

- Permit translation from polish -

**Main Pharmaceutical Inspectorate
GIF (Główny Inspektorat Farmaceutyczny)
GIF-N-P/472/001/2007**

Warsaw, 03.01.2007

PERMIT

According to art. 35 st. 1 and 8 statutes from 29 July, 2005 – against drug addicts (Dz.U. from 2005, no. 179, pos. 1485 with further changes)

**Head Pharmaceutical Inspector
GIF (Główny Inspektorat Farmaceutyczny)**

grants

KATO LABS Sp. z o.o.

ul. Marszałkowska 138/82, 00-004 Warsaw

**the permission for the storage and distribution of narcotics groups I-N, II-N, III-N and
psychotropic substances groups II-P, III-P, IV-P, designated for clinical research**

KRS Company Registry no.: 0000100735

**Permission for the manufacturing of healthcare products: no. GIF-IW-
4001/103/06/4001/41/06**

Permission for the import of healthcare products: no. GIF-IW-4000/I/11/05

Place of manufacturing and import: Warsaw, ul. Instalatorów 9

The permission is granted provided the regulations according to narcotics and psychotropic substances are followed, specifically:

-the appointment of a Pharmacist to be responsible for the manufacturing, storage and circulation of narcotics and psychotropic substances, and holding control books,

- agreement with the Head Pharmaceutical Inspector before the 28th of February each year the amount needed, amount to be manufactured and the amount stored for medical treatments and scientific purposes,

- submitting reports to the Head Pharmaceutical Inspector on the manufacturing of the narcotics and psychotropic substances,

- setting up a technical settlement of norms for usage of the outgoing substances, recognised as narcotics and psychotropic substances, and used in the process of manufacturing for permitted losses during particular stages of production

- securing the narcotics and psychotropic substances against any usage by unauthorised persons for a reason not meant for their allocation.

Direct supervision of the manufacturing, storage and circulation is done by the organs of Pharmaceutical Inspection.

This permit should be held at the manufacturer and should be shown on every request by authorities.

This permit can be withdrawn in case of not following regulations.

Upon finishing the manufacture of the listed narcotics and psychotropic substances, the permission should be returned to Head Pharmaceutical Inspector.

JUSTIFICATION:

According to art. 107 st. 4 from the statute book of administrative proceedings, justification was withdrawn since the decision was taken into account in full on request of the party.

Information:

According to art. 127 st. 3 from the statute book of administrative proceedings, the side may proceed to the Head Pharmaceutical Inspector with an application for appeal on this matter.

GIF seal
signed Zofia Ulz

Received:

- 1) Kato Labs Sp. z o.o.
ul. Marszałkowska 138/82, 00-004 Warsaw
- 2) Appropriate Manufacturing Inspector
- 3) a/a.