

Certification of Substances Division

**Certificate of suitability**  
**No. R1-CEP 1996-066-Rev 04**

1 *Name of the substance:*

2 **DOXYCYCLINE HYCLATE**

3 *Name of holder:*

4 **HOVIONE PHARMASCIENCE LIMITED**

5 Estrada Coronel Nicolau De Mesquita

6 Macao- Taipa

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9

**THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

10

**R1-CEP 1996-066-REV 03**

11 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**

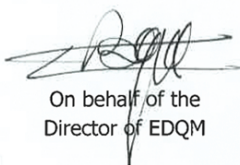
31 Failure to comply with these provisions will render this certificate void.

32 This certificate is renewed from **26 May 2002** according to the provisions of  
33 Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any  
34 subsequent amendment, and the related guidelines.

35 This certificate has three annexes, the first of 1 page, the second of 5 pages and the third of  
36 3 pages.

37 This certificate has:

38 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 14 March 2014