



ATTESTATION OF INSPECTION

Inspected sites	Unimark Remedies Ltd Phase I, Plot N° 41, GIDC, Valsad Dt., Gujarat IND - 396 195 Vapi
	Mangalam Drugs and Organics Ltd Unit I, Plot 187, 2nd Phase GIDC, Valsad IND - 396 195 Vapi
Holder of the Certificates of Suitability	Unimark Remedies Ltd 19 Crystal, 1st Floor, Juhu Road Santa Cruz (West) IND - 400 054 Mumbai
References of Certificate	• CEP 2001 - 350 / Nimesulide
Inspection dates	3 rd to 6 th December 2006
Inspectors	 Ms Régine SCHWARZ, Inspector, Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH, AGES PharmMed, (Austria); Mr Tobias GOSDSCHAN, Inspector, Swiss Agency for Therapeutic Products, SWISSMEDIC (Switzerland).
GMP/QA rules applied by the manufacturer	EU guidelines on Good Manufacturing Practice for Active Substance 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 dossier 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, 5 September 2007

On behalf of the Director of EDQM & HealthCare

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