Egyptian Drug Authority
Central Administration of Operation

General Administration for Factories Inspection

Notice to applicant.

Adoption of The Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practices guidelines

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The Egyptian Drug Authority (EDA), in accordance with the Law No. 151 of 2019 concerning the establishment and regulation of the Egyptian Drug Authority, announces the adoption of the **PIC/S GMP Guide Documents for Industry**

All PIC/S documents publically available are listed below

Gmp	Reference
PIC/S GMP Guide (PE 009-17) Introduction	PE 009-17 (Intro)
PIC/S GMP Guide (PE 009-17) Part I	PE 009-17 (Part I)
PIC/S GMP Guide (PE 009-17) Part II	PE 009-17 (Part II)
PIC/S GMP Guide (PE 009-17) Annexes	PE 009-17 (Annexes)

This decision emphasizes the EDA's commitment to upholding the highest standards of quality and safety for pharmaceutical products manufactured in Egypt.
The Good Manufacturing Practices (GMP) outlined in these documents provides essential guidance for ensuring the quality, safety, and efficacy of human, herbal, veterinary, and disinfectant products.

Manufacturers are expected to:

- Follow and comply with the guidelines set forth by the PIC/S for GMP Guide.
- These guidelines align with internationally recognized texts and represent best practices for ensuring product quality.
- Adopt acceptable and appropriate international standards within their facilities and operations.
- Validate any departure from recommended practices to demonstrate equivalence or better standards are achieved.

The EDA will closely monitor compliance with these guidelines during factory inspections. Manufacturers are encouraged to familiarize themselves with the updated GMP and take necessary steps to ensure their operations adhere to these standards.

Contact information:

For further information or clarification, please contact:

General Administration for Factories Inspection
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