

Certification of Substances Division

Certificate of suitability
No. R0-CEP 2009-034-Rev 00

1 *Name of the substance:*
2 **COLLAGEN**

3 *Name of holder:*
4 **VYZKUMNY USTAV PLETARSKY, A.S.**
5 Sujanovo Namesti 3
6 Czech Republic-602 00 Brno

7 *Site(s) of production:*
8 **VYZKUMNY USTAV PLETARSKY, A.S.**
9 Sujanovo Namesti 3
10 Czech Republic-602 00 Brno

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

17 - country(ies) of origin of source materials: Czech Republic
18 - nature of animal tissues used in manufacture: Bovine hides
19 - manufacturing process: Alkaline process

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


23 Manufacture of the substance shall take place in accordance with a suitable quality
24 assurance system such as ISO 9001 and ISO 13485, and in accordance with the
25 dossier submitted.

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

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

29 This certificate is granted within the framework of the procedure established by the
30 European Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a
31 period of five years starting from **3 March 2010**. Moreover, it is granted according to the
32 provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
33 amendment, and the related guidelines.

34 This certificate has:
35 lines.


On behalf of the
Director of EDQM



Strasbourg, 3 March 2010

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

VYZKUMNY USTAV PLETARSKY, A.S., as holder of the certificate of suitability

R0-CEP 2009-034-Rev 00 for COLLAGEN

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)*: