

ATTESTATION OF INSPECTION

Inspected site	JP Laboratories Private Ltd Midc, Block A-76 Chemical Zone Kurkumbh IND – 413 801 Daund, Pune
Holder of the Certificate of Suitability	JP Laboratories Private Ltd Midc, Block A-76 Chemical Zone Kurkumbh IND – 413 801 Daund, Pune
References of Certificates	• CEP 2002 – 104 / Isosorbide mononitrate diluted
Inspection dates	27 th to 29 th December 2006
Inspectors	<ul style="list-style-type: none"> • Ms Elisabetta Montesoro, Inspector, Istituto Superiore di Sanità, (Italy) ; • Mr Guillaume Renaud, Inspector, Agence Française de Sécurité Sanitaire des Produits de Santé, (France).
GMP/QA rules applied by the manufacturer	EU guidelines on Good Manufacturing Practice for Active Substances used as Starting Materials (as published in the Rules governing Medicinal Products in the European Union, Volume 4).
Scope of the inspection	The inspection focussed on the compliance with the information provided in the above mentioned dossiers for certification. Compliance with Quality Assurance and Good Manufacturing Practices has also been checked for items directly related to the inspected products.
Conclusion	The company operates in accordance with the certification dossier and requirements of the resolution AP-CSP (93) 5 as amended.

Strasbourg, 26th September 2007

On behalf of the
Director of EDQM & HealthCare