

ATTESTATION OF INSPECTION

Inspected sites	INDUKERN Chemie GmbH Afrikastrasse 4 D- 20457 Hamburg SCHWARZE & Cons. GmbH Afrikastrasse 4 D- 20457 Hamburg
Holder of the Certificates of Suitability	INDUKERN Chemie AG Wiesenstrasse 33, CH – 8952 Schlieren
References of Certificates	<ul style="list-style-type: none"> • All CEPs granted to INDUKERN Chemie AG
Inspection dates	30th March 2007
Inspectors	<ul style="list-style-type: none"> • Ms Florence Benoit-Guyod, Inspector, EDQM, France ; • Mr Michel Keller, Inspector, Swissmedic, Switzerland ; • Mr Michael Martens, Inspector, Behörde für Soziales, Familie, Gesundheit und Verbraucherschutz, Germany.
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 (99) 4.

Strasbourg, 13 July 2007



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