



# Health Products Regulatory Authority

CERTIFICATE NUMBER: 19617/ASR12228/00001

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

### 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: SK Biotek Ireland Limited

Site address: Watery Lane, Swords, Co. Dublin, K67 AY91, 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 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.

I certify this is an original document.

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VINCENT SHANNON NOTARY PUBLIC 29 Main Street, Swords

County Dublin, Ireland

Health Products Regulatery Authority

Document Reviewed by

Pate: 2200 50400 2018

Online EudraGMDP, Ref key: 45505

Issuance Date: 2017-12-22

Signatory: Mr. Paul Sexton

Page 1 of 6

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland

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.

<sup>&</sup>lt;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.

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This Apostule fully certifies the authenticity of the signature and the capacity of the person who has signed the public documents and where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not perfusible content of the document for which it was issued. To verify the Issuance of this Apostille, see www.authentications.dfat.ie

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

APIXABAN(en)

ATAZANAVIR SULPHATE(en)

DACLATASVIR DIHYDROCHLORIDE (en)

DAPAGLIFLOZIN PROPANEDIOL(en)

DASATINIB( en)

ENTECAVIR(en)

IXABEPILONE(en)

SAXAGLIPTIN(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
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
	Crystallisation (Purification Step Only)
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

Activ	e Substance: ATAZANAVIR SULPHATE
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:
	Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, Delumping
	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

Online EudraGMDP, Ref key: 45505

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Signatory: Mr. Paul Sexton

Page 2 of 6

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	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:  Crystallisation
3.5	General Finishing Steps
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	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	Crystallisation (purification step only)  General Finishing Steps
	3.5.1 Physical processing steps:
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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
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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:
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Page 3 of 6

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Crystallisation (Purification Steps Only)  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)  Quality Control Testing		3.1.2 Manufacture of crude active substance
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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)  Quality Control Testing		
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)  Quality Control Testing	3.5	
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)  Quality Control Testing		
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)  Quality Control Testing	H	
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)  Quality Control Testing		which is in direct contact with the substance)
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)  Quality Control Testing		
identification or traceability (lot numbering) of the active substance)  Quality Control Testing		material or container. This also includes any labelling of the material which could be used for
3.6 Quality Control Testing		identification or traceability (lot numbering) of the active substance)
	3.6	
3.6.1 Physical / Chemical testing		3.6.1 Physical / Chemical testing

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	3.6.2 Microbiological testing excluding sterility testing
Acti	ive Substance : SAXAGLIPTIN
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	Crystallisation (Purification Step Only)  General Finishing Steps
0.5	
	3.5.1 Physical processing steps:
	Drying, Delumping  3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material)
	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
	ve Substance : BECLABUVIR HYDROCHLORIDE
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 :  Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Delumping
	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
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing
0.0	
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

This certificate is only applicable to GMP activities performed at the Watery Lane facility from the 1st of January 2018, following the transfer of ownership of the Watery Lane facility from Bristol Meyer Squibb (BMS) to SK Biotek.

Page 5 of 6

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- Addition	
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Name and signature of the authorised person of the

Competent Authority of Ireland
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Health Products Regulatory Authority

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