edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2003-096-Rev 03

Name of the substance:
NYSTATIN
Non-micronised and micronised

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

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-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 listed in annex, 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 2)
  Acetone not more than 0.5%
  Methanol not more than 0.3%

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

  A risk management summary for elemental impurities has been provided. (Annex 3)

– Test for particle size by laser diffraction (Annex 4)
  Non-micronised grade:
  d_{90} not more than than 45 µm
  Micronised grade:
  d_{90} not more than than 10 µm
  d_{100} not more than than 15 µm

  The re-test period of the substance is 30 months if stored protected from light in either one or two polyethylene bag(s) in a triple laminated bag (polyethylene terephthalate / aluminium / polyethylene), placed in a cardboard box.

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