European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

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

Name of the substance:
NYSTATIN

Name of holder:
ANTIBIOTICE SA
1 Valea Lupului Street
Romania-707410 Iasi

Site(s) of production:
ANTIBIOTICE SA
1 Valea Lupului Street
Romania-707410 Iasi

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

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

– Test for residual solvents by gas chromatography (Annex 1)

Acetone	not more than 0.5%
Methanol	not more than 0.3%

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

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

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

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

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : http://www.edqm.eu

AFAQ ISO 9001

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

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.

This certificate is renewed from **13 May 2010** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 2 pages.
This certificate has:
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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