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 2014-335 - Rev 00

Name of the substance:
CEFUROXIME SODIUM
Sterile

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 2014-335 - REV 01

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 SODIUM** no. 992 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 related substances by liquid chromatography (Annex 2)
  - Lactic acid and sodium lactate: not more than 0.7%
  - Acetic acid and sodium acetate: not more than 0.5%
- Test for residual solvents by gas chromatography (Annex 3)
  - Ethanol: not more than 5000 ppm
  - Acetone: not more than 5000 ppm

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

A risk management summary for elemental impurities has been provided. (Annex 4)

The test for 2-Ethylhexanoic acid described in the monograph is not necessary since this compound cannot be present with the route of synthesis used.

The test for *N,N*-Dimethylaniline described in the monograph is not necessary since this compound is not used in the synthesis.

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Titan Pharmaceutical

The re-test period of the substance is 2 years if stored in sterile aluminium bottles with aluminium caps using a butyl rubber sealing ring.

The substance is sterile and shall comply with the test for sterility (2.6.1) of the European Pharmacopoeia. The method used for sterilisation is a sterile filtration and the sterilisation process has been assessed and approved.

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 **24 February 2022** 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 four annexes, the first of 1 page, the second of 2 pages, the third of 1 page and the fourth of 2 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 17 January 2022

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 2014-335 - Rev 00 for Cefuroxime sodium

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*):

Titan Pharmaceutical