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 ☐ b ☐ c ☐ d ☐ 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 ☒ b ☐ c ☐	2B.3 Why is marketing authorization lacking? **N.A.** Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A. 4 Is summary basis of Approval appended? N.A. Yes ☐ No ☐	2B. 4 Remarks : **N.A.**
2A.5 Is the attached officially approved product information complete and consonant with the license ? Yes ☒ No ☐ Not Provided ☐	
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 :

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:

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

Signature:

Stamp and date:

Asst. Commissioner
Food & Drugs Controls Administration
Gujarat State

- 4 OCT 2023

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

No. of Certificate: MFG/COPP/ARKRAY/2022/ 053968

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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) **N.A.**
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 ☐ b ☐ c ☐ d ☐ 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 ☒ b ☐ c ☐	2B.3 Why is marketing authorization lacking? **N.A.** Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A. 4 Is summary basis of Approval appended? N.A. Yes ☐ No ☐	2B. 4 Remarks : **N.A.**
2A.5 Is the attached officially approved product information complete and consonant with the license ? Yes ☒ No ☐ Not Provided ☐	
2A. 6 Applicant for certificate if different from license holder **: Licence Holder is same as Applicant**	

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

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

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Yes ☐ No ☐ Not applicable ☒

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Tel: 91-79-232 53417 Fax: 91-79-232 53400
Date of Approval:

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

Signature:

Stamp and date:
Asst. Commissioner
Food & Drugs Controls Administration
Gujarat State
04 OCT 2023