European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

**Certification of Substances Division**

# Certificate of suitability
# No. R1-CEP 2007-292-Rev 00

*Name of the substance:*
**CHOLECALCIFEROL**

*Name of holder:*
**FERMENTA BIOTECH LIMITED**
DIL Complex, Ghodbunder Road
Majiwada
India-400610 Thane (W)

*Site(s) of production:*
**SEE ANNEX 1**

**THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
**R0-CEP 2007-292-REV 04**

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

– Test for residual solvents by gas chromatography (Annex 2)
Methyl formate not more than 5000 ppm
Benzene not more than 2 ppm

The re-test period of the substance is 36 months if stored at a temperature between 2°C and 8°C, either in aluminium bottles under inert gas placed in corrugated boxes or in glass ampoules under vacuum placed in a carton or in a polyethylene bag under vacuum placed in an aluminium bag.

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 listed in annex, we certify that the substance **CHOLECALCIFEROL** 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.

– Nature of animal tissues used in manufacture:
Sheep wool

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F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet: http://www.edqm.eu

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 the Good Manufacturing Practice and in accordance with the dossier submitted.

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

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

This certificate is renewed from **12 August 2014** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has two annexes, the first of 1 page and the second of 4 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 6 August 2014

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

**R1-CEP 2007-292-Rev 00 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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