

No. CERTI/ARKRAY/Sc-3/2023/

53966-68
/B

The Commissioner of
Food and Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No. 8, 1st Floor,
GANDHINAGAR. - 382010

Date:

04 OCT 2023

To,
M/s. ARKRAY Healthcare Pvt. Ltd.,
Plot No. 336, 338, 340, Road No. 3,
G.I.D.C., SACHIN : 394 210, Dist. Surat

Sub: Drugs & Cosmetics Act 1940 and Rules thereunder.
Issue of Certificates.

Sirs,

Ref: Your letter AMI/FDA/15/2023-24/

dated 04.10.2023

I send herewith Certificate of a Pharmaceutical Product as desired by you.

Yours faithfully,


For Commissioner
Food and Drugs Control Administration

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

No. of Certificate: MFG/COPP/ARKRAY/2023/

053967

Exporting (Certifying) Country: **INDIA**

Importing (requesting) Country: **KAZAKHSTAN, MONGOLIA, CHILE, COLUMBIA, EGYPT, IRAN, KENYA, MALAYSIA, MOLDOVA, PERU**

1. Name and dosage form of products: Tuberculin Diluted: Tuberculin P.P.D. 5 TU/0.1 ml for Mantoux Test Only

1.1 Active ingredient (s) and amount (s) per unit dose :

Active Ingredient : Tuberculin PPD


Amount per unit : 5 Tuberculin units per 0.1 ML dose (1ML, 2ML and 5 ML)

Complete qualitative composition including excipients, N.A.

1.2 Is this product licensed to be placed on the market for use in the exporting country? Yes ☒ No ☐

1.3 Is this product actually on the market in the exporting country ? Yes ☒ No ☐

If the answer to 1.2 is yes., continue with section 2 A and If the answer to 1.2 is no. continue section 2 B

2A.1 Number of product license : Manufacturing Lic. No. G/28/1507 Dtd. 26.02.2015.	2B.1 Applicant for certificate (name and address) NA
2A.2 Product license holder : M/s. ARKRAY HEALTHCARE PVT. LTD. Plot No. 336, 338, 340, Road No. 3 G.I.D.C. Sachin Dist.: Surat - 394230 Gujarat State, INDIA	2B. 2 Status of applicant : N.A. a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> d <input type="checkbox"/> 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form :
2A.3 Status of product – license Holder : Manufacturer of the dosage form a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>	2B.3 Why is marketing authorization lacking? N.A. Not <input type="checkbox"/> Not <input type="checkbox"/> Under <input type="checkbox"/> Refused <input type="checkbox"/> Required Requested Consideration
2A. 4 Is summary basis of Approval appended? N.A. Yes <input type="checkbox"/> No <input type="checkbox"/>	2B. 4 Remarks : N.A.
2A.5 Is the attached officially approved product information complete and consonant with the license ? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not Provided <input type="checkbox"/>	
2A. 6 Applicant for certificate if different from license holder : Licence Holder is same as Applicant	

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

Yes ☒ No ☐ Not applicable ☐

If no or not applicable proceed to question 4

3.1 Periodically of routine inspections (Years) : **Annually (Once in a year)**

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?

Yes ☐ No ☐ Not applicable ☒

If no, explain:

This Certificate valid up to **2 Years from Date of Issue**

Address of certifying authority :

Name of the Authorized Person : **Mrs. B. N. Vyas**

The Commissioner Food & Drug Control Administration

1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA

Tel: 91-79-232 53417 Fax: 91-79-232 53400

Date of Approval:

Signature:

Stamp and date:

Asst. Commissioner

Food & Drugs Controls Administration
Gujarat State

4 OCT 2023

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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053968

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<p>2A.2 Product license holder : M/s. ARKRAY HEALTHCARE PVT. LTD. Plot No. 336, 338, 340, Road No. 3 G.I.D.C. Sachin Dist.: Surat - 394230 Gujarat State, INDIA</p>	<p>2B. 2 Status of applicant : N.A. a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> d <input type="checkbox"/> 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form :</p>
<p>2A.3 Status of product - license Holder : Manufacturer of the dosage form a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/></p>	<p>2B.3 Why is marketing authorization lacking? N.A. Not <input type="checkbox"/> Not <input type="checkbox"/> Under <input type="checkbox"/> Refused <input type="checkbox"/> Required Requested Consideration</p>
<p>2A. 4 Is summary basis of Approval appended? N.A. Yes <input type="checkbox"/> No <input type="checkbox"/></p>	<p>2B. 4 Remarks : N.A.</p>
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