

CERTIFICATE No. GIF-IW-400/0013_01_01/04/79/14

*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 Medycyny Pracy im. prof. dra med. Jerzego Nofera
8 Świętej Teresy od Dzieciątka Jezus Str., 91-348 Łódź, POLAND**

site address

**Instytut Medycyny Pracy im. prof. dra med. Jerzego Nofera
Zakład Laboratorium Badań Produktów Leczniczych i Weterynaryjnych
w Systemie Jakości GMP
8 Świętej Teresy od Dzieciątka Jezus Str., 91-348 Łódź, POLAND**

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-N-4001/WTC013/260/11** in accordance with Art. 40 of Directive 2001/83/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 **01-02/04/2014**, 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 18 months 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 in EudraGMP. If it does not appear, please contact the issuing authority.



date: 2014 -07- 23

Main Pharmaceutical Inspectorate
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Zofia Ulz
Main Pharmaceutical Inspector

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.6 Quality control testing

1.6.4 *Biological*



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