

Certification of Substances Division

Certificate of suitability
No. R0-CEP 2007-292-Rev 03

1 *Name of the substance:*

2 **CHOLECALCIFEROL**

3 *Name of holder:*

4 **FERMENTA BIOTECH LIMITED**

5 DIL Complex, Ghodbunder Road

6 Majiwada

7 India-400610 Thane (W)

8 *Site(s) of production:*

9 **FERMENTA BIOTECH LIMITED**

10 Village: Takoli

11 District: Mandi, Himachal Pradesh

12 India-175121 Nagwain

13 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
14 **R0-CEP 2007-292-REV 02**

15 After examination of the information provided on the manufacturing method and
16 subsequent processes (including purification) for this substance on the site(s) of
17 production mentioned above, we certify that the quality of the substance is suitably
18 controlled by the current version of the monograph **CHOLECALCIFEROL** no. 72 of the
19 European Pharmacopoeia, current edition including supplements, only if it is
20 supplemented by the test(s) mentioned below, based on the analytical procedure(s)
21 given in annex.

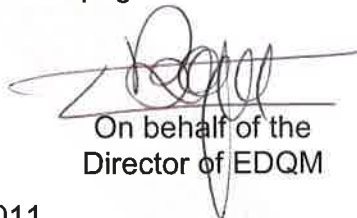
22 – Test for residual solvents by gas chromatography (Annex 1)
23 Methyl formate not more than 5000 ppm

24 The re-test period of the substance is 36 months if stored at a temperature between
25 2°C and 8°C, in aluminium bottles under inert gas or under vacuum in glass
26 ampoules packaged into carton.

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

33 – nature of animal tissues used in manufacture: Sheep wool
34 The submitted dossier must be updated after any significant change that may alter the
35 quality, safety or efficacy of the substance, or that may alter the risk of transmitting
36 animal spongiform encephalopathy agents.
37 Manufacture of the substance shall take place in accordance with the Good
38 Manufacturing Practice and in accordance with the dossier submitted.
39 Failure to comply with these provisions will render this certificate void.
40 The certificate is valid provided that there has been no deterioration in the TSE status of
41 the country(ies) of origin of the source material.
42 This certificate is granted within the framework of the procedure established by the
43 European Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a
44 period of five years starting from **12 August 2009**. Moreover, it is granted according to
45 the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
46 amendment, and the related guidelines.

47 This certificate has one annex of 3 pages.
48 This certificate has:
49 lines.


On behalf of the
Director of EDQM



Strasbourg, 27 September 2011

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

FERMENTA BIOTECH LIMITED, as holder of the certificate of suitability

R0-CEP 2007-292-Rev 03 for CHOLECALCIFEROL

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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