2024 -08- 30

ISF.405.105.2024.IP.1
WTC/0374_01_01/188

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

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 transposed in the following national legislation: Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2024, item 686) in connection with the entry in the Register no **85/WTC0374/API/15**.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **07/06/2024,** it is considered that it complies with the Good Manufacturing Practice requirements laid down 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.

Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu /

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 EudraGMDP. If it does not appear, please contact the issuing authority.

GŁÓWNY INSPEKTOR FARMACEUTYCZNY

Chief Pharmaceutical Inspector
Łukasz Pietrzak

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

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 - blending) **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** (storage and distribution)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

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Part 2

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Magnesium lactate dihydrate

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, sieving, homogenization - blending) **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** (storage and distribution)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

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