HPRA CERTIFIED

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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 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.*

Health Products Regulatory Authority
Document Reviewed by:
HPRA Reference: CIX/1507 GMP-17-0084
Date: 19TH JULY 2017

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, D02XP77, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • www.hpra.ie

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

Health Products Regulatory Authority
Document Reviewed by:
HPRA Reference: C17/1507 GMP-17-0084
Date: 19TH JULY 2017

Mr. Oisin Daly
Health Products Regulatory Authority
Tel: *+353 31 6764971*
Fax:

Noel McDonald Notary Public
Seamus Maguire & Co. Solicitors
10 Main Street, Blanchardstown,
Dublin 15, Ireland.
Tel: 00353 1 8211288
www.seamusmaguire.ie

1/8/2017

APOSTILLE (Convention de La Haye du 5 octobre 1961)			
1. Country: Pays/País:	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	Noel Mc Donald		
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	--------		
Certified Attesté / Certificado			
5. at à / en	Dublin	**6. the** le / el día	15/08/2017
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	1932912017		
9. Seal / stamp: Sceau / timbre: Sello / timbre:	**10. Signature:** Signature: Firma:		

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

AN ROINN GNÓTHAÍ EACHTRACHA AGUS TRÁDÁLA
DEPARTMENT OF FOREIGN AFFAIRS AND TRADE