

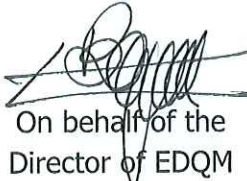
Certification of Substances Department

ATTESTATION OF INSPECTION

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|--|---|
| Inspected site | Anuh Pharma Ltd E-17/3 & E 17/4 M.I.D.C. Tarapur Taluka Palghar, District Thane India-401 506 Boisar, Maharashtra |
| Holder of the Certificate of Suitability | Anuh Pharma Ltd 3-A, Shivsagar Estate, North Wing Dr Annie Besant Road, Worli India-400 018 Mumbai, Maharashtra |
| References of CEP dossier | CEP 2007-235 / Erythromycin ethylsuccinate CEP 2005-059 / Pyrazinamide |
| Inspection dates | 14/09/2016 to 16/09/2016 |
| Inspector / Name of organisation | ROQUE Daniel, AGENCE NATIONALE DE SECURITE DU MEDICAMENT ET DES PRODUITS DE SANTE, France ; Mr TEMLEITNER Arpad, EDQM, Council of Europe. |
| Scope of the inspection | The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4. |
| Conclusion | The company operates in accordance with the application submitted and the requirements of the Resolution AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above. |

EDQM Inspection Reference number: INSP 2009-021 P04

Strasbourg, 19 December 2016


 On behalf of the
 Director of EDQM



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