

426613
Chile



AstraZeneca UK Limited
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom
T: +44 (0) 20 3749 5000

astrazeneca.com

TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

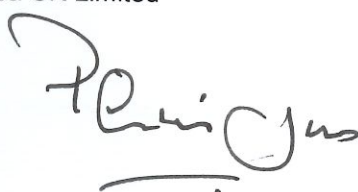
It is hereby confirmed that the attached Certificate is a true copy of the original document.



Signed: 
Vicky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

Dated 11/2/19

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 1EN, England,
Tel: 01753 851591



12/2/19

AstraZeneca UK Limited is a subsidiary of AstraZeneca PLC
Registered in England No. 3674842
Registered office: 1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom

283/19

APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Phillip H Jones
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public
Certified Attesté / Certificado	
5. at à / en	London
6. the le / el día	13 February 2019
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-1309531
9. Seal / stamp Sceau / timbre Sello / timbre 	10. Signature Signature Firma L. Smethurst 

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If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country

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French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 17MPP017HFR01

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 France confirms the following:

The manufacturer: **MINAKEM DUNKERQUE PRODUCTION**

Site address: **224 avenue de la Dordogne, Zone d'entreprises du Nord Gracht, DUNKERQUE, 59640, France**

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 **2017-03-09**, it is considered that it complies with :

- The principles of GMP for active substances³ 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.

**Vu pour la certification
conforme à l'original**

Part 2

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

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE(en) / **ESOMEPRAZOLE MAGNESIQUE TRIHYDRATE**(fr)

ESOMEPRAZOLE SODIUM(en) / **ESOMEPRAZOL SODOWY**(pl) / **ÉSOMÉPRAZOLE SODIQUE**(fr)
ESOMEPRAZOLE MAGNESIUM DIHYDRATE(en) / **ESOMEPRAZOLE MAGNESIQUE DIHYDRATE**(fr)

OMEPRAZOLE(en) / **OMÉPRAZOLE**(fr)

OMEPRAZOLE MAGNESIUM(en)

OMEPRAZOLE SODIUM(en) / **OMÉPRAZOLE SODIQUE**(fr)

BUDESONID(de) / **BUDESONIDUM**(cs) / **BUDESONIDE**(en) / **BUDEZONIDU**(pl) / **BUDÉSONIDE**(fr)

PRAZQUANTEL(en) / **PRAZQUANTEL**(fr)

POSACONAZOLE(en) / **POSACONAZOLE**(fr)

VERUBECESTAT(en)

LACOSAMIDE(fr) / **LACOSAMIDE**(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : **ESOMEPRAZOLE MAGNESIUM TRIHYDRATE**

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	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance : **ESOMEPRAZOLE SODIUM**

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	General Finishing Steps

Online EudraGMDP, Ref key: 41344

Issuance Date: 2017-05-03

Signatory: Mr.

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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)
	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
	3.6.2 Microbiological testing excluding sterility testing
Active Substance : ESOMEPRAZOLE MAGNESIUM DIHYDRATE	
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	General Finishing Steps
	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 : OMEPRAZOLE	
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	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation
	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
	3.6.2 Microbiological testing excluding sterility testing
Active Substance : OMEPRAZOLE MAGNESIUM	
3.1	Manufacture of Active Substance by Chemical Synthesis

Online EudraGMP, Ref key: 41844

Issuance Date: 2017-05-03

Signatory: Mr. G. P. P.

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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	General Finishing Steps
	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 3.6.2 Microbiological testing excluding sterility testing
Active Substance : OMEPRAZOLE SODIUM	
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	General Finishing Steps
	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 3.6.2 Microbiological testing excluding sterility testing
Active Substance : BUDESONIDE	
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	General Finishing Steps
	3.5.1 Physical processing steps : Micronisation 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)

Online EudraGMDP, Ref key: 41344

Issuance Date: 2017-05-03

Signatory: Mr

pour la certification
Conforme à l'original

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Active Substance : PRAZIQUANTEL	
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
3.5	General Finishing Steps
	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 : POSACONAZOLE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	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 : VERUBECESTAT	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	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 : LACOSAMIDE	

Online EudraGMDP, Ref key: 41344

Issuance Date: 2017-05-03

Signatory: Mr. G. H. H.

Vu pour la certification
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3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	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)

Posaconazole manufacturing limited to the PAZ-D intermediate /// Verubecestat manufacturing limited to the MK-8931-J intermediate /// Lacosamide manufacturing limited to the SPM20200 intermediate

2017-05-03

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

Le chef du pôle inspection des matières premières
Direction de l'inspection


Guillaume RENAUD

Mr. Guillaume Renaud
French National Agency for Medicines and Health
Products Safety
Tel: +33 1 55873911
Fax: +33 1 55873912

Vu pour la certification
conforme à l'original



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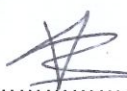
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TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

It is hereby confirmed that the attached Certificate is a true copy of the original document.

