The Drug Licensing & Controlling Authority, Directorate of Health Services,
Danda Lakhond, Sahastradhara Road, Dehradun, Uttarakhand

File No. ---------- Date:

CERTIFICATE OF PHARMACEUTICAL PRODUCT [1]

This certificate conforms to the format recommended by the World Health Organization

No. of Certificate 17P/1/227/2007/13864 : WHO-GMP-CERT/ Valid Up to: 24/04/2019

Exporting (Certifying) country : INDIA

Importing (requesting) country : Albania, Andorra, Armenia, Azerbaijan, Algeria. Argentina, Australia, Austria, Bangladesh, Belize, Belgium, Bolivia, Bosnia and Herzegovina, Brazil, Bulgaria, Belarus, Canada, China, Chile, Colombia, Costa Rica, Croatia, Cyprus, Caribbean Islands, Czech Republic, Domingo, Dubai, Denmark, Ecuador, Egypt, Estonia, Finland, France, Germany, Georgia, Ghana, Greece, Guatemala, Hong-Kong, Honduras, Hungary, Indonesia, Iceland, Iran, Iraq, Israel, Ireland, Italy, Japan, Jordan. Korea, Kazakhstan. Kenya, Latvia. Lithuania, Liechtenstein, Luxembourg, Lebanon, Former Yugoslav, Republic of Macedonia, Malaysia, Malta. Mexico, Moldova, Monaco, Montenegro, Morocco, The Netherlands, Namibia, Nigeria, Nicaragua, Norway, Oman, Pakistan, Panama, Palestine, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Russia, San Marino, Serbia, Singapore, Slovenia, Slovakia, South Africa, South Korea, Spain, Saudi Arabia, Serbia, Montenegro, Sudan, Sweden, Switzerland, Syria, Taiwan, Tajikistan, Thailand, Turkey, Tunisia, Ukraine, UK, Uruguay, United Arab Emirates, Uzbekistan, USA, Vatican City Slate, Venezuela, Vietnam, Yemen, Cambodia, Afghanistan, Fiji, Myanmar, Mongolia, Nepal, Liberia, Ethiopia Tanzania, Libya, Mozambique Madagascar, Mauritius DR Congo, Angola, Botswana, Zimbabwe Zambia & Sri Lanka.

Name and dosage form of product : **Benzathine Benzyl Penicillin Injection 1.2 MIU BP**

1.1 Active ingredients(s)[2] and amount (s) /per unit dose[3] :

Each vial contains:
Benzathine Benzyl Penicillin BP..... 1200,000 Units

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[5]? ☑ Yes ☐ No ☐ Unknown

If the answer to 1.2 is yes, continue with section 2A and omit section2B.
If the answer to 1.2 is no, omit section 2A and continue with section 2B[6].

2A.

2A.1 Number of product license[7] and date of issue :
Mfg. License No.150/UA/SC/P-2007 Dated: 20/06/2014

2A.2 Product License holder (Name and Address) : M/S Maxmed Lifesciences Pvt. Ltd. Plot No. 54 Sector IIDC Sidcul Rudrapur

2A.3 Status of Product License Holder[8] a ☑ b ☐ c ☐

2A.3.1 For categories (b) and (c) the Name and address of the Manufacturer producing the dosage form is [9]: **N.A.**

2A.4. Is Summary Basis of Approval Appended[10]?
☐ Yes ☑ No

2A.5 Is the attached, officially approved product information complete and consonant with the license [11]? ☐ Yes ☐ No ☑ Not Provided.

2A.6 Applicant for certificate, if different from license holder (name and address) [12] : **N.A.**

2B.

2B.1 _____

2B.2 Status of applicant: ☐ a ☐ b ☐ c

2B.2.1 For categories (b) and (c) the name and address of manufacturer producing the dosage form is [9]?

2B.3 Why is marketing authorization lacking?
☐ Not Required ☐ Not Requested
☐ Under Consideration ☐ Refused

2B.4 Remarks[13] :

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced [14]?
☑ Yes ☐ No ☐ Not Applicable.

If No or Not applicable proceed to question 4

3.1 Periodicity of routine inspections (years): **Yearly**

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

3.3 Do the facilities and operations conform 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: **The Drug Licensing & Controlling Authority, Directorate of Health Services, Danda Lakhond Sahastradhara Road, Dehradun, Uttarakhand**

Telephone /Fax Number :

Name of authorized person : (Hemant Singh Negi) Drug Licensing Authority Sabhag, Kumaon Mandal Uttarakhand

Signature :

Stamp and Date : 13.12.17

Digitally signed by Gutan Ghenadie
Date: 2022.03.30 13:12:23 EEST
Reason: MoldSign Signature
Location: Moldova