

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 <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 : **Mr. H. L. Ravat**

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:

(Handwritten Signature)

Stamp and date:

Deputy Commissioner
Food & Drugs Controls Administration
Gujarat State

2 DEC 2020