



**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/

confirms the following:
the manufacturer:

**Instytut Farmaceutyczny
8, Rydygiera, 01-793 Warsaw, POLAND**

site address:

**Instytut Farmaceutyczny
8, Rydygiera, 01-793 Warsaw, POLAND**

In an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC/ Art. 80(1) Dyrektywy 2001/82/EC transposed in pharmaceutical law of 6 September 2001 (Dz. U. z 2004r. Nr 53, poz. 533 z późn. zm.)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **10-12 VII 2007**, it is considered that it complies with the Good Manufacturing Practice requirements¹ laid down in 2003/94/EC/The principles of GMP for active substances¹.

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.

¹These requirements fulfil the GMP recommendations of WHO.

date: 05.09.2007

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 Medicinal Products

1 MANUFACTURING OPERATIONS

Manufacturing of active substance

Manufacture of active substance.

Names of substances subject to inspection:

Alfacalcidol

Calcifediol

Calcipotriol

Calcitriol

Tacalcitol

date: 05.09.2007



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

A handwritten signature in blue ink, appearing to read "Zofia Ulz".

Zofia Ulz
Main Pharmaceutical Inspector