

Certification of Substances Division

**Certificate of suitability
No. R0-CEP 2006-143-Rev 01**

1 *Name of the substance:*

2 **TINIDAZOLE**

3 *Name of holder:*

4 **ZHEJIANG SUPOR PHARMACEUTICAL CO. LTD**

5 Yuedong Road

6 Paojiang Industrial Zone

7 China-312071 Shaoxing

8 *Site(s) of production:*

9 **ZHEJIANG SUPOR PHARMACEUTICAL CO. LTD**

10 Yuedong Road

11 Paojiang Industrial Zone

12 China-312071 Shaoxing

13 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
14 **R0-CEP 2006-143-REV 00**

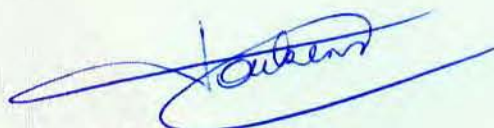
15 After examination of the information provided on the manufacturing method and
16 subsequent processes (including purification) for this substance on the site(s) of
17 production mentioned above, we certify that the quality of the substance is suitably
18 controlled by the current version of the monograph **TINIDAZOLE** no. 1051 of the
19 European Pharmacopoeia, current edition including supplements, only if it is
20 supplemented by the test(s) mentioned below, based on the analytical procedure(s)
21 given in annex.

22 – Test for residual solvents by gas chromatography (Annex 1)
23 Ethanol not more than 1000 ppm
24 O-Xylene not more than 195.3 ppm

25 The re-test period of the substance is 2 years if stored in double polyethylene bags in
26 fibre containers.

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

- 29 The submitted dossier must be updated after any significant change that may alter the
30 quality, safety or efficacy of the substance.
- 31 Manufacture of the substance shall take place in accordance with the Good
32 Manufacturing Practice and in accordance with the dossier submitted.
- 33 Failure to comply with these provisions will render this certificate void.
- 34 This certificate is granted within the framework of the procedure established by the
35 European Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a
36 period of five years starting from **16 December 2008**. Moreover, it is granted according
37 to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any
38 subsequent amendment, and the related guidelines.
- 39 This certificate has one annex of 2 pages.
40 This certificate has:
41 lines.



On behalf of the
Director of EDQM



Strasbourg, 25 November 2010

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

Zhejiang Supor Pharmaceutical Co. Ltd, as holder of the certificate of suitability
R0-CEP 2006-143-Rev 01 for TINIDAZOLE

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)*:

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
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