

**7-5/2015/EU/WC-0336**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**International Cell**

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Dated:

11 MAR 2022

To,

M/s. JPN Pharma Pvt. Ltd.,  
Plot No. T-108/109, MIDC, Tarapur,  
Boisar-401 506, Taluka: Palghar, Dst: Thane,  
Maharashtra State, India

**SUB:- Application for amendment of the Written Confirmation of M/s. JPN Pharma Pvt. Ltd., Plot No. T-108/109, MIDC, Tarapur, Boisar-401 506, Taluka: Palghar, Dst: Thane, Maharashtra State, India as per requirement of EU for import of 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 from India-Reg.**

Sir,

Please refer to your email dated 08.2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended certificate. The condition of the Written Confirmation as required 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 from India will remain same.

Please acknowledge the receipt.

Yours faithfully,



(Dr. V. G. Somani)  
Drugs Controller General (India)



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. JPN Pharma Pvt. Ltd.,  
Plot No. T-108/109, MIDC, Tarapur,  
Boisar-401 506, Taluka: Palghar, Dst: Thane,  
Maharashtra State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Eosin Y Disodium Salt FP	Manufacturing & Packing

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 16.12.2024

Signature

Stamp of the authority and date



11 MAR 2022