MUNDIPHARMA LABORATORIES GmbH

Basel (Switzerland)

Julio 2018

A QUIEN INTERESE:

El titular que suscribe certifica que el producto **COSOPT Solución Oftálmica con principio Activo CLORHIDRATO DE DORZOLAMIDA 20 mg/ml + Maleato de Timolol 5 mg/ml (Registro ISP Nro. F-1875)** el cual se exporta a Chile a su titular ALPES CHEMIE S.A, producto fabricado en MSD Chibret (Mirabel) Francia bajo normas GMP:

Empresa	GMP vigente
MSD Chibret – Francia	24 de abril 2020 – Certificado 2018/HPF/FR/021

Se extiende el presente certificado a petición del titular de los registros en Chile.

Alba Rocio Castillo Pabón – Q.F. & MSc.
Gerente Regional Asuntos Regulatorios & D.T.
Colombia, Países Andinos y Cono Sur

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***2018/HPF/FR/021***

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: ***LABORATOIRES MERCK SHARP & DOHME CHIBRET - CLERMONT FERRAND CEDEX 9***
Site address: ***Route de Marsat, Riom, CLERMONT FERRAND CEDEX 9, 63963, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 15/238*** in accordance with Art. 40 of Directive 2001/83/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 ***2015-04-24*** , 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 Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products 1.3.1.5 Biotechnology products
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products 1.3.2.5 Biotechnology products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical* *2.1.4 Biological*

2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.3 Biological medicinal products 2.2.3.2 Immunological products 2.2.3.5 Biotechnology products
2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

This good practice certificate is valid until April 24th, 2020. --- Signatory: Mrs Mélanie Cachet, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good practice certificates.

2018-01-17

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***

Hélène MAZUEL
PHARMACIEN RESPONSABLE
n°RPPS 10001861029
Laboratoires Merck Sharp & Dohme Chibret
Route de Marsat - RIOM
63963 Clermont-Ferrand Cedex 9 - FRANCE

RÉPUBLIQUE FRANÇAISE
LEGALISATION
(DECRET N° 2007 - 1205 DU 10 AOUT 2007)
DESTINATION DE L'ACTE (PAYS OU AUTORITE)
Colombie
DATE : 01 MARS 2018
NOM ET QUALITE DE L'AGENT : J-C. SANITELAMIO
BUREAU DES LEGALISATIONS
SIGNATURE ET CACHET OBLIGATOIRE :

Je soussignée Maître Angelique CHEN
Notaire à Paris, certifie uniquement
la signature de M.me Hélène MAZUEL
apposée ci-dessus
Paris, le 28 Fevrier 2018.

CONSULADO GENERAL DE COLOMBIA
PARIS - FRANCIA
AUTENTICACIÓN DE FIRMA
El (La) Cónsul de Colombia
CERTIFICA

Que JEAN-CLAUDE NANITELAMIO, quien firma y otorga al presente documento, ejercita legalmente a la fecha ahi expresada el cargo de OFICIAL ADMINISTRATIVO DE OFICINA LEGALIZACIONES, y que la firma y sello en el documento aparecen como suyos, son los que usa y acostumbra en todos sus actos.

El Ministerio de Relaciones Exteriores de Colombia, no asume responsabilidad por el contenido del documento.

Derechos	EUR 26,00
FONDO ROTATORIO	EUR 17,00
TIMBRE	EUR 9,00

Fecha de Expedición: 02 marzo 2018

Impresión No.: 1

MINISTERIO DE RELACIONES EXTERIORES DE COLOMBIA
DANIEL ALARCON PEREIRA
CONSUL DE SEGUNDA
Firmado Digitalmente

La autenticidad de este documento puede ser verificada en:
http://verificacion.cancilleria.gov.co
Código de Verificación:AFSDC23537259