Certificate of Pharmaceutical Product [1]

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

No. of certificate 507

Exporting (certifying country): INDIA
Importing (requesting country): CHILE

1 Name and dosage form of the product: **GELOXIB-200**
Celecoxib Capsules

1.1 Active Ingredient(s)[2] and amount(s) per unit dose [3] (complete qualitative composition)[4]
Each Capsule contains:
Celecoxib BP 200 mg

Qualitative and Quantitative composition
API- Celecoxib BP 200.000 mg
Excipients- Microcrystalline Cellulose BP 3.400 mg, Lactose BP 3.000 mg, Povidone K-30 BP 0.600 mg, Isopropyl Alcohol BP q.s., Sodium Lauryl Sulphate BP 3.000 mg, Dark Green/Dark Green Empty Hard Gelatin Capsule Shell of Size "2" I.H.S 1 Nos.

1.2 Is this product licenced to be placed on the market for use in the exporting country?[5] **YES :** See Block 2A **NO -** See Block 2B[6]

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

2A		2B	
2.A.1	Number of product license[7] and date of issue: **288/2 dt. 20.03.04**	2.B.1	Applicant for certificate (name and address):
2.A.2	Product license Holder: (name & address) : **M/s. Gracure Pharmaceuticals Ltd., E-1105 RIICO Industrial Area, Phase III, Bhiwadi, Alwar, (Rajasthan), India**	2.B.2	Status of Applicant: (Key in appropriate category as defined in footnote 8) A B C
2.A.3	Status of product licence holder[8]: (Key in appropriate category as difined in note 8) ☑ A B C **Manufactuers the dosage forms**	2.B.2.1	For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]
2.A.3.1	For categories b & c the name and address of the manufacturer producing the dosage form is[9]: **NOT APPLICABLE**	2.B.3	Why is marketing authorization lacking? (not required/not requested/under consideration/refused)
2.A.4	Is summary basis of approval appended?[10] ☑ YES / NO		
2.A.5	Is the attached, officially approved product information complete and consonent with the license?[11] ☑ YES / NO/Not Provided	2.B.4.	Remarks[13]
2.A.6	Applicant for certificate if different from license holder (name & address)[12]: **NOT APPLICABLE**		

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 not or not applicable proceed to question 4.

3.1 Periodicity of routine inspection (years) : **At least once a year:**

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 WHO?[15] ☑ YES / NO / not applicable

4 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacturer of the product[16]: (yes/no)
if no, explain.

Address of certifying authority : **Swasthya Bhawan, Tilak Marg, Jaipur.**

Telephone/Fax: 0141 2221670

Validity: 31.10.2022

Name of Authorized person **(Raja Ram Sharma)**
Licensing Authority Cum
Drugs Controller
Rajasthan, Jaipur

Signature

Stamp & Date 13 MAR 2020

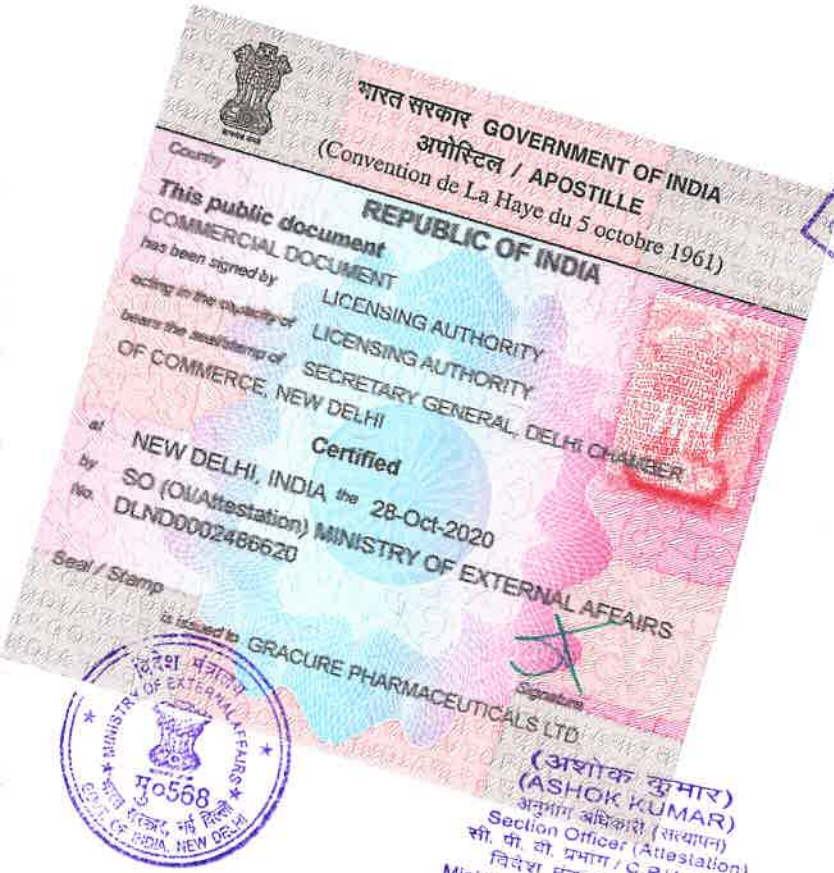
DELHI CHAMBER OF COMMERCE ATTESTED NEW DELHI

26 OCT 2020

(JASBIRENDRA S. SODHI, IAS)
Secretary General
Delhi Chamber of Commerce
New Delhi

ATTESTED PHOTO COPY
Notary Public, Delhi
26 OCT 2020

26 OCT 2020



भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by
LICENSING AUTHORITY
acting in the capacity of
LICENSING AUTHORITY
bears the seal/stamp of
SECRETARY GENERAL, DELHI CHAMBER
OF COMMERCE, NEW DELHI

Certified
at NEW DELHI, INDIA the 28-Oct-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. DLND0002486620

Seal / Stamp

is issued to GRACURE PHARMACEUTICALS LTD

Signature

(अशोक कुमार)
(ASHOK KUMAR)
अनुभाग अधिकारी (सत्यापन)
Section Officer (Attestation)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

The Ministry of External Affairs accepts no responsibility for the contents of the above document

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS
No.568
GOVT. OF INDIA, NEW DELHI