



European Directorate for the  
Quality of Medicines & HealthCare

Certification of Substances Division



## Certificate of suitability No. R1-CEP 2002-186-Rev 00

1 *Name of the substance:*

2 **GELATIN**

3 Limed Hide Gelatin

4 *Name of holder:*

5 **SAMMI INDUSTRIAL CO LTD**

6 222, Palgog Il-Dong

7 Republic of Korea-425-200 Ansan-Si, Kyunggi-Do

8 *Site(s) of production:*

9 **SAMMI INDUSTRIAL CO LTD**

10 222, Palgog Il-Dong

11 Republic of Korea-425-200 Ansan-Si, Kyunggi-Do

12 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
13 **R0-CEP 2002-186-REV 01**

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

20 – countries of origin of source materials: United States, Canada and  
21 Australia  
22 – nature of animal tissues used in manufacture: Bovide hides  
23 – manufacturing process: Alkaline process

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


27 Manufacture of the substance shall take place in accordance with a suitable quality  
28 assurance system such as GMP and ISO 9002, and in accordance with the dossier  
29 submitted.

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

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

33 This certificate is renewed from **26 February 2008** according to the provisions of  
34 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
35 2001/82/EC and any subsequent amendment, and the related guidelines.

36 This certificate has:  
37 lines.

*PP*  
  
On behalf of the  
Director of EDQM & HealthCare



Strasbourg, 18 February 2008

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

**Sammi Industrial Co Ltd**, as holder of the certificate of suitability

**R1-CEP 2002-186-Rev 00 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)*: