

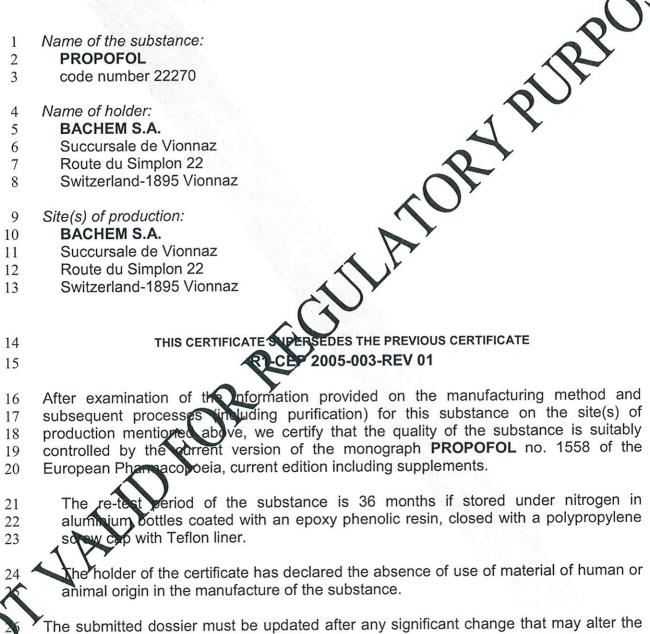
quality, safety or efficacy of the substance.

29



## **Certification of Substances Division**

Certificate of suitability No. R1-CEP 2005-003-Rev 02



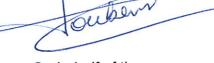


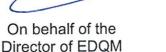
Manufacture of the substance shall take place in accordance with the Good

Manufacturing Practice and in accordance with the dossier submitted.

- Failure to comply with these provisions will render this certificate void.
- 31 This certificate is renewed from 19 December 2010 according to the provisions of
- 32 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive
- 33 2001/82/EC and any subsequent amendment, and the related guidelines.
- 34 This certificate has:

35 lines.





Strasbourg, 8 August 2011

DECLARATION OF ACCESS (to be filled in by the certificate holder unox bein own responsibility)

BACHEM S.A., as holder of the certificate of suitability

R1-CEP 2005-003-Rey 02 for PROPOFOI

hereby authorises .....

(name of the phormaceutical 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 mare since the granting of this version of the certificate.

Date and Signature (of the CEP holder):