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 1EN, England,
Tel: 01753 851591

Signed: 
Vicky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

Dated 31/1/19



1/2/19

AstraZeneca UK Limited is a subsidiary of AstraZeneca PLC
Registered in England No. 3674842
Registered office: 1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom

185/14

APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Country: Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
This public document Le présent acte public / El presente documento público	
2. Has been signed by a été signé par ha sido firmado por	Phillip H Jones
3. Acting in the capacity of agissant en qualité de quien actúa en calidad de	Notary Public
4. Bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public
Certified Attesté / Certificado	
5. at à / en	London
6. the le / el día	07 February 2019
7. by par / por	Her Majesty's Principal Secretary of State for Foreign and Commonwealth Affairs
8. Number sous no / bajo el numero	APO-1297153
9. Seal / stamp Sceau / timbre Sello / timbre	
10. Signature Signature Firma	D. Brigden 

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French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 2019/HPF/FR/035

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER ^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of France confirms the following:

The manufacturer: **ASTRAZENECA DUNKERQUE PRODUCTION**

Site address: **224 avenue de la Dordogne, DUNKERQUE, 59640, France**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **M 19/028** in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:

Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-12-21**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing³ Practice laid down in Directive 2003/94/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.

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.

Part 2

Human Investigational Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i>
	1.2.1.9 Pressurised preparations
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i>
	1.5.1.9 Pressurised preparations
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i>
	<i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

This site is not authorised for blinding operations. Signatory: Mrs Dominique Debourges, deputy head of the pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2019-01-29

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

Confidential
French National Agency for Medicines and Health
Products Safety
Tel: *Confidential*
Fax: *Confidential*



AstraZeneca UK Limited
1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom
T: +44 (0) 20 3749 5000

astrazeneca.com

TO WHOM IT MAY CONCERN

Good Manufacturing Practice Certificate

is hereby confirmed that the attached Certificate is a true copy of the original document.

Signature Attested by Phillip Jones
Solicitor and Notary
Windsor House, Victoria Street,
Windsor, Berks, SL4 1EN, England,
Tel: 01753 851591

igned: 

Ricky Beattie
Regulatory Project Assistant
Regulatory Project Management Group
AstraZeneca UK Limited

Dated 8/11/17


4/11/17

AstraZeneca UK Limited is a subsidiary of AstraZeneca PLC
Registered in England No. 3674842
Registered office: 1 Francis Crick Avenue
Cambridge Biomedical Campus
Cambridge, CB2 0AA
United Kingdom

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. **Country:** United Kingdom of Great Britain and Northern Ireland
Pays / Pais:

This public document

Le présent acte public / El presente documento público

2. **Has been signed by**
a été signé par Phillip H Jones
ha sido firmado por

3. **Acting in the capacity of**
agissant en qualité de Notary Public
quien actúa en calidad de

4. **Bears the seal / stamp of**
est revêtu du sceau / timbre de The Said Notary Public
y está revestido del sello / timbre de

Certified

Attesté / Certificado

5. **at** London
à / en
6. **the** 15 November 2017
le / el día

7. **by** Her Majesty's Principal Secretary of State
par / por for Foreign and Commonwealth Affairs

8. **Number** APO-618764
sous no / bajo el numero

9. **Seal / stamp**
Sceau / timbre
Sello / timbre



10. **Signature** A. Northcott
Signature
Firma

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Medical Products Agency

CERTIFICATE NUMBER: 6.2.1-2017-029336

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 Sweden confirms the following:

The manufacturer: **AstraZeneca AB**

Site address: **Forskargatan 18, Södertälje, 15185, Sweden**

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 **2017-05-05** , it is considered that it complies with :

- The principles of GMP for active substances³ 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.



Part 2

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

FELODIPINE(en)

FORMOTEROL FUMARATE DIHYDRATE(en)

METOPROLOL TARTRATE(en)

METOPROLOL SUCCINATE(en)

TICAGRELOR(en)

TERBUTALINE SULPHATE(en)

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : FELODIPINE

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	General Finishing Steps
	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 : FORMOTEROL FUMARATE DIHYDRATE

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	General Finishing Steps
	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 : METOPROLOL TARTRATE



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	General Finishing Steps
	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
	3.6.2 Microbiological testing excluding sterility testing
Active Substance : METOPROLOL SUCCINATE	
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	General Finishing Steps
	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 : TICAGRELOR	
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	General Finishing Steps
	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 : TERBUTALINE 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 : -
3.5	General Finishing Steps
	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 3.6.2 Microbiological testing excluding sterility testing
Active Substance : ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	
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	General Finishing Steps
	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)

QC analysis can be done at address Forskargatan 18 and Gärtunavägen, Södertälje. (Analys får utföras på Forskargatan 18 och Gärtunavägen, Södertälje.)

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Name and signature of the authorised person of the

Signatory: Mr. Bengt Berglund





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