7-5/2013/EU/WC-0241
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (HQ)
(International Cell)

FDA Bhawan, Kotla Road
New Delhi
Dated 07 OCT 2019

To,

M/s Halcyon Labs Ltd.
Plot No. 409, Phase – IV
GIDC Estate, Naroda
Ahmedabad – 382 330, India

Subject: Application to update the WC Certificate Number – Regarding

Sir

This is in reference to your letter No Nil dated 23.08.2019 and 24.09.2019 received vide e-office P-1475864 dated 28.08.2019 and P-1520837 dated 30.09.2019 on the subject cited above, wherein, it is requested to re-issue the WC Certificate with correct WC No.

In this regards, your request for re-issue of the WC Certificate with correct Number, i.e, WC-0241 has been considered and herewith the amended WC certificate is issued. The other conditions of WC Certificate remain same.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)
03-10-19

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **(Amended) WC-0241**

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Halcyon Labs Pvt. Ltd.,
Plot No.409, Phase – IV, GIDC Estate, Naroda,
Ahmedabad- 382 330, India

2. Manufacturer's licence number: G/1223 and G/896

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1 & 2

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 24.10.2018 and 25.10.2018

The Written Confirmation remains valid until: **Three (03) years from date of issue**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. V. G. Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

07 OCT 2019