



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 as amended

Main Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

Instytut Farmaceutyczny

8, Rydygiera Str., 01-793 Warsaw, POLAND

site address

Instytut Farmaceutyczny

8, Rydygiera Str., 01-793 Warsaw, POLAND

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).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **16-18/09/2008**, 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.

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



date: 10.11.2008

Zofia Ulz

Main Pharmaceutical Inspector

Active substances

1 MANUFACTURING OPERATIONS

Purchase of starting materials

Control operations regarding supervision of production processes

Batch Release

Storage

Distribution

Names of substances subject to inspection:

Karwedilol

Olanzapina

Clopidogrel



date: 10.11.2008

Main Pharmaceutical Inspectorate
38/40, Długa Str., 00-238 Warsaw, Poland
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A handwritten signature in blue ink, appearing to read "Zofia Ulz".

Zofia Ulz
Main Pharmaceutical Inspector