2021 -02- 0 5

CHIEF PHARMACEUTICAL INSPECTOR

IWSC.405.4.2021.PFa.1
WTC/0098_01_04/15

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 as amended

Chief Pharmaceutical Inspector

/the Competent Authority of Poland/

confirms the following:

the manufacturer

ICN Polfa Rzeszów S.A.

ul. Przemysłowa 2, 35-959 Rzeszów, POLAND

site address

ICN Polfa Rzeszów S.A.

ul. Przemysłowa 2, 35-959 Rzeszów, 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 2020, item 944) in connection with registration no **98/WTC0098/API/15.**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **18 – 23.11.2020**, 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.

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

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Bisoprolol fumarate
- Tolperisone hydrochloride

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates **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) **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** (homogenization of batches)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Magnesium valproate

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) **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** (homogenization of batches)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** – Aluminium acetate tartrate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates **3.1.2 Manufacture of crude active substance** **3.1.3 Salt formation**
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, milling) **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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** **4.1 Distribution**

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** - Chlorquinaldol

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates **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) **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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** **4.1 Distribution**

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

– 2-phenoxyethanol

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance **3.1.4 Other** (distillation)
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (homogenization of batches)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** **4.1 Distribution**

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s):

- Choline salicylate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates **3.1.2 Manufacture of crude active substance** **3.1.4 Other** (distillation)
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **3.5.4 Other** (homogenization of batches)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** **4.1 Distribution**

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3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES **Active Substance(s):** - Sulfathiazole

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates **3.1.2 Manufacture of crude active substance** **3.1.3 Salt formation**
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps (drying, milling) **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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing **3.6.2 Microbiological testing** (excluding sterility testing)
4	**OTHER ACTIVITIES - ACTIVE SUBSTANCES** **4.1 Distribution**

Any restrictions or clarifying remarks related to the scope of this certificate:

The certificate was issued on the basis of remote inspection.

acting Chief Pharmaceutical Inspector
Hanna Myjak
Director General

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