Chief Pharmaceutical Inspector

IWZJ.405.13.2017.ER.1
WTC/0374_01_01/248

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC and Art. 80(5) of Directive 2001/82/EC with amendments

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

NOVICHEM Sp. z o.o.
ul. Główna 4, 41-508 Chorzów, POLAND

site address

NOVICHEM Sp. z o.o.
ul. Główna 3, 41-508 Chorzów, POLAND

is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2016, item 2142) in connection with registration no **85/WTC0374/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **26-28/09/2017**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC, Directive 91/412/EEC and the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

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.

acting Chief Pharmaceutical Inspector

Zbigniew Niewójt

date: 2017 -12- 07

Chief Pharmaceutical Inspectorate
ul. Senatorska 12, 00-082 Warszawa, Poland
Tel. +48 22 635 99 51, fax. +48 22 635 99 57

Zbigniew Niewójt
Chief Pharmaceutical Inspector

Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** - Magnesium hydrogen DL-aspartate tetrahydrate - Potassium hydrogen DL-aspartate semihydrate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.3 Salt formation / Purification steps** (crystallisation)
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, milling, homogenization) **3.5.2 Primary Packaging** (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.3 Secondary Packaging** (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **3.5.4 Other** (blending)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** Distribution, storage

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector

Zbigniew Niewójt

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