

Manufacturer/Importer Authorisation ¹

1. Authorisation Number MIAE-CH-511265-102704327
2. Name of authorisation holder F. Hoffmann-La Roche AG (ORG-100001445 / LOC-100000954)
3. Address(es) of manufacturing site(s) F. Hoffmann-La Roche AG (ORG-100001445 / LOC-100001980),
Wurmisweg, Kaiseraugst, 4303, Switzerland
F. Hoffmann-La Roche AG (ORG-100001445 / LOC-100000954),
Grenzacherstrasse 124, Basel Town, 4058, Switzerland
- 3.a Additional details on units inspected of manufacturing site(s) address(es)
4. Legally registered address of authorisation holder Grenzacherstrasse 124, Basel Town, 4058, Switzerland
5. Scope of authorisation and dosage forms¹ ANNEX 1 and/ or ANNEX 2
6. Legal Basis of authorisation Issued under the provisions of the Mutual Recognition Agreement between the European Union and Switzerland
7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation confidential
8. Signature
9. Date 2023-09-08
10. Annexes attached Annex 1 and/or Annex 2
Optional Annexes as required:
Annex 3(Addresses of Contract Manufacturing Site(s))
Annex 4(Addresses of Contract laboratories)
Annex 5(Name of Qualified Person)
Annex 6(Name of responsible persons)
Annex 7(Date of inspection on which authorisation granted, scope of last inspection)
Annex 8(Manufactured/ imported products authorised)

¹Guidance on the interpretation of this template can be found in the Interpretation of the Union format for Manufacturer/Importer Authorisation.

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: F. Hoffmann-La Roche AG, Wurmisweg, Kaiseraugst, 4303, Switzerland

Additional Details:

| |
|-------------------------------|
| Human Medicinal Products |
| Veterinary Medicinal Products |

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

| | |
|------------|--|
| 1.1 | Sterile products |
| | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Rocephin(en) |
| | <i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile products |
| | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets |
| | <i>1.2.2 Batch certification</i> |
| 1.3 | Biological medicinal products (list of product types) |
| | <i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products |
| | <i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products |
| 1.5 | Packaging |
| | <i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.8 Other solid dosage forms |

| | |
|------------|---|
| | 1.5.1.13 Tablets |
| | <i>1.5.2 Secondary packaging</i> |
| 1.6 | Quality control testing |
| | <i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i> |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

LOC-100001980 is valid for two at Swissmedic registered sites: Site 1: Herstellung, Verpackung und Prüfung Arzneimittel (NCA Reference Key 1000114) with following assigned operations: 1.1.1.2; 1.1.1.4; 1.1.1.6; 1.1.2.3; 1.1.3: 1.2.1.1; 1.2.1.8; 1.2.1.13; 1.2.2; 1.3.1.5; 1.3.2.5; 1.5.1.1; 1.5.1.2; 1.5.1.8; 1.5.1.13; 1.5.2; 1.6.1; 1.6.2; 1.6.3; 1.6.4. Site 2: Herstellung klinischer Versuchspräparate (NCA Reference Key 1005102): no assigned operations for scope H/V

SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : F. Hoffmann-La Roche AG, Wurmisweg, Kaiseraugst, 4303, Switzerland

Additional Details:

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| Human Investigational Medicinal Products |
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

| | |
|------------|--|
| 1.1 | Sterile products |
| | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids |
| 1.2 | Non-sterile products |
| | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets |
| 1.3 | Biological medicinal products (list of product types) |
| | <i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products |
| 1.5 | Packaging |
| | <i>1.5.1 Primary Packaging</i> 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets |
| | <i>1.5.2 Secondary packaging</i> |
| 1.6 | Quality control testing |
| | 1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

LOC-100001980 is valid for two at Swissmedic registered sites: Site 1: Herstellung, Verpackung und Prüfung Arzneimittel (NCA Reference Key 1000114) with following assigned operations:

1.1.1.2; 1.1.1.4; 1.2.1.1; 1.2.1.8; 1.2.1.13; 1.3.1.5; 1.5.1.8; 1.6.1; 1.6.2. Site 2: Herstellung klinischer
Versuchspräparate (NCA Reference Key 1005102): with following assigned operations: 1.5.1.8

EudraGMP

GMP

SCOPE OF AUTHORISATION

ANNEX 1

Name and address of the site: F. Hoffmann-La Roche AG, Grenzacherstrasse 124, Basel
Town, 4058, Switzerland

Additional Details:

| |
|-------------------------------|
| Human Medicinal Products |
| Veterinary Medicinal Products |

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

| | |
|------------|--|
| 1.1 | Sterile products |
| | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids |
| | <i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile products |
| | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets |
| | <i>1.2.2 Batch certification</i> |
| 1.3 | Biological medicinal products (list of product types) |
| | <i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products |
| | <i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products |
| 1.5 | Packaging |
| | <i>1.5.1 Primary Packaging</i> 1.5.1.8 Other solid dosage forms |
| 1.6 | Quality control testing |
| | <i>1.6.2 Microbiological: non-sterility</i> |

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| <i>1.6.3 Chemical/Physical</i> |
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| <i>1.6.4 Biological</i> |
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Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

LOC-100000954 is valid for three at Swissmedic registered sites: Site 1: Herstellung klinischer Versuchspräparate (NCA Reference Key 1001523) with following assigned operations: no assigned operations for scope H/V. Site 2: Herstellung Wirkstoffe und Arzneimittel (NCA Reference Key 1005965): with following assigned operations: 1.2.1.8; 1.2.1.13; 1.2.2; 1.5.1.8; 1.6.2; 1.6.3; Site 3: F. Hoffmann-La Roche AG Basel Contract Organizations (NCA Reference Key 1100181): with following assigned operations: 1.1.3; 1.2.2; 1.3.2.5



SCOPE OF AUTHORISATION

ANNEX 2

Name and address of the site : F. Hoffmann-La Roche AG, Grenzacherstrasse 124, Basel
Town, 4058, Switzerland

Additional Details:

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

| Part 1 - MANUFACTURING OPERATIONS | |
|--|--|
| 1.1 | Sterile products |
| | <i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids |
| | <i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids |
| | <i>1.1.3 Batch certification</i> |
| 1.2 | Non-sterile products |
| | <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets |
| | <i>1.2.2 Batch certification</i> |
| 1.3 | Biological medicinal products (list of product types) |
| | <i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products |
| | <i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products |
| 1.5 | Packaging |
| | <i>1.5.1 Primary Packaging</i> 1.5.1.8 Other solid dosage forms |
| 1.6 | Quality control testing |
| | 1.6.3 Chemical/Physical |

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations (for Public users)

LOC-100000954 is valid for three at Swissmedic registered sites: Site 1: Herstellung klinischer Versuchspräparate (NCA Reference Key 1001523) with following assigned operations: 1.1.1.2; 1.1.1.4; 1.1.2.3; 1.1.3; 1.2.1.1; 1.2.1.8; 1.2.1.13; 1.2.2; 1.3.1.5; 1.3.2.5; 1.5.1.8; 1.6.3; 1.6.4. Site 2: Herstellung Wirkstoffe und Arzneimittel (NCA Reference Key 1005965): with following assigned operations: 1.2.1.8; 1.2.1.13; 1.5.1.8; 1.6.2; Site 3: F. Hoffmann-La Roche AG Basel Contract Organizations (NCA Reference Key 1100181): no assigned operations for scope I

Update operation comments in english

replaced by updated MIA entry (new issued authorisation)