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

Certificate of a Pharmaceutical Product[1]

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)[2] and amount(s) per unit dose[3]

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

For complete qualitative composition including excipients, see attached [4] : As per annexure

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5] 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 [6].

2 A

2.A.1 Number of product license[7] and date of issue: **DD/376 dated 18.08.2018**

2.A.2 Product licence holder : **Macleods Pharmaceuticals Ltd.**
Office : Atlanta Arcade, 3rd 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 [8] :

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[9]
: **Not applicable**

2.A.4 Is summary basis of Approval appended?[10]
: No

2.A.5 Is the attached, officially approved product information complete and consonant with the licence?[11]
: Not provided

2.A.6 Applicant for certificate if different from licence holder: [12] : **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[9]

: **Not applicable**

2. B.3 Why is marketing authorization lacking?

: **Not applicable**

2.B.4 Remark : [13] --

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu

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 ?[15] Yes

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]
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

Signature:

Stamp and date:

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

19 AUG 2023

ANNEXURE TO CERTIFICATE NO : **DD/376/453/2022/PER-I** **Valid up to: 28/11/2025**

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)
Dry Mixing				
1.	Microcrystalline Cellulose	BP	Capsule filler	16.66
Binding				
2.	Povidone (K-30)	BP	Binder	1.34
3.	Isopropyl alcohol #	BP	Solvent	8.66
Pre- Lubrication				
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
Lubrication				
8.	Magnesium Stearate	BP	Lubricant	6.66
Total weight				**332.68**
9.	Hard gelatin capsule of size "0" scarlet/scarlet coloured	IHS	Capsule shell	1(No.)

BP : British Pharmacopoeia;

IHS : In-house specifications;

: Does not appear in the final product;

** : Rifampicin Particle size : D10 : NMT 8µ, D50 : 30 to 70µ, D90 : NMT 185µ

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu सहायक औषधि नियंत्रक एवं अनुज्ञापन प्राधिकारी दादरा एवं नगर हवेली एवं दमण एवं दीव सत्यमेव जयते

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:

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY (Vc)
सहायक औषधि नियंत्रक एवं अनुज्ञापन प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधि नियंत्रक विभाग
U.T. OF DADRA & NAGAR HAVELI AND DAMAN & DIU
संघप्रदेश दादरा एवं नगर हवेली एवं दमण एवं दीव

19 AUG 2023