

Arab Republic of Egypt

Egyptian Drug Authority

Central Administration of Operations
Factories of pharmaceutical, herbal
And veterinary preparations and
disinfectants



جمهورية مصر العربية

هيئة الدواء المصرية

الإدارة المركزية للعمليات

مصانع المستحضرات الصيدلانية والعشبية

والبيطرية والمطهرات

Certificate of Good Manufacturing Practices

This certificate conforms to the format recommended by the World Health Organization

- 1. Purpose of this certificate:** To be introduced to Ministry of Health of Bolivia for the purpose of Registration.
- 2. Certificate No.:** 287/2021
- 3. Name and address of site:** Egypt Otsuka Pharmaceutical Co., S.A.E. (10th of Ramadan City industrial zone 53 - part no 5,6)
 - On the basis of the inspection carried out on 2019 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in the Table 1 below
- 4. Manufacturer's license number:** 1-20190-130-020 (License issued from Industrial Development Authority)
- 5. Table 1:**

| Dosage form(s) | Category(ies) | Activities carried out by the company |
|--|--------------------------|---------------------------------------|
| I.V. Solution large volume and small volumes - Tablets | General Category(ies) | Production and Packaging |

- The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.
- This certificate remains valid until 18/5/2022 it becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Dr. Maram Abbas Sayed

Maram 1813
Deputy General Manager for
Pharmaceutical Factory Inspection



Dr. Yasin Ragaey

Yasin Ragaey
Head of Central Administration of Operations

Note: Not valid without stamp

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