

# FOOD & DRUGS CONTROL ADMINISTRATION, GUJARAT STATE CERTIFICATE OF A PHARMACEUTICAL PRODUCT<sup>1</sup>

This certificate conforms to the format recommended by the World Health Organization  
(General instructions and explanatory notes attached)

VALID UP TO: 08.08.2019

No. of Certificate  
Exporting (certifying) country  
Importing (requesting) country

MFGMWHO-COPPMWOCKHARDT/2018/  
INDIA  
MOLDOVA

1 Name and dosage form of product

Metamizole Sodium, Pirofenone Hydrochloride and Fenpiverinium Bromide  
Injection 5ml Ampoule

1.1 Active ingredient<sup>2</sup> (s) and  
Amount (s) per unit dose<sup>3</sup>

Each ml contains:  
Metamizole Sodium 500mg  
Pirofenone Hydrochloride 2.0 mg  
Fenpiverinium Bromide 0.02mg  
Water for Injections q.s. to 1 ml.

For complete qualitative composition including excipients, see attached<sup>4</sup>. N.A.

1.2 Is this product licensed to be placed on the market for use in the exporting country?<sup>5</sup> Yes ☐ No ☒  
1.3 Is this product actually on the market in the exporting country? Yes ☐ No ☒ Unknown ☐

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.  
If the answer to 1.2 is no, omit section 2A and continue with section 2B<sup>6</sup>.

|  |  |  |
|--|--|--|
| 2A.1 No. of product license  | : NA   | 2B.1 Applicant for certificate<br>(name and address) : Wockhardt Limited<br>At: Zen Pharma (P) Ltd.,<br>75/1, G.I.D.C., VAPL-396 195,<br>Gujarat, India.   |
| A.1 And date of issue  | : NA   | B.2 Status of applicant:<br>a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>  |
| A.2 Product License holder   | : NA   | B.2.1 For categories b and c the name<br>and address of the Manufacturer<br>producing the dosage form are  |
| A.3 Status of Product-license <sup>8</sup><br>Holder   | : a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>   | B.3 Why is marketing authorization<br>lacking?<br>Not <input type="checkbox"/> Not <input type="checkbox"/> Under <input type="checkbox"/><br>Required Requested consideration<br>Refused <input type="checkbox"/> |
| A.3.1 For categories b and c,<br>The name and address of the<br>Manufacturer producing the<br>Dosage form are <sup>9</sup>   | : Yes <input type="checkbox"/> No <input type="checkbox"/><br>: Yes <input type="checkbox"/> No <input type="checkbox"/> Not provided <input type="checkbox"/> | B.4 Remark <sup>13</sup><br>No. of product license: G/28A/4612-A<br>and Date of issue: 14/11/2017  |
| A.4 Is summary Basis of<br>Approval appended? <sup>10</sup>  | : Yes <input type="checkbox"/> No <input type="checkbox"/>   |  |
| A.5 Is the attached, officially  | : Yes <input type="checkbox"/> No <input type="checkbox"/>   |  |
| A.6 Approved product information copy of this document/CERTIFICATE<br>Complete and consent with the<br>Licensee <sup>11</sup> has been recorded with the Chamber<br>Applicant for certificate if<br>different from License holder <sup>12</sup> : N.A. |  |  |
| Authorized Signatory<br>Bombei Chamber of Commerce and Industry<br>Regn. No. 38316 Date: 27 MAR 2018<br>MR. SAMIR PAUL PINTO   |  |  |

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced

☒ Yes ☐ No ☐ Not

If no or not applicable, proceed to question 4

3.1 Periodicity of routine inspection (years)

Once in a year

3.2 Has the manufacture of this type of dosage form been inspected?

☒ Yes ☐ No

3.3 Do the facilities and operations confirm to GMP as recommended  
by the World Health Organization<sup>15</sup>?

☒ Yes ☐ No ☐ Not applicable

4. Does the information submitted by the applicant satisfy the certifying  
authority on all aspects of the manufacture of the product?<sup>16</sup>

☐ Yes ☐ No ☒ Not applicable

If no, explain:

Address of Certifying Authority  
Food & Drugs Control Administration  
1<sup>st</sup> Floor, 8<sup>th</sup> Block, Old Sachi Kalaya,  
Gandhinagar, Gujarat, INDIA

Name of the authorized person: Mr. R. L. VAISHYA

Signature

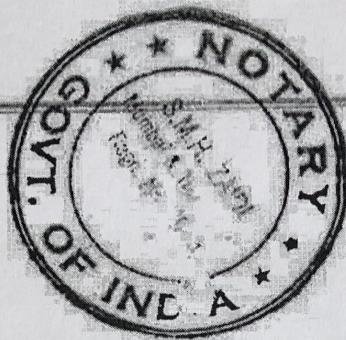
Stamp and Date : Joint Commissioner

Food and Drugs Control Administration  
Gandhinagar, Gujarat State, India

Tel. No. : (079) 23253399  
Fax No. : (079) 23253417

5 JAN 2018





Office of The Commissioner,  
Food & Drugs Administration, M.S.  
Bandra - Kurla Complex,  
Bandra (E),  
Mumbai - 400 051

Date: 24/4/2017

### CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.  
(General instructions and explanatory notes attached).

Certificate No.: NEW-WHO-GMP/CERT/AD/53624/2017/11/19044

On the basis of the inspection carried out on 23/01/2017, 24/01/2017 and 13/04/2017, we certify that the site indicated on this Certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : WOCKHARDT LIMITED  
Address : H-14/2, MIDC, WALUJ, AURANGABAD 431136  
MAHARASHTRA STATE, INDIA
2. Licence No. : AD068 In Form 25,  
AD052 In Form 28

Table 1

| Sr.No. | Dosage Form(s)  | Category(ies)  | Activity(ies)   |
|--------|---|--|---|
| 1      | Capsules  | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 2      | Injectables / SVP / Eye Drops / Ophthalmic Preparations | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 3      | Tablets   | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

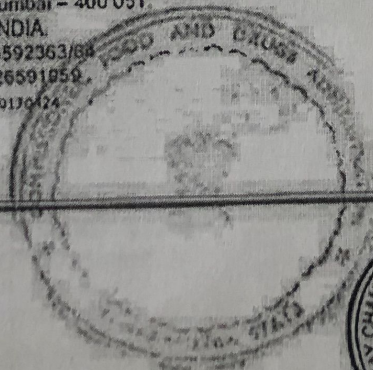
This certificate remains valid until 23 Apr 2019. It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :  
Food & Drug Administration, M.S.  
Bandra-kurla Complex,  
Bandra (E), Mumbai - 400 051,  
Maharashtra, INDIA.  
Tel: +91-22-26592363/64  
Fax: +91-22-26591059  
170142645362420170424

Name of the Authorised person : O S SADHWANI

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling  
Authority  
Food & Drug Administration, M.S.  
Bandra (E), Mumbai  
Maharashtra State, India  
Date: 24 Apr 2017



A copy of this document/CERTIFICATE  
has been recorded with the Chamber

Authorised Signatory  
Bombay Chamber of Commerce and Industry