

Certification of Substances Division

**Certificate of suitability**  
**No. R1-CEP 1997-115-Rev 06**

- 1 *Name of the substance:*  
2 **DOXYCYCLINE MONOHYDRATE**
- 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 1997-115-REV 05**


- 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**

- 30 This certificate is renewed from **15 January 2004** according to the provisions of Resolution AP-  
31 CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
32 amendment, and the related guidelines.
- 33 This certificate has three annexes, the first of 1 page, the second and the third of 4 pages each.  
34 This certificate has:  
35 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 10 November 2015