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 Department

Certificate of suitability
No. R1-CEP 2017-034 - Rev 00

Name of the substance:
CEFUROXIME AXETIL
Amorphous

Name of holder:
TITAN PHARMACEUTICAL CO., LTD. (GUANGDONG)
Guojing Road
Lantang Town, Zijin County
China-517 447 Heyuan City, Guangdong Province

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2017-034 - REV 02

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 **CEFUROXIME AXETIL** no. 1300 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.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.10%.

– Test for the following impurity by GC-MS/MS (Annex 2)
N-Nitrosodimethylamine (NDMA) not more than 0.080 ppm

– Tests for residual solvents by gas chromatography
Ethyl acetate not more than 5000 ppm (Annex 3)
Dimethylacetamide not more than 1090 ppm (Annex 4)

A risk management summary for elemental impurities has been provided. (Annex 5)

– Test for physical characteristics by microscopy (Annex 6)
Crystallinity amorphous

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

The re-test period of the substance is 36 months if stored in double polyethylene bags, placed in a cardboard drum.

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.

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 renewed from **17 May 2023** 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 six annexes, the first of 1 page, the second, the third and the fourth of 2 pages each, the fifth of 1 page and the sixth of 2 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 20 April 2023

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

TITAN PHARMACEUTICAL CO., LTD. (GUANGDONG), as holder of the certificate of suitability

R1-CEP 2017-034 - Rev 00 for Cefuroxime axetil

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*):