European Directorate for the
Quality of Medicines & HealthCare

Certification of Substances Division

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

# Certificate of suitability
# No. R1-CEP 2000-140-Rev 03

*Name of the substance:*
**GELATIN**
Limed Hide Gelatin - Sodium Hydroxide Hide Gelatin

*Name of holder:*
**PB GELATINS**
Marius Duché Straat 260
Belgium-1800 Vilvoorde

*Site(s) of production:*
**PB GELATINS GMBH**
Grosse Drakenburgerstrasse 43
Germany-31582 Nienburg

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2000-140-REV 02

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 mentioned above, 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.

| | |
|---|---|
| - countries of origin of the source materials: | Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxemburg, the Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom, Argentina and Brazil |
| - nature of animal tissues used in manufacture: | Bovine hide splits |
| - manufacturing process: | Alkaline process |

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
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Internet : http://www.edqm.eu

AFAQ ISO 9001

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 a suitable quality assurance system such as GMP, ISO 9001 and HACCP, and in accordance with the dossier submitted.

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

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

This certificate is renewed from **18 July 2005** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 12 October 2010

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

**PB Gelatins**, as holder of the certificate of suitability

**R1-CEP 2000-140-Rev 03 for GELATIN**

hereby authorises ANY OF ITS PHARMACEUTICAL CUSTOMERS
*(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)*

PRODUCTS CONTAINING GELATIN SUPPLIED BY PB GELATINS

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)*:
14/10/2010

Dominique ROLIN
BU Regulatory Affairs Manager

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PB Gelatins

TO WHOM IT MAY CONCERN

Statement: 193
Edition : 1
Date : May 19, 2011

Subject: EDQM certificates

We, PB Gelatins, Division of the Tessenderlo Group, herewith confirm that the bovine limed bone gelatin, lime or NaOH treated hide gelatin and acid treated bone gelatin produced by PB Gelatins in Nienburg, Germany, by PB Gelatins in Treforest, United Kingdom and by PB Leiner in Santa Fe, Argentina covered by EDQM certificates:

R1-CEP 2000-045 Rev 02 Limed bone gelatin- European origin
R1-CEP 2000-140 Rev 03 Limed hide gelatin - sodium hydroxide hide gelatin
R1-CEP 2001-122 Rev 00 Limed bone gelatin - USA origin
R1-CEP 2002-110 Rev 00 Limed bone gelatin - Indian origin
R1-CEP 2002-150 Rev 00 Acid bone gelatin - Indian origin
R1-CEP 2004-022 Rev 00 Alkaline hide gelatin – Argentina Paraguay and Uruguay

meets the criteria described in the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA 410/01 rev. 3)

Dr. Dominique Rolin
BU Regulatory Affairs Manager
Email:dominique.rolin@tessenderlo.com