

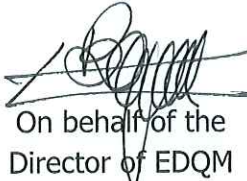
Certification of Substances Department

ATTESTATION OF INSPECTION

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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