Certification of Substances Department

Certificate of suitability
No. R0-CEP 2019-220 - Rev 00

Name of the substance:
TACALCITOL, MONOHYDRATE

Name of holder:
LUKASIEWICZ RESEARCH NETWORK- INDUSTRIAL CHEMISTRY INSTITUTE
8 Rydygiera Str.
Poland-01-793 Warsaw

Site(s) of production:
SEE ANNEX 1

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 **TACALCITOL, MONOHYDRATE** no. 2272 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)

Acetone	not more than 0.5%
Benzene	not more than 2 ppm

In the last steps of the synthesis water is used as solvent.

The following elemental impurities are intentionally introduced in the synthesis of the substance: Lithium, Mercury.

– Test for elemental impurities by ICP-MS (Annex 3)

Mercury	not more than 3 ppm

The substance is packed in amber glass vials or bottles closed with a melamine screw cap with polytetrafluoroethylene lined cap under an inert gas.

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

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: https://www.edqm.eu

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.

This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **27 April 2023**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has three annexes, the first of 1 page, the second and the third of 5 pages each.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 27 April 2023

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

LUKASIEWICZ RESEARCH NETWORK- INDUSTRIAL CHEMISTRY INSTITUTE, as holder of the certificate of suitability

R0-CEP 2019-220 - Rev 00 for Tacalcitol, monohydrate

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*):