

**Certification of Substances Division**

**Certificate of suitability  
No. R1-CEP 2003-096-Rev 00**

1 *Name of the substance:*

2 **NYSTATIN**

3 *Name of holder:*

4 **ANTIBIOTICE SA**

5 1 Valea Lupului Street

6 Romania-707410 Iasi

7 *Site(s) of production:*

8 **ANTIBIOTICE SA**

9 1 Valea Lupului Street

10 Romania-707410 Iasi

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
12 **R0-CEP 2003-096-REV 02**

13 After examination of the information provided on the manufacturing method and  
14 subsequent processes (including purification) for this substance on the site(s) of  
15 production mentioned above, we certify that the quality of the substance is suitably  
16 controlled by the current version of the monograph **NYSTATIN** no. 517 of the European  
17 Pharmacopoeia, current edition including supplements, only if it is supplemented by the  
18 test(s) mentioned below, based on the analytical procedure(s) given in annex.

19 — Test for residual solvents by gas chromatography (Annex 1)  
20 Acetone not more than 0.5%  
21 Methanol not more than 0.3%

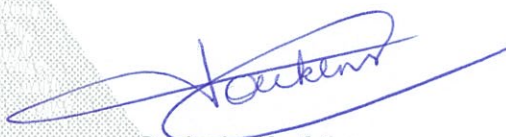
22 In the last steps of the synthesis water is used as solvent.

23 The re-test period of the substance is 36 months if stored protected from light, at a  
24 temperature between 2°C and 8°C in a double polyethylene bag placed inside a  
25 cardboard box.

26 The holder of the certificate has declared the absence of use of material of human or  
27 animal origin in the manufacture of the substance.

28 Compliance with the statements of the Production Section of the monograph is to be  
29 considered in the context of a medicinal product containing this substance.

- 30 The submitted dossier must be updated after any significant change that may alter the  
31 quality, safety or efficacy of the substance.
- 32 Manufacture of the substance shall take place in accordance with the Good  
33 Manufacturing Practice and in accordance with the dossier submitted.
- 34 Failure to comply with these provisions will render this certificate void.
- 35 This certificate is renewed from **13 May 2010** according to the provisions of Resolution  
36 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC  
37 and any subsequent amendment, and the related guidelines.
- 38 This certificate has one annex of 2 pages.  
39 This certificate has:  
40 lines.



On behalf of the  
Director of EDQM



Strasbourg, 6 May 2010

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

**Antibiotice SA**, as holder of the certificate of suitability

**R1-CEP 2003-096-Rev 00 for NYSTATIN**

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)*:

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