Moldova

FOOD & DRUGS CONTROL ADMINISTRATION, GUJARAT STATE
CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

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 : MFG/WHO-COPP/WOCKHARDT/2018/
Exporting (certifying) country : INDIA
Importing (requesting) country : MOLDOVA

1. Name and dosage form of product : Metamizole Sodium, Pitofenone Hydrochloride and Fenpiverinium Bromide Injection 5ml Ampoule
SPASGAN INJECTION 5 ML.

1.1 Active ingredient[2](s) and Amount (s) per unit dose[3] : Each ml contains

Metamizole Sodium	500mg
Pitofenone Hydrochloride	2.0 mg
Fenpiverinium Bromide	0.02mg
Water for Injections	q.s. to 1 ml.

For complete qualitative composition including excipients, see attached[4]: N.A.

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] 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[6].

2A.

A.1 No. of product license And date of issue : NA NA
A.2 Product License holder : NA
A.3 Status of Product-licence[8] Holder : a ☐ b ☐ c ☐
A.3.1 For categories b and c, The name and address of the Manufacturer producing the Dosage form are[9] :
A.4 Is summary Basis of Approval appended?[10] : Yes ☐ No ☐
A.5 Is the attached, officially Approved product information Complete and consonant with the License?[11] : Yes ☐ No ☐ Not provided ☐
A.6 Applicant for certificate if Different from License holder[12] : N. A.

Copy of this document/CERTIFICATE has been recorded with the Chamber
Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 38316 Date 27 MAR 2018

2B

B.1 Applicant for certificate (name and address) : **Wockhardt Limited**
At.: Zen Pharma (P) Ltd.,
75/1, G.I.D.C., VAPI-396 195.
Gujarat, India.

B.2 Status of applicant: a ☒ b ☐ c ☐

B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are

B.3 Why is marketing authorization lacking? Not Required ☐ Not Requested ☐ Under consideration ☐ Refused ☐

B.4 Remark[13] :
No. of product license: **G/28A/4612-A**
and Date of Issue: **14/11/2017**

3. Does the certifying authority arrange for periodic inspection of the applicable[14] manufacturing plant in which the dosage form is produced : ☒ Yes ☐ No ☐ Not
If no or not applicable, proceed to question 4

MR. SAMIR PAUL PINTO
ASSISTANT TRADER

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[15] ? : ☒ 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 ?[16] : ☐ Yes ☐ No ☒ Not applicable

If no, explain:

Address of Certifying Authority:
Food & Drugs Control Administration
1st Floor, 8th Block, Old Sachivalaya,
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

05 JAN 2018

Digitally signed by Margină Veaceslav
Date: 2019.03.18 21:36:57 EET
Reason: MoldSign Signature
Location: Moldova

NOTARY GOVT. OF INDIA

FDA MAHARASHTRA

NOTARY GOVT. OF INDIA

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)	Categor(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. +91-22-26592363/68
Fax: +91-22-26591952
ICDW264536242017042A

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

FOOD AND DRUGS ADMINISTRATION

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★1836★

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

Authorised Signatory
Bombay Chamber of Commerce and Industry