



European Directorate for the Quality of Medicines  
Certification Unit



**Certificate of suitability**  
**No. R1-CEP 2000-269-Rev 00**

1 *Name of the substance:*

2 **STEARIC ACID**

3 *Name of holder:*

4 **AMBROGIO PAGANI SPA**

5 **Via Stezzano-Lat Cascinello 9**

6 **I - 24126 Bergamo**

7 *Site of production:*

8 **AMBROGIO PAGANI SPA**

9 **Via Stezzano-Lat Cascinello 9**

10 **I - 24126 Bergamo**

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
12 **R0-CEP 2000-269-REV 02**

13 After examination of the information provided on the origin of raw material(s) and type of  
14 tissue(s) used and on the manufacturing process for this substance on the site of production  
15 mentioned above, I - 24126 Bergamo, we certify that the substance **STEARIC ACID** meets the  
16 criteria described in the current version of the monograph Products with risk of transmitting  
17 agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current  
18 edition including supplements.

19 The submitted dossier must be updated after any significant change that may alter the quality,  
20 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform  
21 encephalopathy agents.


22 Manufacture of the substance shall take place in accordance with a suitable quality assurance  
23 system such as ISO 9001:2000, and in accordance with the dossier submitted.

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

25 The certificate is valid provided that there has been no deterioration in the TSE status of the  
26 country(ies) of origin of the source material.

27 This certificate is renewed from **13 February 2006** according to the provisions of Resolution  
28 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any  
29 subsequent amendment, and the related guidelines.

30 This certificate has 30 lines only.



Dr. A. ARTIGES  
Director of the Quality of Medicines

Strasbourg, 1 February 2006

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

**AMBROGIO PAGANI SPA**, as holder of the certificate of suitability

**R1-CEP 2000-269-Rev 00 for STEARIC ACID**

hereby authorises .....  
*(name of the pharmaceutical 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  
made since the granting of this version of the certificate.

Date and Signature *(of the CEP holder)*: