CERTYFICATE No. (

ODPIS

Main Pharmaceutical Inspector

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC as amended

Main Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

site address

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/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 **10-13/01/2012**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

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

date: 2014 -01- 14

Main Pharmaceutical Inspectorate
12, Senatorska Str., 00-082 Warsaw, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Main Pharmaceutical Inspector

CERTYFICATE No. (

Part 2

Names of substances subject to inspection:

A.	Manufacture of Active Substance by Chemical Synthesis
	1. Upstream Chemical Synthesis (Manufacture of intermediates) *2. Downstream Chemical Synthesis (Final synthetic steps)* *3. Salt formation / Purification steps : salt formation*
E	General Finishing Steps
	1. Physical processing steps: centrifugation, filtration, drying, screening, milling / micronisation, sieving *2. Primary Packaging* *3. Secondary Packaging* *4. Other: homogenization of batches, storage*
F	Quality Control Testing
	1. Physical / Chemical testing *2. Microbiological testing (excluding sterility testing)*
G	Other activities relating to active substances
	2. Distribution

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

date: 2014 -01- 14

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