CHILI 31/6

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

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: ***17MPP090HFR01***

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: ***SANOFI CHIMIE***
Site address: ***Le Bourg, VERTOLAYE, 63480, 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 ***2017-11-17***, 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.

---

[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.*

REPUBLIQUE FRANÇAISE
LEGALISATION
(DECRET N° 2007-1205 DU 10 AOUT 2007)
DESTINATION DE L'ACTE (PAYS OU AUTORITE) Chili
DATE : 01 JUIN 2018
NOM ET QUALITE DE L'AGENT : N. DRUTINUS
BUREAU DES LEGALISATIONS
SIGNATURE ET CACHET OBLIGATOIRE

POUR ADMINISTRATION ETRANGERE CHILI
POUR COPIE CONFORME
à l'original qui nous a été présenté
et aussitôt rendu
ANTONY, le 30 MAI 2018

MAIRIE D'ANTONY 92 (Hts-de-Seine)

Le Maire
Pour le Maire
et par délégation
Valérie GODARD
Adjoint administratif principal

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

SERVICIO CONSULAR 2018 10 10 US$ CHILE US$

SERVICIO CONSULAR 2018 2 2 US$ CHILE US$

Actuacion N° 3107 Arancel Articulo N° 4110
Derechos US$ 12 Diferencia 10% 1,20
Total percibido en US$ 13,20
Pagado en moneda local 11 €
Paris, 04 JUIN 2018

CONSULADO GENERAL DE CHILE EN PARIS

EL CONSUL GENERAL DE CHILE QUE SUSCRIBE CERTIFICA LA AUTENTICIDAD DE LA FIRMA DE DON
M. DAUTINOS
FUNCIONARIO DEL MINIST. DE RR. EE. DE FRANCIA

CONSULADO DE CHILE PARIS

CRISTOBAL ORTIZ
CONSUL

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

Part 2

Manufacture of active substance. Names of substances subject to inspection :
CORTIVAZOL(fr) / CORTIVAZOL(en)
PROPIONATE DE FLUTICASONE(fr) / FLUTICASONE PROPIONATE(en)
HYDROCORTISONE VALERATE(en) / HYDROCORTISONE (VALERATE D')(fr)
NILUTAMIDE(fr) / NILUTAMIDE(en)
PRISTINAMYCINE(fr) / PRISTINAMYCIN(en)
RILUZOLE(fr) / RILUZOLE(en)
ROXITHROMYCIN(en) / ROXITHROMYCINE(fr)
TRIAMCINOLONE (ACÉTONIDE DE)(fr) / TRIAMCINOLONE ACETONIDE(en)
TRIMÉGESTONE(fr) / TRIMEGESTONE(en)
DÉSOXIMÉTASONE(fr) / DESOXIMETASONE(en)
DESOXIMETASONE MONOHYDRATE MICROCRYSTALLIZED(en) / DESOXIMETASONE MONO HYDRATEE MICROCRISTALLISEE(fr)
FLUORométHOLONE(fr) / FLUOROMETHOLONE(en)
PREDNISOLONE HEMISUCCINATE(en) / PREDNISOLONE (HEMISUCCINATE DE)(fr)
DEXAMETHASONE METASULFOBENZOATE SODIUM(en) / DEXAMETHASONE (METASULFO BENZOATE SODIQUE DE)(fr)
HYDROCORTISONE SODIUM PHOSPHATE(en) / HYDROCORTISONE SODIQUE (PHOSPHATE DE)(fr)
PROMÉGESTONE(fr) / PROMEGESTONE(en)
DOCETAXEL(en) / DOCÉTAXEL(fr)
HYDROKORTYZONU OCTAN(pl) / HYDROCORTISONE ACETATE(en) / HYDROCORTISONE, AC ÉTATE D'(fr) / HYDROCORTISON-AZETAT(de)
LOPRAZOLAM METHANE SULFONATE MONOHYDRATE(en) / LOPRAZOLAM (METHANE SUL FONATE DE) MONOHYDRATE(fr)
CABAZITAXEL(en) / CABAZITAXEL(fr)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : CORTIVAZOL	
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 : Homogeneization and Micronization 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**

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

	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance : FLUTICASONE PROPIONATE	
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 : Homogeneization 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 : HYDROCORTISONE VALERATE	
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 : Homogeneization 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 : NILUTAMIDE	
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 : Micronization 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 : PRISTINAMYCIN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps : Purification of crude pristinamycin
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Homogeneization 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 : RILUZOLE

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 : ROXITHROMYCIN

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

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 : Homogeneization 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 : TRIAMCINOLONE ACETONIDE

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 : Micronization 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 : TRIMEGESTONE

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 : Homogeneization and Micronization 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 : DESOXIMETASONE

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 : Homogeneization and Micronization 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 : DESOXIMETASONE MONOHYDRATE MICROCRYSTALLIZED

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 : Homogeneization 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

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

Active Substance : FLUOROMETHOLONE

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 : Homogeneization and Micronization 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 : PREDNISOLONE HEMISUCCINATE

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 : Homogeneization 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 : DEXAMETHASONE METASULFOBENZOATE 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**

	3.5.1 Physical processing steps : Homogeneization 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 : HYDROCORTISONE SODIUM PHOSPHATE

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 : Homogeneization 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 : PROMEGESTONE

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 : Homogeneization and Micronization 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**

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

	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : DOCETAXEL

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 : HYDROCORTISONE ACETATE

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 : Homogeneization, micronization 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 : LOPRAZOLAM METHANE SULFONATE MONOHYDRATE

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 : Homogeneization 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 : CABAZITAXEL	
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)

CABAZITAXEL: Limited to the synthesis of the intermediate DIMEST DOCETAXEL: Limited to the synthesis of the intermediate BHEDITROC

2018-02-15

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

POUR ADMINISTRATION ETRANGERE CHILI
POUR COPIE CONFORME
à l'original qui nous a été présenté
et aussitôt rendu 30 MAI 2018
ANTONY, le .....

MAIRIE D'ANTONY 92 (Hts-de-Seine)

Le Maire
Pour le Maire
et par délégation
Valérie GODARD
Adjoint administratif principal

Mr. Guillaume Renaud
French National Agency for Medicines and Health Products Safety
Tel: *+33 1 55873911*
Fax: *+33 1 55873912*

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

ANSM

Agencia de seguridad de productos medicinales República de Francia

Certificado N°: 17MPP090HFR01

CERTIFICADO DE CUMPLIMIENTO GMP DE UN FABRICANTE

Parte 1

Emitido luego de una inspección en conformidad con el Art. 111(5) de la Directiva 2001/83/EC.

La autoridad competente de Francia, confirma lo siguiente:

El fabricante **SANOFI CHEMIE**

Dirección de la planta **Le Bourg, VERTOLAYE, 63480, Francia**

Es un fabricante de ingredientes activos que ha sido inspeccionado conforme al artículo 111 (1) de la directiva 2001/83/EC.

Según la información obtenida durante la inspección de este fabricante, la última realizada del

2017-11-17, se considera que cumple con los principios y pautas de las Buenas Prácticas de Manufactura (GMP) para ingredientes activos (GMP UE Parte II). Estos principios cumplen las recomendaciones GMP de la OMS.

Este certificado refleja el estado de la planta de fabricación al momento de la inspección indicada arriba y no se debe confiar en el estado de cumplimiento si han transcurrido más de tres años desde la fecha de dicha inspección. Sin embargo, este período de validez podría reducirse o ampliarse usando los principios de gestión de riesgo regulatorio mediante una nota en el campo de comentarios Restricciones o Aclaraciones. Este certificado es válido sólo cuando se presenta con todas sus páginas and ambas partes 1 y 2. La autenticidad de este certificado puede ser verificada en EudraGMDP. Si no aparece, por favor contactar la autoridad emisora.

