

**Certificate of a Pharmaceutical Product<sup>1</sup>**  
This certificate conforms to the format recommended by the World Health Organization  
(General instructions and explanatory notes attached)

No. of Certificate : DD/376/453/2022/PER-I Valid up to: 28/11/2025  
Exporting (Certifying) Country : INDIA  
Importing (Requesting) Country : PERU  
1. Name and dosage form of product : Rifampicin Capsules BP 300mg

1.1 Active ingredient(s)<sup>2</sup> and amount(s) per unit dose<sup>3</sup>

Each capsule contains:  
Rifampicin BP..... 300mg

For complete qualitative composition including excipients, see attached <sup>4</sup>: As per annexure

1.2 Is this product licensed to be placed on the market for use in the exporting country?<sup>5</sup> Yes

1.3 Is this product actually on the market in the exporting country? Yes

If the answer to 1.2 is yes, continue with section 2A and omit section 2 B.

If the answer to 1.2 is no, omit section 2A and continue section 2B <sup>6</sup>.

2 A

2.A.1 Number of product license<sup>7</sup> and date of issue: DD/376 dated 18.08.2018

2.A.2 Product licence holder : **Macleods Pharmaceuticals Ltd.**  
Office : Atlanta Arcade, 3<sup>rd</sup> Floor, Marol Church Road,  
Near Leela Hotel, Andheri (East), Mumbai – 400 059  
Factory : Plot No. 25-27, Survey No. 366, Premier  
Industrial Estate, Kachigam, Daman –396210 (U.T.)

2.A.3 Status of product licence holder <sup>8</sup> :

Manufacturers the dosage forms

2.A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are<sup>9</sup>  
: Not applicable

2.A.4 Is summary basis of Approval appended?<sup>10</sup>  
: No

2.A.5 Is the attached, officially approved product information complete and consonant with the licence?<sup>11</sup>  
: Not provided

2.A.6 Applicant for certificate if different from licence holder:<sup>12</sup> : Not applicable.

2 B Not applicable.

2.B.1 Application for certificate:  
(Name and address)

2.B.2 Status of applicant

: Not applicable

2.B.2.1 For categories b and c the name and address of the Manufacturer producing the dosage form are<sup>9</sup>

: Not applicable

2. B.3 Why is marketing authorization lacking?<sup>13</sup>

: Not applicable

2.B.4 Remark : <sup>13</sup> --



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

3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization ?<sup>15</sup> Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?<sup>16</sup>  
Yes  
If no, explain.

Address of certifying authority:  
UT Administration of Dadra & Nagar Haveli and Daman & Diu,  
Assistant Drugs Controller & Licensing Authority,  
Drugs Control Department,  
Primary Health Centre,  
Moti Daman – 396 220.

Telephone Number : (0260) 2230470

Fax Number : (0260) 2230570

Name of the authorised person: (S. ASKER ALI) IAS

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY (I/c)

Signature:

सहायक औषधि नियंत्रक एवं अनुमति प्राप्तिकारी

Stamp and date:

DRUGS CONTROL DEPARTMENT

औषधि नियंत्रक विभाग  
U.T. OF DADRA & NAGAR HAVELI  
AND DAMAN & DIU

पंजीकृत न सारवा एवं कक्षा कोठी एवं चपक हर्बल वीज

19 AUG 2023

Qualitative and Quantitative Formula**Product** : Rifampicin Capsules BP 300 mg**Composition:** Each capsule contains:

Rifampicin BP.....300 mg

Sr. No.	Ingredients	Pharmacopoeial Grade	Rationale	Qty / Capsule (mg)
<b>Dry Mixing</b>				
1.	Microcrystalline Cellulose	BP	Capsule filler	16.66
<b>Binding</b>				
2.	Povidone (K-30)	BP	Binder	1.34
3.	Isopropyl alcohol #	BP	Solvent	8.66
<b>Pre- Lubrication</b>				
4.	Rifampicin (Compacted)**	BP	Medicament	300.00
5.	Starch	BP	Disintegrant	1.34
6.	Sodium Lauryl Sulphate	BP	Surfactant	3.34
7.	Purified Talc	BP	Glidant	3.34
<b>Lubrication</b>				
8.	Magnesium Stearate		Lubricant	6.66
<b>Total weight</b>				<b>332.68</b>
9.	Hard gelatin capsule of size "0" scarlet/scarlet coloured		Capsule shell	1(No.)

BP : British Pharmacopoeia;

IHS : In-house specifications;

# : Does not appear in the final product;

\*\* : Rifampicin Particle size : D10 : NMT 8 $\mu$ , D50 : 30 to 70 $\mu$ , D90 : NMT 185 $\mu$ **Address of certifying authority:**

UT Administration of Dadra &  
Nagar Haveli and Daman & Diu,  
Assistant Drugs Controller &  
Licensing Authority,  
Drugs Control Department,  
Primary Health Centre,  
Moti Daman - 396 220.

Telephone Number : (0260) 2230470

Fax Number : (0260) 2230570

Name of the authorised person: (S. ASKER ALI) IAS

Signature:

Stamp and date:

*ah*

ASSISTANT DRUGS CONTROLLER  
& LICENSING AUTHORITY (I/c)  
स्वास्थ्यक और चिकित्सा नियंत्रक एवं अनुज्ञापन प्राधिकारी  
DRUGS CONTROL DEPARTMENT  
औद्योगिक विभाग  
U.T. OF DADRA & NAGAR HAVELI  
AND DAMAN & DIU

संख्यप्रदेश दायरा एवं नगर हवेली एवं दमण एवं दीव

19 AUG 2023