Norwegian Medicines Agency

CERTIFICATE NUMBER: ***23/02878-19***

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

Part 1

Issued following an inspection in accordance with :
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 111(5) of Directive 2001/83/EC as amended
Art. 63 of Regulation (EU) 536/2014

The competent authority of Norway confirms the following:
The manufacturer: ***Pharma Production AS***
Site address: ***Karihaugveien 22, Oslo, 1086, Norway***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034036*** / ***LOC-100053789***

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC, Art. 61 of Regulation (EU) No 536/2014 and Art. 88 of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-03-10***, 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 [3]
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

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.

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[1] *The certificate referred to in paragraph Art. 80(5) of Directive 2001/82/EC, Art. 111(5) of Directive 2001/83/EC and Art. 15 of Directive 2001/20/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

Part 2

Veterinary Medicinal Products
Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use Special Requirements 7 Other: Verruxin 200 mg/200 mg solution / Verruxin solution(en) 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids Special Requirements 7 Other: Verruxin gel(en) 1.2.1.17 Other: Nasal spray solution, unidose / Veterinary liquid preparations for cutaneous application (Dip concentrates)(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use Special Requirements 7 Other: Verruxin 200 mg/200 mg solution / Verruxin solution(en) 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids Special Requirements 7 Other: Verruxin gel(en) 1.5.1.17 Other non-sterile medicinal products: Nasal spray, solution, unidose / Veterinary liquid preparations for cutaneous application (Dip concentrates)(en)
	1.5.2 Secondary packaging

1.6	Quality control testing
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

Has been inspected in connection with MIA no. 22/25703-1. \| In addition to the products listed under 1.2.1; sections 1.2.2 and 1.6 apply to the following active pharmaceutical ingredients: - Methadone hydrochloride, imported from Switzerland and India, - Levomethadone hydrochloride, imported from Switzerland and India, - Naloxone hydrochloride, imported from Switzerland. \| For IMP these sections apply: 1.2.1.5, 1.2.2, 1.3.1.5, 1.3.2.5 , 1.5.1.5, 1.5.2 and 1.6.2. 1.3 applies only to IMP.

2023-07-03

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

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Norwegian Medicines Agency
Tel:***Confidential***
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