Italian Medicines Agency

CERTIFICATE NUMBER: ***IT-API/135/H/2017***

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 Italy confirms the following:
The manufacturer: ***F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.***
Site address: ***Via Dovaro, snc, LONIGO, 36045, Italy***

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 ***2017-02-17*** , 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.

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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.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :
DILTIAZEM CLORIDRATO(it) / DILTIAZEM HYDROCHLORIDE(en)
VIMINOLO P-IDROSSIBENZOATO(it) / VIMINOL P-HYDROXYBENZOATE(en)
FOSFOMICINA TROMETAMOLO(it) / FOSFOMYCIN TROMETAMOL(en)
NIFEDIPINA(it) / NIFEDIPINE(en)
TIAMFENICOLO GLICINATO CLORIDRATO(it) / THIAMPHENICOL GLYCINATE HYDROCHLORIDE(en)
BAZEDOXIFENE ACETATO(it) / BAZEDOXIFENE ACETATE(en)
PROPOFOL(it) / PROPOFOL(en)
FOSAPREPITANT DIMEGLUMINA(it) / FOSAPREPITANT DIMEGLUMINE(en)
NIFURTOINOLO(it) / NIFURTOINOL(en)
ACETILCISTEINA(it) / ACETYLCYSTEINE(en)
GABAPENTINA(it) / GABAPENTIN(en)
MORCLOFONE(it) / MORCLOFONE(en)
DORZOLAMIDE CLORIDRATO(it) / DORZOLAMIDE HYDROCHLORIDE(en)
SULINDAC(it) / SULINDAC(en)
PIRFENIDONE(it) / PIRFENIDONE(en)
ZALEPLON(it) / ZALEPLON(en)
NEBIVOLOLO CLORIDRATO(it) / NEBIVOLOL HYDROCHLORIDE(en)
SAFINAMIDE METANSOLFONATO(it) / SAFINAMIDE METHANSULFONATE(en)
TIAMFENICOLO GLICINATO ACETILCISTEINATO(it) / THIAMPHENICOL GLYCINATE ACETYLCYSTEINATE(en)
CARVEDILOLO(it) / CARVEDILOL(en)
RIFAXIMINA(it) / RIFAXIMIN(en)
TIAMFENICOLO(it) / THIAMPHENICOL(en)
OLOPATADINA CLORIDRATO(it) / OLOPATADINE HYDROCHLORIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : DILTIAZEM HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : VIMINOL P-HYDROXYBENZOATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : FOSFOMYCIN TROMETAMOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : NIFEDIPINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates

3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : THIAMPHENICOL GLYCINATE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : BAZEDOXIFENE ACETATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7. Other : Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps :

	drying,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : PROPOFOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : distillation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : FOSAPREPITANT DIMEGLUMINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : NIFURTOINOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**

	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : ACETYLCYSTEINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : GABAPENTIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : MORCLOFONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : DORZOLAMIDE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : SULINDAC

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : PIRFENIDONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : ZALEPLON

3.5	**General Finishing Steps**
	3.5.4 Other : Batch certification only
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : NEBIVOLOL HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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)

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : SAFINAMIDE METHANSULFONATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : THIAMPHENICOL GLYCINATE ACETYLCYSTEINATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : CARVEDILOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : RIFAXIMIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : THIAMPHENICOL

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.1 Physical processing steps : drying, milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance : OLOPATADINE HYDROCHLORIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : drying,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

4. Other Activities - Active Substances :
Importation of: FOSFOMYCIN PHENYLETHYLAMINE (confidential), GABAPENTIN, ISOXEPAC (confidential), NITROFURANTOIN (confidential), RIFAXIMIN CRUDE (confidential), THIAMPHENICOL CRUDE (confidential), TROMETAMOL CRUDE (confidential)

Clarifying remarks (for public users)

Imported APIs marked as confidential undergo further processing within the importing site.The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 42 months from the last general GMP inspection, which was conducted on 2016/Oct/14. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.Carvedilol is not destined to the European economic area.

2018-04-13

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

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Confidential
Italian Medicines Agency
Tel: ***Confidential***
Fax: ***Confidential***

Instituto de Salud Pública
Ministerio de Salud

Gobierno de Chile

Nº Ref.:ML962116/18
vvc

Resolución Exenta RW N° 2267/18
Santiago, 31 de enero de 2018

VISTO ESTOS ANTECEDENTES: la solicitud de D. Rodrigo Esteban Cisterna Araya, Responsable Técnico y D. Jaime Ramirez Kattan, Representante Legal de Alpes Chemie S.A., ingresada bajo la referencia Nº ML962116, de fecha de 30 de enero de 2018, mediante la cual solicita **cambio de razón social** para los productos farmacéuticos que se señalan en el anexo;

CONSIDERANDO:

PRIMERO: que, mediante la presentación de fecha 30 de enero de 2018, se solicitó cambio de razón social para los productos farmacéuticos que se señalan en el anexo.

