



Health Products Regulatory Authority

CERTIFICATE NUMBER: 16637/ASR11341-2

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: *Astellas Ireland Company Limited*
Site address: *Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, 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 **2017-05-12** , 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.

Health Products Regulatory Authority
Document Reviewed by: 
HPRA Reference: *CIX/ISO7 GMP-1A-0084*
Date: *19TH JULY 2017*

Part 2

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

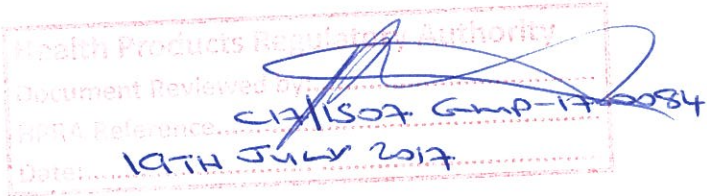
FAMOTIDINE(en) - confidential

TAMSULOSIN HYDROCHLORIDE(en) - confidential

SOLIFENACIN SUCCINATE(en) - confidential

MIRABEGRON(en) - confidential

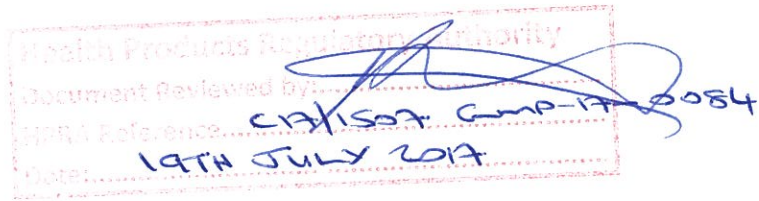
3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : FAMOTIDINE - confidential	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Purification by Crystallization
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
Active Substance : TAMSULOSIN HYDROCHLORIDE - confidential	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Salt Formation and Purification by Crystallization
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
Active Substance : SOLIFENACIN SUCCINATE - confidential	



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 : Salt Formation and Purification by Crystallization
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
Active Substance : MIRABEGRON - confidential	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : Purification by Crystallization
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

Any restrictions related to the scope of this certificate :

The section of this GMP certificate referring to the manufacture of Famotidine relates to product manufactured up until August 2016, at which point manufacturing of this product ceased.



2017-06-21

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

Document Reviewed by: *[Signature]*
HPRA Reference: *C12/ISSA GMP-IT-0084*
Date: *19TH JULY 2017*

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1/8/2017

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4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de		-----	
Certified Attesté / Certificado			
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7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	1932912017		
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