Directors of the Egyptian Drug Authority.
4. Decree of the Chairman of the Authority No. (343) of 2021 regarding the adoption of rules for the registration of biological products.
5. Decree of the Chairman of the Authority No. (123) of 2022 regarding the listing and marketing of cosmetic products.
6. Decree of the Chairman of the Authority No. (461) of 2022 regarding the rules of the Rapid Alert, Recall, and Prohibition System for Medical and Biological Products.
7. Decree of the Chairman of the Authority No. (425) of 2023 regarding the adoption of the policy and rules for the release of biological product batches.
8. Decree of the Chairman of the Authority No. (783) of 2023 regarding the regulation of procedures for withdrawing and analysing samples of human medical products.
9. Decree of the Chairman of the Authority No. (444) of 2023 regarding the rules of procedures for importation and customs clearance of pharmaceutical products and raw materials.

7.List of amendments

Summary of Changes	Issue Date	Issue No.
Amending the Decree of the Chairman of the Authority No. 783 of 2022 and expanding the scope to include biological products and devices.	05/2026	03
Amending the code of the Regulatory Guide due to changing the name of the Central Administration from the "Central Administration of Operations" to the "Central Administration of Inspection on Pharmaceutical Institutions".		