Parte 2

Elaboración de ingredientes activos / Nombres de substancias sujetas a inspección*:

CORTIVAZOL (fr) / CORTIVAZOL (in)

PROPIONATO DE FLUTICASONA (fr) / FLUTICASONA PROPIONATO (in)

HYDROCORTISONA VALERATE (in) / HYDROCORTISONA (VALERATO D') (fr)

NILUTAMIDA (fr) / NILUTAMIDA (in)

PRISTINAMICINA (in) / PRISTINAMICINA (fr)

RILUZOL (fr) / RILUZOL (fr)

ROXITROMICINA (in) / ROXITROMICINA (fr)

TRIAMCINOLONA (DE ACETÓNICO) (fr) / TRIAMCINOLONA ACETÓNIDO (in)

TRIMEGESTONA (fr) / TRIMEGESTONA (in)

DESOXIMETASONA (fr) / DESOXIMETASONA (in)

DESOXIMETASONA MONOHIDRATO MICROCISTALIZADO (in) / DESIXOMETASONA HIDRATO MICROCRISTALIZADO (fr)

FLUOROMETOLONA (fr) / FLUOROMETOLONA (in)

PREDNISOLONA HEMISUCCINATO (in) / PREDNISOLONA (DE HEMISUCCINATO) (fr)

DEXAMETASONA METASULFOBENZOATO DE SODIO (in) / DEXAMETASONA (METASULFOBENZOATO SODICO) (fr)

HYDROCORTISONA FOSFATO DE SODIO (in) / HIDROCORTISONA SÓDICA (DE FOSFATO) (fr)

PROMEGESTONA (fr) / PROMEGESTONA (in)

DOCETAXEL (in) / DOCETAXEL (fr)

HYDROCORTIZONU OCTAN (pl) / HIDROCORTISONA ACETATO (en) / HIDROCORTISONA DE ACETATO (fr) /DYDROCORTISON-ACETAT (all)

LOPRAZOLAM METASO SULFONATO MONOHIDRATO (en) / LOPRAZOLAM (METANOSULFONATO) MONOHIDRATO (fr)

CABAZITAXEL (en) / CABAZITAXEL (fr)

3. OPERACIONES DE MANUFACTURA – SUSTANCIAS ACTIVAS

Sustancia Activa: DEXAMETASONA

3.1 Fabricante de la sustancia activa por Síntesis Química

3.1.1 Fabricante de intermediarios de la sustancia activa

3.1.2 Fabricante de la sustancia activa bruta

3.1.3 Formación de sal / Etapas de purificación:

-

3.5 Pasos generales de acabado

3.5.1 Etapas de procesamiento físico:

Homogenización y micronización

3.5.2 Empaque primario (Encerrar / sellar la sustancia activa dentro de un material de embalaje que está en contacto directo con la sustancia)

3.5.3 Empaque secundario (colocar el paquete primario sellado dentro de un envase o material de embalaje externo. Esto también incluye cualquier etiquetado del material que podría usarse para la identificación o trazabilidad (numeración de lotes) de la sustancia activa)

3.6 Pruebas de Control de Calidad

3.6.1 Pruebas físicas / químicas

3.6.2 Pruebas microbiológicas a excepción de esterilidad.

Sustancia Activa: DEXAMETASONA MONOHIDRATO MICROCRISTALIZADA

3.1 Fabricante de la sustancia activa por Síntesis Química

3.1.1 Fabricante de intermediarios de la sustancia activa

3.1.2 Fabricante de la sustancia activa bruta

3.1.3 Formación de sal / Etapas de purificación:

-

3.5 Pasos generales de acabado

3.5.1 Etapas de procesamiento físico:

Homogenización

3.5.2 Empaque primario (Encerrar / sellar la sustancia activa dentro de un material de embalaje que está en contacto directo con la sustancia)

3.5.3 Empaque secundario (colocar el paquete primario sellado dentro de un envase o material de embalaje externo. Esto también incluye cualquier etiquetado del material que podría usarse para la identificación o trazabilidad (numeración de lotes) de la sustancia activa)

3.6 Pruebas de Control de Calidad

3.6.1 Pruebas físicas / químicas

3.6.2 Pruebas microbiológicas a excepción de esterilidad.

Restricciones o notas aclaratorias relacionadas con el alcance de este certificado:

Cabazitaxel: Limitado a la síntesis del intermediario DIMEST DOCETAXEL: Limitado a la síntesis del intermediatio BHEDITROC.

Fecha: 2018-02-15

Nombre y firma de la persona autorizada de la Autoridad Competente de Francia (ANSM)