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. R0-CEP 2010-026-Rev 01

Name of the substance:
CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE FOR INJECTION
Sterile

Name of holder:
ANTIBIOTICOS DO BRASIL LTDA.
Rodovia Professor Zeferino Vaz
SP-332, Km 135
Brazil-13150-000 Cosmopolis, Sao Paulo

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2010-026-REV 00

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 **CEFTAZIDIME PENTAHYDRATE WITH SODIUM CARBONATE FOR INJECTION** no. 2344 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 0.3%

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

The substance is packed in a sterile double polyethylene bag in a foil laminated bag in double polyethylene bags placed in a container.

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.

Address: 7 Allée Kastner, CS 30026
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.

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 **10 April 2013**. 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 two annexes, the first of 1 page and the second of 5 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 28 August 2015

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

ANTIBIOTICOS DO BRASIL LTDA., as holder of the certificate of suitability

R0-CEP 2010-026-Rev 01 for Ceftazidime pentahydrate with sodium carbonate for injection

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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