



OGYÉI
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National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: OGYÉI/18271-6/2017

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:

The manufacturer: *Gracure Pharmaceutical Ltd.*

Site address: *E-1105, Industrial Area, Phase-III, Bhiwadi, Alwar District, Rajasthan, 301019, India*

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2017-06-02, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

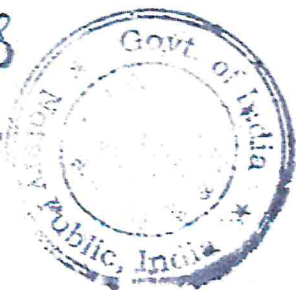
³ These requirements fulfil the GMP recommendations of WHO.

ATTESTED

NOTARY PUBLIC
DELHI (INDIA)

3 MAY 2018

3 MAY 2018

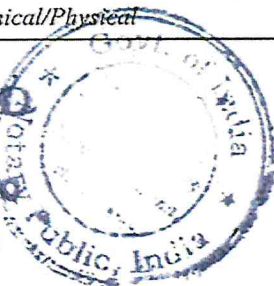


Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	1.2.1 <i>Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use Special Requirements 7 Other: Syrups and suspensions(en) 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.17 Other: Other(en) Special Requirements 7 Other: Powder for oral suspension(en)
1.5	Packaging
	1.5.1 <i>Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use Special Requirements 7 Other: Syrups and suspensions(en) 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products Special Requirements 7 Other: Powder for oral suspension(en)
	1.5.2 <i>Secondary packing</i>
1.6	Quality control testing
	1.6.2 <i>Microbiological: non-sterility</i> 1.6.3 <i>Chemical/Physical</i>

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3 MAY 2018



Name and signature of the authorised person of the
Competent Authority of Hungary



[Handwritten signature]

Ms. Csilla Pozsgay
National Institute of Pharmacy and Nutrition
Tel: +36 1 8869328
Fax:



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3 MAY 2018

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(JASBIRENDRA S. SODHBANSI)
Secretary General
Delhi Chamber of Commerce
New Delhi

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

The Ministry of External Affairs
accredits this document for the
purpose of the Convention.

This public document of the type
COMMERCIAL DOCUMENT

is issued to GRACURE PHARMACEUTICALS

has been signed by JASBIRENDRA S SODHBANS

with the seal / stamp of SECRETARY GENERAL, DELHI CHAMBER
OF COMMERCE, NEW DELHI

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 07-May-2018 at NEW DELHI, INDIA

with reference no. DLND0015626718

Seal / Stamp

Signature



(देबाब्रता तालु)
(DEBABRATA TAU)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (O.I.)
स.पा.वि. प्रभाग, C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi