

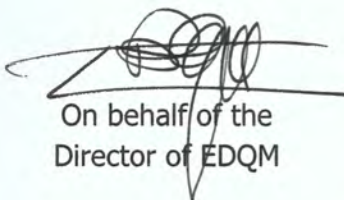
Certification of Substances Department

ATTESTATION OF INSPECTION

Inspected site	FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. 14, G.I.D.C. Industrial Estate, Nandesari Vadodara District India-391 340 Vadodara, Gujarat
Holder of the Certificate of Suitability	FARMSON PHARMACEUTICAL GUJARAT PVT. LTD. 14, G.I.D.C. Industrial Estate, Nandesari Vadodara District India-391 340 Vadodara, Gujarat
References of CEP dossier	CEP 2002-020 / Paracetamol
Inspection dates	22/05/2017 to 24/05/2017
Inspector / Name of organisation	Dr TASI Gergely, OGYEI, NATIONAL INSTITUTE OF PHARMACY AND NUTRITION, HUNGARY 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 2014-006 P02

Strasbourg, 25 August 2017


 On behalf of the
 Director of EDQM

