

Certification of Substances Division

SHILPA MEDICARE LIMITED
Dr Unnam SESHACHALAM
10/80 Rajendra Gunj
IN - 584 102
Raichur, Karnataka, India

CEP_RZ_PH_INSP 2015-007-0813680

Strasbourg, 17 August 2015

ATE / pja

EDQM Inspection Programme – Final Report and Attestation

EDQM Inspection number : INSP 2015-007 P01

Dear Dr SESHACHALAM,

Please find enclosed a copy of the final report concerning the inspection of the manufacturing site:

SHILPA MEDICARE LIMITED
Plot No. 33, 33A, 40 to 47
Raichur Industrial Growth Centre
Wadloor Road, Chicksugur Cross, Chicksugur
India-584 134 Raichur, Karnataka

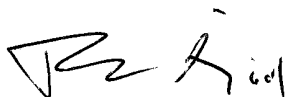
The CEP dossier / substance that was the topic of the inspection is:

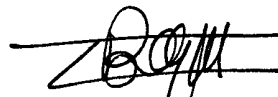
CEP 2004-201 – Ambroxol hydrochloride

The inspection was performed between 18 March 2015 to 20 March 2015.

Also enclosed is an EDQM Attestation of Inspection that you may use as proof that you have been inspected under this programme.

Yours sincerely,


Arpad TEMLEITNER
Inspector


Hélène BRUGUERA
Head of Division

Enclosures:

- Final Inspection Report
- Attestation of Inspection

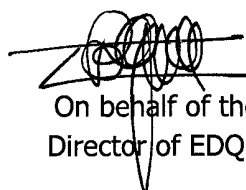
Certification of Substances Division

ATTESTATION OF INSPECTION

Inspected site	SHILPA MEDICARE LIMITED Plot No. 33, 33A, 40 to 47 Raichur Industrial Growth Centre Wadloor Road, Chicksugur Cross, Chicksugur India-584 134 Raichur, Karnataka
Holder of the Certificate of Suitability	SHILPA MEDICARE LIMITED 10/80 Rajendra Gunj India-584 102 Raichur, Karnataka
References of CEP dossier	CEP 2004-201 / Ambroxol hydrochloride
Inspection dates	18/03/2015 to 20/03/2015
Inspector / Name of organisation	Mr TEMLEITNER Arpad, EDQM, Council of Europe ; Mr KELLER Michel, SWISSMEDIC, Switzerland.
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 2015-007 P01

Strasbourg, 17 August 2015


On behalf of the
Director of EDQM



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