



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

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

has been inspected under the national inspection programme in connection with manufacturing authorisation No. **GIF-IW-N-4001/148/08** in accordance with Art. 40 of Directive 2001/83/EC transposed in pharmaceutical law of 6<sup>th</sup> of September 2001 (Dz. U. z 2008 r. Nr 45, poz. 271 i Nr 227, poz. 1505)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **26-28/11/2008**, 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.



date: 4.02.2009

Main Pharmaceutical Inspectorate  
38/40, Długa Str., 00-238 Warsaw, Poland  
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Zofia Ulz  
Main Pharmaceutical Inspector

Part 2

Human Medicinal Products

**1 MANUFACTURING OPERATIONS**

**Purchase of starting materials**

**Batch Release**

**Storage**

**Distribution**

**1.1**

**Sterile Products**

**1.1.1 Aseptically prepared (list of dosage forms)**

1.1.1.2 Lyophilisates

**1.2**

**Non-sterile products**

**1.2.1 Non-sterile products (list of dosage forms)**

1.2.1.2 Capsules, soft shell

**1.6**

**Quality control testing**

**1.6.3 Chemical/Physical**



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