No. U-25/12/NSQ/2021 - Med. V

Dated: 11.05.2021

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


Sir/Madam,

It is hereby informed that the Drug as detailed below has been reported as "Not of Standard Quality", you are directed to stop use of the batch of the following item immediately which has been reported as "Not of Standard Quality": (copy enclosed)

<table>
<thead>
<tr>
<th>NSQ Reported by</th>
<th>Name of the Firm</th>
<th>Item Name/ Brand Name</th>
<th>RC No/ Item No/ Page No</th>
<th>Batch No./ DOM/ DOE</th>
<th>Report No &amp; date</th>
<th>Name of the Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>8</td>
<td>12.2018</td>
<td>Dt.- 04.03.2021</td>
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<td></td>
<td></td>
<td></td>
<td>3</td>
<td>11.2021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It is also directed that action may be taken as per clause no. 17, for "Testing of Drugs Quality Control" of Terms & Conditions of DG-ESIC RC. Replacement of supplies or cost of the material is to be recovered along with testing charges, if any, from the firm.

Action taken is to be intimated to this office.

This issues with the approval of Medical Commissioner.

Yours faithfully,

(Jai Singh)
Assistant Director (RC)

Copy for information to:
1. The State Drug Controller, Food & Drug Administration, Palace Rd, Near Karnataka Public Service Commission, Racecourse, Gandhi Nagar, Bengaluru, Karnataka 560001 with the request to take appropriate action on 'NSQ' reported for the above said batch under intimation to this office. (Copy of Test Report enclosed)
2. The State Drug Controller, Food and Drug Administration, Survey No. 341, 2nd Floor, Bandra Kurla Complex, Opposite Reserve Bank of India, Kala Nagar, Bandra East, Mumbai, Maharashtra 400051 with the request to take appropriate action on 'NSQ' reported for the above said batch under intimation to this office. (Copy of Test Report enclosed)
3. M/s Wallace Pharmaceuticals Pvt. Ltd., B 307-312, Floral Deck, Plaza, Off Central MIDC Road, Andheri (East), Mumbai, Maharashtra-400093
4. Sh. Pranaya Kumar, Dy. Director (PR), Hqrs. e-mail pranaya.kumar@esic.nic.in with request for uploading on ESIC website
5. Rajbhasha Shakha for translation.
6. Guard file

Assistant Director (RC)
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST
(Under section 25 (1) of the Drugs & Cosmetic Act. 1940)

Name of Inspector from whom received.  
Shri. Lokesh Gupta
D.I. Indore

Serial No. and date of Inspectors Memorandum.  
D/LG/IND/20/21/07
dt: 30.07.2020

Number of sample.  
$64

Date of receipt.  
04.08.2020

Name of drug purporting to be contained in the sample.  
Meclopramide Tablets I.P.
Maxaron Tablets

Mfg. by Wallace Pharmaceuticals Pvt. Ltd.,  
Plot No. 231P-240P,
K.I. A.D.B. Belur Ind. Area, Belur
Dharwad, Karnataka 580 011

Condition seals on the package.  
Intact & Identical with the specimen

Result of test or analysis with protocol of Test or analysis applied.  
Is given below

In the opinion of the undersigned the sample referred to above is not of standard quality as defined in the Drugs & Cosmetics Act. 1940 and rules there under for the reason given below.

Reason: The sample fails to comply in respect of description (Out of 100 tablets 27 tablets found in broken condition).

Requirement: Tablet should be sufficiently hard to withstand handling with out cracking.

Contd -2
Mfg. Date No.  Mfg date  Expiry Date.

Container: Ten tablets contained in strip. Such ten strips are received.

Formula: Each uncoated tablet contains
         Metoclopramide Hydrochloride IP.
         Eq. to anhydrous Metoclopramide Hydrochloride IP. -- 10 mg

Description: White flat beveled edged tablets having a bifurcating line on one side.
Out of 100 tablets 27 tablets found in broken condition while taking out from the strip.
(Requirement: Tablets should be sufficiently hard to withstand handling without cracking.)

Average Weight: 126.30 mg

Identification: Gives test for Metoclopramide hydrochloride

Assay

<table>
<thead>
<tr>
<th>Metoclopramide Hydrochloride Calculated as anhydrous</th>
<th>10.001 mg</th>
<th>10 mg</th>
<th>100.10%</th>
<th>90.0% to 110.0%</th>
</tr>
</thead>
</table>

Signature: A.B. Atre

Government Analyst
Drugs Testing Laboratory
Food & Drugs Administration
Bhopal