

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2000-397-Rev 01

1 *Name of the substance:*

2 **CALCITRIOL**

3 *Name of holder:*

4 **INSTYTUT FARMACEUTYCZNY**

5 Ul. Rydygiera 8

6 Poland-01-793 Warsaw

7 *Site(s) of production:*

8 **INSTYTUT FARMACEUTYCZNY**

9 Ul. Rydygiera 8

10 Poland-01-793 Warsaw

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
12 **R1-CEP 2000-397-REV 00**

13 After examination of the information provided on the manufacturing method and
14 subsequent processes (including purification) for this substance on the site(s) of
15 production mentioned above, we certify that the quality of the substance is suitably
16 controlled by the current version of the monograph **CALCITRIOL** no. 883 of the
17 European Pharmacopoeia, current edition including supplements, only if it is
18 supplemented by the test(s) mentioned below, based on the analytical procedure(s)
19 given in annex.

20 The following impurities are detected by the test for related substances of the
21 monograph and their limits are set at:

22 Impurity RRT 0.44 not more than 0.15%

23 Any other detectable impurity* not more than 0.10%

24 *and other than those already mentioned in the monograph

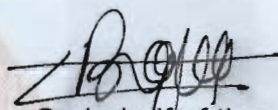
25 – Test for residual solvents by gas chromatography (Annex 1)

26 Chloroform not more than 60 ppm

27 Methyl formate not more than 5000 ppm

28 The holder of the certificate has declared the absence of use of material of human or
29 animal origin in the manufacturing of the substance.

- 30 The submitted dossier must be updated after any significant change that may alter the
31 quality, safety or efficacy of the substance.
- 32 Manufacture of the substance shall take place in accordance with the Good
33 Manufacturing Practice and in accordance with the dossier submitted.
- 34 Failure to comply with these provisions will render this certificate void.
- 35 This certificate is renewed from **4 March 2008** according to the provisions of Resolution
36 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
37 and any subsequent amendment, and the related guidelines.
- 38 This certificate has one annex of 3 pages.
39 This certificate has:
40 lines.



On behalf of the
Director of EDQM & HealthCare



Strasbourg, 26 May 2008

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

Instytut Farmaceutyczny, as holder of the certificate of suitability

R1-CEP 2000-397-Rev 01 for CALCITRIOL

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)*: