Certificate of suitability
No. CEP 2005-205 - Rev 13

Name of the substance:
ERYTHROMYCIN

Details of holder:
ANUH PHARMA LTD.
3-A, Shivsagar Estate, North Wing
Dr Annie Besant Road, Worli
India-400 018 Mumbai, Maharashtra
SPOR ORG ID: 100021566
SPOR LOC ID: 100030259

After examination of the information provided on the production method and control strategy for the substance, we certify that its quality is suitably controlled by the current version of the European Pharmacopoeia monograph for **ERYTHROMYCIN** No. 179 and any supplementary tests deemed necessary which are mentioned below. The approved site(s) of production and any supplementary test procedure(s) are included on the following pages as annexes, which constitute an integral part of this certificate.

– Test for residual solvents by gas chromatography (Annex 2)
Methylene chloride not more than 600 ppm

In the last steps of the process, water is used as solvent.

The re-test period of the substance is 4 years if stored in double polyethylene bags, placed in either a polyethylene or fibre drum.

No material of human or animal origin is used in the production of the substance.

The holder of the certificate should fulfil the following conditions in order to maintain the validity of this certificate.

The dossier submitted must be updated in accordance with EDQM guidance on the requirements for revision of certificates of suitability.

Production of the substance shall take place in accordance with the dossier submitted and Good Manufacturing Practice.

Necessary information from the submitted dossier shall be shared with authorised users in order to enable them to evaluate the suitability of this substance for its intended use. This includes informing them of any relevant change in the associated dossier.