

Arab Republic of Egypt Egyptian Drug Authority C.A. of Operations



جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للعمليات

0015258

CERTIFICATE OF GMP COMPLIANCE

Certificate Number: P-150/2024

Part 1:

EDA confirms the following:

Name of Manufacturing Site: ATCO Pharma for Pharmaceutical Industries.

Address of Manufacturing Site: Parts no. 1 - third Phase-Mubarak industrial zone-Quisna-Elmenofiya. Operation License Number: 112020090200002.

Purpose of the certificate: for Central Administration for Pharmaceutical Products-(EDA).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted in **09/2023**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice according to WHO guidelines and/or other approved international guidelines for the pharmaceutical dosage forms, categories and/or activities listed in the part 2.

Part 2:

Production Lines Human /Veterinary Products 1. Non sterile products 1.1 Solid dosage form including: (powder to be packed in sachets & cans - Hard gelatin capsule to be packed in jars -hard gelatin capsules packed in bisters ---tablets' film coated-sugar coated' added on 27/5/2015) - bilayer tablets was added on 22/3/2021 1.2 Liquid dosage form includes (syrup - suspension). 1.3 Veterinary β-lactam "pencillin" was added on 22/3/2021. Veterinary powder (sachet" AL-AL" Poly ethylene pack in cans 2. Packaging 2.1 Primary packaging & Secondary packaging for all products.

- The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.
- This certificate reflects the status of the manufacturing site at the time of the inspection noted above and the period of validity may be reduced or extended using regularity risk management principle by an entry in the Restrictions or Clarifying remarks field.
- The certificate remains valid until <u>28/02/2025</u> it becomes invalid if the activities and/or categories certified here with are changed or if the site is no longer considered to be in compliance with GMP.

Dr. Amal Adel

on behalf of Dr. Nermine Mohan

Manager of

Administration of inspection of pharmaceutical factories for human, Herbal, Veterinary and Disinfector

Authenticated,

Dr. Amira Mahgoub

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Follow up Affairs

Issue Date of certificate: 04/03/2024

The authenticity of this certificate can be verified via scanning the QR-Code at the upper right corner

0 (CPG) 0 CAO.037.01

Issue/Rev.No:3/0

Issue date:12/11/2023

Rev. Date: .../ J...

جمع البصدارات المؤمنة والذكية - ASPS



WE ARE PLEASURE TO ANNOUNCE THE MANAGEMENT SYSTEM OF



ATCO PHARMA FOR PHARMACEUTICAL INDUSTRIES

Main Site: Quesna Industrial Zone, Quesna, El-Monofya, Egypt

Has Successfully Implemented In Their Unit

5S WORKPLACE MANAGEMENT SYSTEM

Audit Was Performed and its Was Found That All The Requirements

Are Fulfilled For the following Scope

Design, Manufacturing, Sales and Marketing of Pharmaceutical & Veterinary Products

Accreditation Number.: UK12085 Registration Date.: 14/12/2023

1ST Survillance Audit.: 13/12/2024 2ND Survillance Audit.: 13/12/2025

Recertificate Date .: 15/12/2026





This Certificate is The Property Of

ISO CERT INTERNATIONAL LTD

Kemp House, 160 City Road, London, United Kingdom, EC1V 2NX Web :- www.iso-certs.co.uk

E-mail :- info@iso-certs.co.uk Phone:- +44-7831-205918

Company Registered in United Kingdom with Company Number 13294434







CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ATCO PHARMA FOR PHARMACEUTICAL INDUSTRIES

Main Site: Quesna Industrial Zone, Quesna, El-Monofya, Egypt has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Design, manufacturing, sales and marketing of pharmaceutical & veterinary products Certificate Number: 0094402

Initial Certification Date: 26 July 2013

Last Certificate Expiry Date:

25 July 2022

Date of Last Recertification Audit:

22 August 2022

Certification Cycle Start Date:

07 November 2022

Issuing Date:

07 November 2022

Valid Until: 25 July 2025









Calin Moldovean President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 82F, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.









CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ATCO PHARMA FOR PHARMACEUTICAL INDUSTRIES

Main Site: Quesna Industrial Zone, Quesna, El-Monofya, Egypt has been registered by Intertek as conforming to the requirements of:

ISO 14001:2015

The management system is applicable to:

Design, manufacturing, sales and marketing of pharmaceutical & veterinary products

Certificate Number: 0094404

Initial Certification Date: 26 July 2013

Last Certificate Expiry Date:

25 July 2022

Date of Last Recertification Audit:

22 August 2022

Certification Cycle Start Date:

07 November 2022

Issuing Date:

07 November 2022

Valid Until:

25 July 2025







Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 82F, United Kingdom

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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ATCO PHARMA FOR PHARMACEUTICAL INDUSTRIES

Main Site: Quesna Industrial Zone, Quesna, El-Monofya, Egypt has been registered by Intertek as conforming to the requirements of:

ISO 45001:2018

The management system is applicable to:

Design, manufacturing, sales and marketing of pharmaceutical & veterinary products

Certificate Number: 0094405

Initial Certification Date: 26 July 2013

Last Certificate Expiry Date:

25 July 2022

Date of Last Recertification Audit:

22 August 2022

Certification Cycle Start Date:

07 November 2022

Issuing Date:

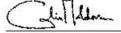
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