

Certification of Substances Division

**Certificate of suitability
No. R0-CEP 2007-314-Rev 00**

1 *Name of the substance:*

2 **CEFIXIME**

3 *Name of holder:*

4 **SURYA PHARMACEUTICAL LTD.**

5 S.C.O. 164, 165

6 Sector 9-C, Madhya Marg

7 India-160 009 Chandigarh

8 *Site(s) of production:*

9 **SURYA PHARMACEUTICAL LTD.**

10 Vill. Banur, Teh. Rajpura

11 District Patiala

12 India-140 601 Near Chandigarh, Punjab

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 **CEFIXIME** no. 1188 of the European
17 Pharmacopoeia, current edition including supplements, only if it is supplemented by the
18 test(s) mentioned below, based on the analytical procedure(s) given in annex.

19 Any other impurity than those mentioned in the monograph and detected by the test
20 for related substances of the monograph is individually limited to not more than
21 0.10%.

22 – Test for residual solvents by gas chromatography (Annex 1)
23 Ethyl acetate not more than 5000 ppm

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

25 The test for ethanol described in the monograph is not necessary since this solvent is
26 not used in the synthesis.

27 The re-test period of the substance is 24 months if stored between 2°C and 8°C
28 under nitrogen in a double polythene bag, within an aluminium bag placed in an
29 HDPE drum.

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

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

34 Manufacture of the substance shall take place in accordance with the Good
35 Manufacturing Practice and in accordance with the dossier submitted.

36 Failure to comply with these provisions will render this certificate void.

37 This certificate is granted within the framework of the procedure established by the
38 European Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a
39 period of five years starting from **21 January 2010**. Moreover, it is granted according to
40 the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
41 amendment, and the related guidelines.

42 This certificate has one annex of 4 pages.
43 This certificate has:
44 lines.



On behalf of the
Director of EDQM

Strasbourg, 21 January 2010

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

SURYA PHARMACEUTICAL LTD., as holder of the certificate of suitability

R0-CEP 2007-314-Rev 00 for CEFIXIME

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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