



**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:

ALKAT Sp. z o.o.
63, J. Conrada Str., 31-357 Kraków, POLAND

site address:

ALKAT Sp. z o.o.
92, Piłsudskiego Ave., 41-308 Dąbrowa Górnicza, POLAND

Has been inspected under the national inspection programme in connection with manufacturing authorisation - no. **GIF-IW-4001/32/05/FAO-W/306/2000** in accordance with Art. 40 of Directive 2001/83/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 **19-21 IX 2006**, it is considered that it complies with the Good Manufacturing Practice requirements¹ laid down in Directive 2003/94/EC¹.

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: 21. 12. 2006

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Zofia Ulz
Main Pharmaceutical Inspector

