

मुख्यालय, कर्मचारी राज्य बीला लिगम HEADQUARTERS, EMPLOYEES' STATE INSURANCE CORPORATION एं उदीप भवन, सी.आई.जी. मार्ग, नई दिल्ली-110002 PANCHDEEP BHAWAN: C.I.G. ROAD: NEW DELHI – 110 002 TelFax: 011-23234334, E-mail: <u>dmc-rc@esic.nic.in</u>



No. U-25/12/NSQ-143/2020 - Med. V / 335

Dated: 04.10.2021

To,

Director (Medical) Delhi /Director (Medical) Noida Deans/Medical Superintendents - All ESIC Medical College/Hospitals. Directors, ESI Schemes - All states

## Sub:Suspension of Product License to manufacture of Tab. Canditral 100 – reg.Ref.:ESIC, HQ Letter No. U 25/12/NSQ-143/2020-Med V dated 20.11.2020

Sir/Madam,

It is hereby informed that the Drug as detailed below has been declared "Not of Standard Quality" vide ESIC letter No. U-25/12/NSQ-143/2020-Med V dated 20.11.2020, further direction in respect of the caid item is as under:

| NSQ<br>Reported by   | Name of the<br>Firm   | Item Name/<br>Brand Name                                | RC No/<br>Item No/<br>Page No | Action taken by State Drugs<br>Controllier, Controlling cum<br>Licensing Authority, Baddi  | Instructions   |
|--|---|---|-------------------------------|--|--|
| State Drugs<br>Controller,<br>Controlling cum<br>Licensing<br>Auhtority,<br>Baddi, Distt.<br>Solan,<br>H.P173205 | M/s Glenmark<br>Pharmaceuticals<br>Limited,<br>Village<br>Kishanpura,<br>Baddi-<br>Nalagarh Road,<br>Distt. Solan,<br>H.P173205 | Itraconazole<br>Capsules B.P.<br>100mg<br>Canditral 100 | 145<br>1462<br>10 of 18       | Product License to manufacture for<br>sale and distribution suspended<br>for Tab Canditral 100 (Itraconazole<br>Capsules B.P. 100mg) under<br>Generic name or any brand name<br>under manufacturing Drugs License<br>no. MNB/05/182 & MB/05/226 of<br>this product for 15 days<br>commencing from 23.08.2021 to<br>06.09.2021. | No supply of<br>Itraconazole<br>Capsules B.P.<br>100mg (Tab<br>Canditral 100mg) to<br>be received with<br>date of<br>manufacturing<br>from 23.08.2021 to<br>06.09.2021 |

In above context, if received, it is directed to process the same as per Clause for Testing of Drugs-Quality Control.

This issues with the approval of Medical Commissioner (Procurement).

## Yours faithfully,

Assistant Director (RC)

## Copy for information to: -

- 1. The Central Drugs Star, Jard Control Organization, DGHS, FDA Bhavan, ITO, Kotla Road-110002 (dci@nic.in)
- State Drug Controller, Controlling cum Licensing Auhtority, Baddi, Himachal Pradesh 173205 (sdc4hp@gmail.com)
- Food and Drug Administration, Survey No. 341, 2nd Floor, Bandra Kurla Complex, Opposite Reserve Bank of India, Kala Nagar, Bandra East, Mumbai, Maharashtra 400051 (winogmp.mahafda@gmail.com)
- 4. M/s Glenmark Pharmaceuticals Limited, Glenmark House, B D Sawant Marg, Chakala, Andheri (East) Mumbai, Maharashtra-400099, <u>shantaram.patil2@glenmarkpharma.com</u>
- M/s Glenmark Pharmaceuticals Ltd. situated at Vill. Kishanpura, Baddi-Nalagarh Road, Distt. Solan, H.P. -173205
- 6. WCM with request for uploading on ESIC website.

7. Guard file

Assistant Director (RC)