

Certification of Substances Division

**Certificate of suitability
No. R1-CEP 2001-337-Rev 01**

- 1 *Name of the substance:*
2 **HEART EXTRACT PASTE**
3 Product code 26.014
- 4 *Name of holder:*
5 **ORGANOTECHNIE SAS**
6 27 Avenue Jean Mermoz
7 France-93120 La Courneuve
- 8 *Site(s) of production:*
9 **ORGANOTECHNIE SAS**
10 27 Avenue Jean Mermoz
11 France-93120 La Courneuve

12 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
13 **R1-CEP 2001-337-REV 00**

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 **HEART EXTRACT PASTE**
17 meets the criteria described in the current version of the monograph Products with risk
18 of transmitting agents of animal spongiform encephalopathies no. 1483 of the European
19 Pharmacopoeia, current edition including supplements.

- 20 – countries of origin of source materials: Australia and New Zealand
21 – nature of animal tissues used in manufacture: Bovine heart

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

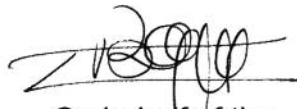
25 Manufacture of the substance shall take place in accordance with a suitable quality
26 assurance system such as ISO 9001, and in accordance with the dossier submitted.

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

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

30 This certificate is renewed from **13 February 2008** according to the provisions of
31 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive
32 2001/82/EC and any subsequent amendment, and the related guidelines.

33 This certificate has:
34 lines.


On behalf of the
Director of EDQM



Strasbourg, 25 January 2012

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

Organotechnie SAS, as holder of the certificate of suitability
R1-CEP 2001-337-Rev 01 for HEART EXTRACT PASTE

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)*: