Regierung Von Oberbayern

CERTIFICATE NUMBER: ***DE_BY_04_GMP_2023_0114***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

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

The competent authority of Germany confirms the following:
The manufacturer: ***PharmaZell GmbH***
Site address: ***Rosenheimer Strasse 43, Raubling, Bavaria, 83064***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012552*** / ***LOC-100021381***
DUNS Number: ***50-663-9652***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***DE_BY_04_MIA_2023_0025*** in accordance with Art. 40 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 ***2022-07-07***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]
- The principles of GMP for active substances [3] 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. 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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products
	1.3.2 Batch Certification (list of product types) 1.3.2.6 Human or animal extracted products
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Biological active starting materials(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.8 Other solid dosage forms
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.3 Biological medicinal products 2.2.3.6 Human or animal extracted products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Manufacture of active substance. Names of substances subject to inspection:
Phospholipid fraction from bovine lung (Surfactant SF-RI1)(en)
Mesalazine(en)
Acetylcysteine(en)
Propafenone Hydrochloride(en)
Balsalazide Disodium(en)
Prucalopride(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES
Active Substance:Phospholipid fraction from bovine lung (Surfactant SF-RI1)

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.2 Extraction of substance from animal source 3.2.6 Purification of extracted substance Animal
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Sieving, 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:Mesalazine

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: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:Acetylcysteine

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Sieving, 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

Active Substance:Propafenone Hydrochloride

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
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

Active Substance:Balsalazide Disodium

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: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying 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

Active Substance:Prucalopride

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: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**

	3.5.1 Physical processing steps: Drying, 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

Ad 1.5.1.8 Powder For the production of the active substance Acetylcysteine are used animal extracted products

2023-08-17

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

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Confidential
Regierung von Oberbayern - Zentrale
Arzneimittelüberwachung Bayern
Tel:***Confidential***
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