

P5-447-3/DC/IR/1

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Tel. direct: +41 22 791 22 46 Dr Amira Nasr Eldin

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Email: prequalinspection@who.int Company (EIPICO)

Industrial Area B1 PO Box 149

10th of Ramadan city

République arabe d'Égypte

In reply please refer to:

Your reference:

9 October 2023

Dear Dr Nasr Eldin,

WHO Prequalification Unit – Inspection Services Closing of Inspection: Egyptian International Pharmaceutical Industries Company (EIPICO)

I refer to the inspection that was performed by the World Health Organization (WHO) Prequalification Unit (PQT) Inspection Services Team (INS) and specifically Dr D. Catsoulacos and Dr M. Kladi the details of which are outlined below:

Name: Egyptian International Pharmaceutical Industries Company (EIPICO). Address: Industrial Area B1 PO Box 149, 10th of Ramadan city, Egypt

Date: 16 -19 January 2023

Thank you for your email correspondence dated 16 April, 8 May, 19 July and 13 September 2023, and the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by INS.

In general, they are acceptable. Therefore, considering these responses, as well as the findings of the inspection, INS has recommended that the site can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) published by WHO for the scope activities listed below:

• Manufacture, packaging, and quality control of small- volume aseptically- processed sterile products.

The inspection findings and your response allow INS to recommend to the Prequalification Assessment Team that the site inspected may continue to be named *as* a manufacturing site in the dossier for the following product(s):

PQT Number	Product	Strength	Dosage Form	Applicant
HA479	Ceftriaxone sodium	1g	powder for solution for injection	EIPICO
HA480	Ceftriaxone sodium	500mg	powder for solution for injection	EIPICO

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Mr Deus Mubangizi

Unit Head

Prequalification Unit

Acting Team Lead, Inspection Services Regulation and Prequalification Department Access to Medicines and Health Products Division