HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

*Health Products Regulatory Authority*

CERTIFICATE NUMBER: *15416/ASR11426/00001*

# 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 Ireland confirms the following:
The manufacturer: ***Swords Laboratories***
Site address: ***Watery Lane, Swords, Co. Dublin, Ireland***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:
***Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-01-13*** , it is considered that it complies with :

- 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. 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.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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.*



An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire

## Part 2

Manufacture of active substance. Names of substances subject to inspection :
***APIXABAN( en)***
***ATAZANAVIR SULPHATE( en)***
***CAPTOPRIL( en)***
***DACLATASVIR DIHYDROCHLORIDE( en)***
***DAPAGLIFLOZIN PROPANEDIOL( en)***
***DASATINIB( en)***
***ENTECAVIR( en)***
***FOSINOPRIL SODIUM( en)***
***IXABEPILONE( en)***
***PACLITAXEL( en)***
***SAXAGLIPTIN( en)***
***STAVUDINE( en)***
***BECLABUVIR HYDROCHLORIDE ( en)***

| **3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES** | |
|---|---|
| Active Substance : APIXABAN | |
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : ATAZANAVIR SULPHATE | |
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping |

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|---|---|
| | 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : CAPTOPRIL

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : DACLATASVIR DIHYDROCHLORIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : DAPAGLIFLOZIN PROPANEDIOL

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |

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|---|---|
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : DASATINIB

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : ENTECAVIR

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Wet Milling<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging |

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| | 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 : FOSINOPRIL SODIUM

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : IXABEPILONE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>3.6.2 Microbiological testing excluding sterility testing |

Active Substance : PACLITAXEL

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| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |

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| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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<br>3.6.2 Microbiological testing excluding sterility testing |

Active Substance : SAXAGLIPTIN

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 : STAVUDINE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation (Purification step only) |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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** |

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|---|---|
| | 3.6.1 Physical / Chemical testing<br>3.6.2 Microbiological testing excluding sterility testing |
| Active Substance : BECLABUVIR HYDROCHLORIDE | |
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.1 Manufacture of active substance intermediates<br>3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps :<br>Crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps :<br>Drying, Delumping<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>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 |

*2017-04-24*

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

CERTIFIED HPRA

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*Health Products Regulatory Authority*
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Fax:

Fingal Dublin CHAMBER
Date: 18.07.2017
Accredited Member of Chambers Ireland

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