

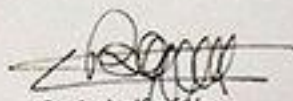
Certification of Substances Division

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	02/06/2014 to 04/06/2014
Inspector / Name of organisation	Ms PSCIUK-SNIEC Magdalena, MAIN PHARMACEUTICAL INSPECTORATE, Poland Mr PARASCHOS Sotirios, 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 P01

Strasbourg, 26 September 2014


On behalf of the
Director of EDQM

