

ATTESTATION OF INSPECTION

Inspected site	EMMENNAR PHARMA PRIVATE LIMITED Unit-II, Plot No. 15, Jawaharlal Nehru Pharma City Parawada Mandal, Vishakapatnam District India-531 019 Tadi Village, Andhra Pradesh
Holder of the Certificate of Suitability	EMMENNAR PHARMA PRIVATE LIMITED Plot No. A-4, Opp. Sanathnagar police station Sanathnagar India-500 018 Hyderabad, Telangana
References of CEP dossier	CEP 2013-320 / Tramadol hydrochloride
Inspection dates	17 October 2022 to 19 October 2022
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 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 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 2022-007-P01

Strasbourg, 30 January 2023


On behalf of the
Director of EDQM