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 2007-235-Rev 03

Name of the substance:
ERYTHROMYCIN ETHYLSUCCINATE

Name of holder:
ANUH PHARMA LTD
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2007-235-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 **ERYTHROMYCIN ETHYLSUCCINATE** no. 274 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.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.2%.

– Test for residual solvents by gas chromatography (Annex 2)
Acetone not more than 5000 ppm

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

The re-test period of the substance is 3 years if stored in a double polyethylene bag placed in a polyethylene drum.

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

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

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