CERTIFICATE OF A PHARMACEUTICAL PRODUCT

No. of Certificate: MFG/COPP/ARKRAY/2020/ 123474

Exporting (Certifying) Country: **INDIA**
Importing (requesting) Country: **CHILE, COLUMBIA, EGYPT, IRAN, KENYA, MALAYSIA, MOLDOVA, PERU, PHILIPPINES, UKRAINE, UZBEKISTAN**

1. Name and dosage form of products: Tuberculin Diluted: Tuberculin P.P.D. 2 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 : 2 Tuberculin units per 0.1 ML dose
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**	

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 Issue:

Digitally signed by Chirtoaca Iurie
Date: 2022.09.29 14:42:24 EEST
Reason: MoldSign Signature
Location: Moldova

Name of the Authorized Person : **Mr. H. L. Ravat**

Signature:

Stamp and date:

Deputy Commissioner
Food & Drugs Controls Administration
Gujarat State

2 DEC 2020