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In reply please
refer to: P5-447-3/XC/1

Your reference:

Dr. Magda Ibrahim
Global Quality General Manager,
Egyptian International Pharmaceutical Industries
Company (EIPICO), 10th of Ramadan City
Industrial Area B1
P.O. Box 149 - 10th
Egypte

20 December 2019

Dear Dr Ibrahim,

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

I refer to the inspection that was performed by Ms. Xingyu Chen and Mr. Mr. Ian Richard Thrussell the details of which are outlined below:

Site name: Egyptian International Pharmaceutical Industries Company (EIPICO)
Block: Cephalosporin Block (Perry II, IMA I)
Address: Tenth of Ramadan City, Industrial Area B1, Egypt
Date: 6 – 9 May 2019

Thank you for your letter dated 24 November 2019 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 the Prequalification Inspection Group.

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

- Manufacture and packaging of aseptically filled powder for solution for injection in the Cephalosporin Block

The inspection findings and your response allow Prequalification Inspection Group to recommend to the Prequalification Assessment Group that the site inspected may continue to be named as a manufacturing site in the dossier for the following products:

<i>PQT Number</i>	<i>Product</i>	<i>Strength</i>	<i>Dosage Form</i>	<i>Applicant</i>
HA479	Ceftriaxone Sodium	500mg	Powder for solution for injection	EIPICO
HA480	Ceftriaxone Sodium	1g	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,



Dr Joey Gouws
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies