426613
Chile

AstraZeneca

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: ..... Dated 11/2/19.

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

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

12/2/19

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 á / 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	FOREIGN AND COMMONWEALTH OFFICE LONDON	**10. Signature** Signature Firma	L. Smethurst

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

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

To verify this apostille go to www.verifyapostille.service.gov.uk

Chile.

ansm
Agence nationale de sécurité du médicament et des produits de santé

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 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.*

Vu pour la certification conforme à l'original

143/147 boulevard Anatole France - F-93285 Saint-Denis Cedex - Tél.: +33(0)1 55 87 30 00 - www.ansm.sante.fr

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)
PRAZIQUANTEL(en) / PRAZIQUANTEL(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**

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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**

	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)

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

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Agence nationale de sécurité du médicament et des produits de santé

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

143/147 boulevard Anatole France F-93285 Saint Denis Cedex - Tél.: +33(0)1 55 87 30 00 -

AZ 65588

Chile

AstraZeneca

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.

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

Signed: ..... Dated 31/1/19

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

1/2/19

185/19

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1.	**Country:** Pays / País:	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** á / 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	FOREIGN AND COMMONWEALTH OFFICE LONDON	
10.	**Signature** Signature Firma	D. Brigden	

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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

To verify this apostille go to www.verifyapostille.service.gov.uk

AZ 6588

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 Manufacturing 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**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.9 Pressurised preparations
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.9 Pressurised preparations
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

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***

A2 6489
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.

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

Signed: ..... Dated 14/12/18

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

20/12/18

3361/18

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** á / en London	6.	**the** le / el día 03 January 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-1241785	
9.	**Seal / stamp** Sceau / timbre Sello / timbre	FOREIGN AND COMMONWEALTH OFFICE LONDON	
10.	**Signature** Signature Firma	J. Allsop-Ward	

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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

To verify this apostille go to www.verifyapostille.service.gov.uk

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Medical Products Agency

CERTIFICATE NUMBER: ***5.9.1-2018-085989***

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: ***Oral Solid Dosage, Gärtunavägen, Södertälje, 151 85, Sweden***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***5.9.1-2018-085989*** in accordance with Art. 40 of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-01-25*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing 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.

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[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.*

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Pellets and granules(en) 1.2.1.13 Tablets
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Buildings at Gärtunavägen: 611, 612, 614, 616, 641, 642 and 643. Buildings at Forskargatan 18: 313 and 317.

2018-11-27

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

Bengt Berglund

Mr. Bengt Berglund
Medical Products Agency
Tel: ***+46 18 174600***
Fax ***+46 18 548566***

LÄKEMEDELSVERKET · SWEDISH MEDICAL PRODUCTS AGENCY ·

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

ESTADOS UNIDOS MEXICANOS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS
COMISIÓN DE AUTORIZACIÓN SANITARIA
SUBDIRECCIÓN EJECUTIVA DE LICENCIAS SANITARIAS

CERTIFICADO No. 173300516A1164

Destinatario:
Addressee:
MINISTERIO DE SALUD
REPÚBLICA DE CHILE

Nombre y Dirección del sitio inspeccionado (incluyendo número de edificio, si aplica)
Name and address of site (including building number, where applicable):
ASTRAZENECA, S.A. DE C.V.
Súper Avenida Lomas Verdes No. 67
Fraccionamiento Lomas Verdes
C.P. 53120, Mpio. Naucalpan de Juárez, México

Número de Licencia del Fabricante
Manufacturer´s licence number(s):
15 057 02 0001

Con fundamento en los Artículos 4 párrafo cuarto, 8 y 14 de la Constitución Política de los Estados Unidos Mexicanos; 2, fracción I, 14, 17, 26, 39, fracciones XXI, XIV de la Ley Orgánica de la Administración Pública Federal; 1, 2, 3, 15, 16 fracciones IV y X, 17 y 17A de la Ley Federal de Procedimiento Administrativo, 1, 3 fracciones XXII y XXVIII, 13 apartado A fracciones IX y X, 17 bis IV y XIII, 194 fracción III, 194 bis, 195, 197, 204, 388, 389 fracción V, 391 bis y 392 de la Ley General de Salud; 1 y 2 inciso c fracción X, 15, 36 y 37 del Reglamento Interior de la Secretaría de Salud; 1, 3 fracciones I inciso b, V, VII, XIII, 4 fracción II inciso c y 11 fracciones VI y XI, y 14 fracciones I y XIV del Reglamento de la Comisión Federal para la Protección Contra Riesgos Sanitarios; 1, 167 fracción VI. párrafo tercero y 208 del Reglamento de Insumos para la Salud, así como Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaria de Salud, a través de la Comisión Federal para la Protección contra riesgos Sanitarios, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Federal de Mejora Regulatoria publicado en el Diario Oficial de la Federación el 28 de enero de 2011 y modificado el 22 de junio de 2011, 10 de mayo, 18 de julio y 23 de octubre de 2012, así como 7 de julio de 2013 en el Diario Oficial de la Federación.

Based on the fourth paragraph of Articles 4, 8 and 14 of the Constitution of the United Mexican States; 2, section I, 14, 17, 26, 39, fractions XXI, XIV of the Organic Law of the Federal Public Administration; 1, 2, 3, 15, 16 paragraphs IV and X, 17 and 17A of the Federal Administrative Procedure Act, 1, 3 fractions XXII and XXVIII, section A 13 sections IX and X, 17a IV and XIII, 194 fraction III, 194a, 195, 197, 204, 388, 389 fraction V, 391 bis and 392 of the General Health Law; 1 and 2 paragraph c fraction X, 15, 36 and 37 of the Internal Regulations of the Ministry of Health; 1, 3 fractions I subsection b, V, VII, XIII, 4 Section II paragraph C and 11 fractions VI and XI, and 14 fractions I and XIV of the Rules of the Federal Commission for Protection Against Health Risks; 1 167 Section VI. third and 208 of 1 167 Section VI. third, paragraph 208 and 223 of the Rules of Health Products, and Agreement disclosed procedures and services, as well as the formats used by the Ministry of Health, through the Federal Commission for Protection against Health Risks , registered in the Federal Register of Formalities and Services of the Federal Regulatory Improvement Commission published in the Official Journal of the Federation on January 28, 2011 and amended on June 22, 2011, May 10, 18 July 23 October 2012 and July 7, 2013 in the Official Gazette.

En relación al sitio de fabricación inspeccionado se otorga el Certificado de Buenas Prácticas de Fabricación para lo siguiente:
Regarding the inspected manufacturing site the present GMP certificate is issued for:

Línea de producción o producto - Categoría Manufacturing line or product - Category	Forma farmacéutica Dosage form	Actividades que realiza Activities
SÓLIDOS ORALES	Tabletas	Producción, Control de Calidad, Acondicionamiento primario, secundario, Importación, Almacenamiento y Distribución

Norma de referencia:
Reference standard:
NOM-059-SSA1-2013, Buenas prácticas de fabricación de medicamentos

Nombre de la autoridad que realiza la inspección si es diferente a la autoridad reguladora emisora:
Name of inspecting authority if different from the issuing regulatory authority:
Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)

Número de Expediente 173300516A1164

COF 026950

CAS-SELS

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

ESTADOS UNIDOS MEXICANOS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS
COMISIÓN DE AUTORIZACIÓN SANITARIA
SUBDIRECCIÓN EJECUTIVA DE LICENCIAS SANITARIAS

CERTIFICADO No. 173300516A1164

Dirección de la autoridad reguladora emisora
Address of the issuing regulatory authority:
Oklahoma No. 14, Col. Nápoles, Del. Benito Juárez, México, D.F., C.P. 03810

Número de acta de inspección:
Number of inspection report:
14-MF-3315-03844-MP

Fecha de inspección:
Date of inspection of the plant.
02 al 13 de junio de 2014

"Establecimiento verificado mediante evaluación documental por tener Nivel de Riesgo A (bajo), del 31 de mayo al 07 de octubre de 2016"

Este certificado tendrá una vigencia hasta:
This certification remains valid until
13 de junio de 2019

Nota: Durante la inspección se realizaron evaluaciones sobre una muestra limitada y aleatoria de documentos, procesos y áreas productivas. Por lo tanto, esta certificación no exime a la empresa de la responsabilidad de cumplir con las normas existentes de buenas prácticas de fabricación, así como para identificar y eliminar las deficiencias y desviaciones no señaladas por el equipo de inspección. Sin embargo, a la luz de nuevas pruebas o información, podrán ser revisadas y ejecutadas por la autoridad sanitaria competente mediante evaluaciones constantes de este sitio de fabricación.

Note: During the inspection were conducted evaluations on a limited and random sample of documents, processes and production areas. Therefore, this certification does not excuse the company's responsibility to comply with existing standards of good manufacturing practices and to identify and eliminate deficiencies and deviations noted by the inspection team. However, in the light of new evidence or information ongoing assessments of the manufacturing site may be reviewed and evaluated by the competent health authority.

Nombre y puesto del responsable
Name and function of the responsible person:
Marcos Laureano Solis Leyva
Subdirector Ejecutivo de Licencias Sanitarias.

Correo electrónico, teléfono, fax:
E-mail, Telephone no., and Fax no.
msolis@cofepris.gob.mx Tel. +52 (55) 50 80 53 66

SUFRAGIO EFECTIVO. NO REELECCION

Firma
Signature

En ejercicio de la facultad delegada en el artículo Vigésimo Primero del Acuerdo por el que se modifica el diverso por el que se delegan las facultades que se señalan, en los órganos administrativos que en el mismo se indican de la Comisión Federal para la Protección contra Riesgos Sanitarios. Publicado en el Diario Oficial de la Federación el 7 de abril de 2010 y el 23 de marzo de 2012.

Sello de la autoridad reguladora y fecha de emisión.
Stamp of the authority and issuing date

ESTADOS UNIDOS MEXICANOS
SECRETARIA DE SALUD
COMISION FEDERAL DE PROTECCION CONTRA RIESGOS SANITARIOS
SUBDIRECCION EJECUTIVA DE LICENCIAS SANITARIAS

Ciudad de México, 13 de octubre de 2017.

c.c.- Expediente de la Comisión de Autorización Sanitaria, 1er piso.

CAS SELS-GFM / Número de Expediente 173300516A1164

MLSL/IVCB/ERRV 12-OCTUBRE-2017 CBPF FIL

Nombre del archivo: Certificado

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SECRETARÍA DE GOBERNACIÓN

MEXICO

038200 / 2017

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

SECRETARÍA DE GOBERNACIÓN

1. País (country/pays): México

El presente documento público

CAS-SELS

COF 026951

En ejercicio de la facultad delegada en el artículo Vigésimo Primero del Acuerdo por el que se modifica el diverso por el que se delegan las facultades que se señalan, en los órganos administrativos que en el mismo se indican de la Comisión Federal para la Protección contra Riesgos Sanitarios. Publicado en el Diario Oficial de la Federación el 7 de abril de 2010 y el 23 de marzo de 2012.

COMISION FEDERAL DE PROTECCION CONTRA RIESGOS SANITARIOS
SUBDIRECCION EJECUTIVA DE LICENCIAS SANITARIAS

Ciudad de México, 13 de octubre de 2017.

c.c.- Expediente de la Comisión de Autorización Sanitaria, 1er piso.

CAS SELS-GFM / Número de Expediente 173300516A1164

MLSL/IVCB/ERRV 12-OCTUBRE-2017 CBPF FIRMA

Nombre del archivo: Certificado

COF 0269

Comisión de Autorización Sanitaria Subdirección Ejecutiva de Licencias Sanitarias Comisión de Autorización Sanitaria Subdirección Ejecutiva de Licencias Sanitarias

CAS-SELS-P-09-POI-01-0-0

CAS-SELS

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SECRETARÍA DE GOBERNACIÓN

MÉXICO

038200 / 2017

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

SECRETARÍA DE GOBERNACIÓN

1. País (country/pays): México

El presente documento público
(This public document / Le présent acte public)

2. ha sido firmado por: Q.F.M. MARCOS LAUREANO SOLIS LEYVA
(has been signed by /a été signé par)

3. quien actúa en calidad de: SUBDIRECTOR EJECUTIVO DE LICENCIAS SANITARIAS DE LA COMISIÓN DE AUTORIZACIÓN SANITARIA DE LA COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS.
(acting in the capacity of / agissant en qualité de)

4. y está revestido del sello/ timbre de: SECRETARÍA DE SALUD
(bears the seal / stamp of/ est revêtu du sceau / timbre de)

Certificado
(Certied/Attesté)

5. en (at/à) CIUDAD DE MÉXICO 6. el día (the /le) 18 DE OCTUBRE DE 2017

7. por (by / par) MARTA TERESA URRUTIA CÁRDENAS, DIRECTORA DE COORDINACIÓN POLÍTICA CON LOS PODERES DE LA UNIÓN, EN AUXILIO DEL TITULAR DE LA UNIDAD DE GOBIERNO, CON FUNDAMENTO EN LOS ARTÍCULOS 10 FRACCIÓN I Y 11 ÚLTIMO PÁRRAFO DEL REGLAMENTO INTERIOR DE LA SECRETARÍA DE GOBERNACIÓN.

8. No. (N°/sous n°) 1 / 34816 / 2017 9. Sello/ timbre (seal/stamp / sceau/timbre) 10.Firma (signature)

Tipo de Documento: CERTIFICADO DE BUENAS PRACTICAS DE FABRICACION
(Type of document / Type d'acte)

Nombre del Titular: ASTRAZENECA, S.A. DE C.V.
(Name of holder of document / Nom du titulaire)

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