CERTIFICATE No. GIF-IW-N-4022/122/09

Główny Inspektor Farmaceutyczny

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC as amended

Main Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Kato Labs Sp. z o.o.
138/82, Marszałkowska Str., 00-004 Warszawa, Poland

site address

Kato Labs Sp. z o.o.
9, Instalatorów Str., 02-239 Warszawa, Poland

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-N-4001/103/06/4001/41/06** in accordance with Art. 13 of Directive 2001/20/EC transposed in Pharmaceutical Law of 6th of September 2001 (Dz. U. z 2008 r. Nr 45, poz. 271, z późn. zm.).

From the knowledge gained during inspection of this manufacturer the latest of which was conducted on **3-4/11/2009**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 15.01.2010

Main Pharmaceutical Inspectorate
38/40, Długa Str., 00-238 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zofia Ulz
Main Pharmaceutical Inspector

Part 2

Human Investigational Medicinal Products

Investigational Medicinal Products for phase I, II, III clinical trials

1 MANUFACTURING OPERATIONS **Batch Release** **Storage** **Distribution**	
1.5	**Packaging only**
	1.5.2 Secondary packing

date: 18.01.2010.

Main Pharmaceutical Inspectorate
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Zofia Ulz
Main Pharmaceutical Inspector