

Certification of Substances Division

Certificate of suitability
No. R1-CEP 1997-078-Rev 05

1 *Name of the substance:*
2 **MINOCYCLINE HYDROCHLORIDE DIHYDRATE**
3 Grade B

4 *Name of holder:*
5 **HOVIONE FARMACIENCIA S.A.**
6 Sete Casas
7 Portugal-2674-506 Loures

8 *Site(s) of production:*
9 **SEE ANNEX 1**

10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
11 **R1-CEP 1997-078-REV 04**

12 After examination of the information provided on the manufacturing method and subsequent

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

37 This certificate is renewed from **1 June 2003** according to the provisions of Resolution AP-CSP
38 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
39 and the related guidelines.

40 This certificate has three annexes, the first of 1 page, the second and the third of 4 pages each.
41 This certificate has:
42 lines.


On behalf of the
Director of EDQM



Strasbourg, 21 October 2015