

Certificate of suitability
No. R1-CEP 1999-045-Rev 02

1 *Name of the substance:*
2 **ROXITHROMYCIN**

3 *Name of holder:*
4 **HOVIONE PHARMASCIENCE LIMITED**
5 Estrada Coronel Nicolau De Mesquita
6 Macao- Taipa

7 *Site(s) of production:*
8 **HOVIONE PHARMASCIENCE LIMITED**
9 Estrada Coronel Nicolau De Mesquita
10 Macao- Taipa

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
12 **R1-CEP 1999-045-REV 01**

13 After examination of the information provided on the manufacturing method and

NOT FOR REGISTRATION PURPOSES

**"For filing purposes please contact
Hovione to obtain a complete
"controlled copy" of this CEP.
Maintaining proper records will
enable you to receive "updates" and
enable us to comply with our change
control requirements"**

Hovione - Regulatory Affairs Department

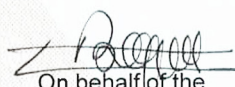
36 Manufacture of the substance shall take place in accordance with the Good
37 Manufacturing Practice and in accordance with the dossier submitted.

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

39 This certificate is renewed from **14 April 2005** according to the provisions of Resolution
40 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
41 and any subsequent 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 & HealthCare



Strasbourg, 26 September 2008