SEGUNDO: que, consta el pago de los derechos arancelarios correspondientes, mediante el comprobante de recaudación Nº 1664098, emitido por Instituto de Salud Pública con fecha 30 de enero de 2018;

TENIENDO PRESENTE: las disposiciones del artículo 96º del Código Sanitario; Ley 19.880, de 2003; lo señalado en el artículo 67° del Reglamento del Sistema Nacional de Control de Productos Farmacéuticos, aprobado por el Decreto Supremo Nº 3 de 2010 del Ministerio de Salud y los artículos 59º letra b), 61º letra b) y 64° del D.F.L. Nº 1, de 2005, y las facultades delegadas por la Resolución Exenta N° 292 de 12 de febrero de 2014, del Instituto de Salud Pública de Chile, dicto la siguiente:

R E S O L U C I Ó N

1.- **TÉNGASE POR NOTIFICADO** y, en consecuencia modificase la razón social de la empresa **ZACH SYSTEM S.P.A.** a la nueva razón social **F.I.S.-FABBRICA ITALIANA SINTETICI S.P.A.** en las funciones de empresa que estan previamente autorizadas cada uno de los respectivos registros sanitarios correspondientes a los productos farmacéuticos que se señalan en el anexo adjunto.

2.- La nueva razón social deberá consignarse claramente en los rótulos de los envases, folleto de información al profesional, folleto de información al paciente y especificaciones de producto terminado, según corresponda, del producto en todas las series o lotes que se fabriquen con posterioridad a la presente resolución, sin perjuicio de cumplir lo dispuesto en el artículo N° 74 del Reglamento del Sistema Nacional de Control de Productos Farmacéuticos.

3.- **DÉJASE ESTABLECIDO** que a contar de la fecha de la presente resolución se otorga un plazo impostergable de 6 meses para agotar stock del material de envase y empaque en cuyos rótulos se señala las condiciones anteriormente autorizadas.

4.- **ESTABLÉCESE** que la presente resolución modifica la razón social de la empresa solicitada, solamente en aquellas funciones previamente autorizadas por resolución en los respectivos registros sanitarios, y en ningún caso autoriza cambios en los sitios de fabricación y en los domicilios de las plantas de manufactura.

Av. Marathon 1.000, Ñuñoa, Santiago
Casilla 48, Correo 21 – Código Postal 7780050
Mesa Central: (56 2) 2575 51 01
Informaciones: (56 2) 2575 52 01
www.ispch.cl

Instituto de Salud Pública
Ministerio de Salud

Gobierno de Chile

5.- **DÉJASE ESTABLECIDO** que la información evaluada en la solicitud para la aprobación de esta modificación al registro sanitario, corresponde a la entregada por el solicitante, el cual se hace responsable de la veracidad de los documentos que adjunta, conforme a lo dispuesto en el Art.210° del Código Penal y que la información proporcionada deberá estar a disposición de la Autoridad Sanitaria, para su verificación, cuando ésta lo requiera.

6.- **DÉJASE ESTABLECIDO** que el titular del registro tendrá un plazo de 6 meses a contar de la fecha de la presente resolución para actualizar la información en los anexos del registro que así lo requieran, sin necesidad de solicitar expresamente esta modificación al Instituto.

ANÓTESE Y COMUNÍQUESE

JEFA (S) SUBDEPTO. REGISTRO Y AUTORIZACIONES SANITARIAS
AGENCIA NACIONAL DE MEDICAMENTOS
INSTITUTO DE SALUD PÚBLICA

Q.F. PATRICIA CARMONA SEPÚLVEDA
JEFE (S) SUBDEPARTAMENTO REGISTRO Y AUTORIZACIONES SANITARIAS
DEPARTAMENTO AGENCIA NACIONAL DE MEDICAMENTOS
INSTITUTO DE SALUD PÚBLICA DE CHILE

DISTRIBUCIÓN:
INTERESADO
UCD

INSTITUTO DE SALUD PÚBLICA DE CHILE
MINISTRO DE FE

Transcrito Fielmente
Ministro de Fe

Av. Marathon 1.000, Ñuñoa, Santiago
Casilla 48, Correo 21 - Código Postal 7780050
Mesa Central: (56 2) 2575 51 01
Informaciones: (56 2) 2575 52 01
www.ispch.cl

Instituto de Salud Pública
Ministerio de Salud
Gobierno de Chile

Nº Ref.:ML962116/18
vvc

RESOLUCIÓN EXENTA RW Nº 2267/18
Santiago, 31 de enero de 2018

REGISTRO - NOMBRE PRODUCTO
F-1875/14 - COSOPT SOLUCIÓN OFTÁLMICA
F-20040/13 - COSOPT PF SOLUCIÓN OFTÁLMICA
F-20041/13 - COSOPT PF SOLUCIÓN OFTÁLMICA
F-79/17 - TRUSOPT SOLUCIÓN OFTÁLMICA 2%

Av. Marathon 1.000. Ñuñoa. Santiago
Casilla 48. Correo 21 - Código Postal 7780050
Mesa Central: (56 2) 2575 51 01
Informaciones: (56 2) 2575 52 01
www.ispch.cl