

## Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet

CERTIFICATE NUMBER: *OGYÉI/64170-6/2022*

### CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1,2</sup>

#### Part 1

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

The competent authority of Hungary confirms the following:

The manufacturer: ***Iol Chemicals And Pharmaceuticals Limited***

Site address: ***Village Fatehgarh Channa, Mansa Road, Trident Complex, Barnala, 148101, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100017919 / LOC-100026712***

DUNS Number: ***67-760-5646***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-11-17***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569<sup>3</sup>
- The principles of GMP for active substances<sup>3</sup> 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 EudraGMDP. If it does not appear, please contact the issuing authority.

<sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection:

**IBUPROFEN(en)**

**LAMOTRIGINE(en)**

**METFORMIN HYDROCHLORIDE(en)**

**FENOFIBRATE(en)**

**CLOPIDOGREL HYDROGEN SULFATE(en)**

**PANTOPRAZOLE SODIUM SESQUIHYDRATE(en)**

**GABAPENTIN(en)**

**LEVETIRACETAM(en)**

**LOSARTAN POTASSIUM(en)**

**PARACETAMOL(en)**

**IBUPROFEN SODIUM DIHYDRATE(en)**

**IBUPROFEN LYSINATE(en)**

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:IBUPROFEN

#### 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:

#### 3.5 General Finishing Steps

- 3.5.1 Physical processing steps:
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
- 3.5.3 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

Active Substance:LAMOTRIGINE

#### 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:

#### 3.5 General Finishing Steps

	<p>3.5.1 Physical processing steps:</p> <p>.</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:METFORMIN HYDROCHLORIDE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	<p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps:</p> <p>.</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p>3.5.1 Physical processing steps:</p> <p>.</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:FENOFIBRATE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps:</p> <p>.</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p>3.5.1 Physical processing steps:</p> <p>.</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p>3.6.1 Physical / Chemical testing</p>

	3.6.2 Microbiological testing excluding sterility testing
Active Substance:CLOPIDOGREL HYDROGEN SULFATE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps: 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance:PANTOPRAZOLE SODIUM SESQUIHYDRATE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps: 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance:GABAPENTIN	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
<b>3.5</b>	<b>General Finishing Steps</b>

	<p>3.5.1 Physical processing steps:</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:LEVETIRACETAM	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	<p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps:</p> <p>.</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p>3.5.1 Physical processing steps:</p> <p>.</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:LOSARTAN POTASSIUM	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps:</p> <p>.</p>
<b>3.5</b>	<b>General Finishing Steps</b>
	<p>3.5.1 Physical processing steps:</p> <p>.</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>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)</p>
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing

	3.6.2 Microbiological testing excluding sterility testing
Active Substance:PARACETAMOL	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: .
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance:IBUPROFEN SODIUM DIHYDRATE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.3 Salt formation / Purification steps: .
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps: . 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance:IBUPROFEN LYSINATE	
<b>3.1</b>	<b>Manufacture of Active Substance by Chemical Synthesis</b>
	3.1.3 Salt formation / Purification steps: .
<b>3.5</b>	<b>General Finishing Steps</b>
	3.5.1 Physical processing steps: .

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 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)
<b>3.6</b>	<b>Quality Control Testing</b>
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing

2023-01-16

Name and signature of the authorised person of the  
Competent Authority of Hungary

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*Confidential*  
*National Institute of Pharmacy and Nutrition*  
Tel: *Confidential*  
Fax: *Confidential*