European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2000-182-Rev 02

Name of the substance:
GELATIN
Limed Hide Gelatin (GLF)

Name of holder:
LAPI GELATINE SPA
Via Lucchese 164
Italy-50053 Empoli (Fi)

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2000-182-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **GELATIN** no. 330 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis water is used as solvent.

After examination of the information provided on the origin of raw material(s) and type of tissue(s) used and on the manufacturing process for this substance on the site(s) of production listed in annex, we certify that the substance **GELATIN** meets the criteria described in the current version of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

- country(ies) of origin of source materials:
  Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, Mexico, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, United Kingdom and United States of America.

- nature of animal tissues used in manufacture:
  Bovine hide splits

- manufacturing process:
  Alkaline process

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F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform encephalopathy agents.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

The certificate is valid provided that there has been no deterioration in the TSE status of the country(ies) of origin of the source material.

This certificate is renewed from **6 September 2005** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 12 March 2018

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

Lapi Gelatine SpA, as holder of the certificate of suitability

R1-CEP 2000-182-Rev 02 for Gelatin

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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Annex 1: Site(s) of production for R1-CEP 2000-182-Rev 02

Production of Gelatin:
Lapi Gelatine SpA
Via Lucchese 164
Italy-50053 Empoli (Fi)