Cyndea PHARMA	**Manufacturers** Cyndea Pharma, SL (total manufacturer)	**Address** Poligono Industrial Emiliano Revilla Sanz. Avenida de Agreda, 31, Olvega 42110 (Soria), Spain

CHILE

Batch Certificate **№ 201424 dated 13 May 2020**

NAME OF PRODUCT, DOSAGE FORM, STRENGTH, PACKAGE SIZE AND TYPE

DUTASVITAE GALENICUM 6OB 0,5 mg 30 C CHL

Marketing Authorization number: F-23154/16

Bulk Batch No.: 201748 Finished Product Batch No.: 201424	Number of units in lot : 9757
Manufacturing Date: 05/05/2020	Expiry Date: 05/2023

ENSAYOS / ***TESTS***	ESPECIFICACIONES / ***SPECIFICATIONS***	RESULTADOS / ***RESULTS***
Descripción / ***Description***	Cápsula de gelatina blanda oblonga opaca, amarilla que contiene una solución oleosa amarillenta / ***Oblong, opaque and yellow soft gelatin capsule, containing an oily and yellowish liquid***	Cápsula de gelatina blanda oblonga opaca, amarilla que contiene una solución oleosa amarillenta / ***Oblong, opaque and yellow soft gelatin capsule, containing an oily and yellowish liquid***
Identificación Dutasterida / ***Dutasteride identification***	HPLC (DAD): Espectro similar al estándar / ***Spectrum similar to standard***	Espectro similar al estándar / ***Spectrum similar to standard***
	HPLC: Tiempo de retención similar al estándar / ***Retention time similar to the standard***	Tiempo de retención similar al estándar / ***Retention time similar to the standard***
Identificación BHT / ***BHT identification***	HPLC (DAD): Espectro similar al estándar / ***Spectrum similar to standard***	Espectro similar al estándar / ***Spectrum similar to standard***
	HPLC: Tiempo de retención similar al estándar / ***Retention time similar to the standard***	Tiempo de retención similar al estándar / ***Retention time similar to the standard***
Disgregación / ***Disintegration***	≤ 30 min.	4 min
Peso medio contenido cápsulas / ***Average mass of the content***	367.6 mg ± 7.5% (340.0 – 395.2 mg)	375.9 mg
Uniformidad de masa / ***Uniformity of mass***	Media / ***Mean*** ± 7.5 % (Min. 18 caps.) Media / ***Mean*** ± 15 %	19 caps 0 caps
Uniformidad de dosis / ***Uniformity of dosage units***	A.V. ≤ 15.0	A.V. = 6.2
Disolución / ***Dissolution*** (HPLC)	No menos del 80% (Q=75%) in 30 minutos / ***NLT 80% (Q=75%) in 30 minutes***	97%
Valoración Dutasterida / ***Dutasteride assay*** (HPLC)	95.0% - 105.0%	100.7%
Valoración BHT / ***BHT assay*** (HPLC)	90.0% - 110.0%	100.0%

Impurezas / ***Impurities*** (HPLC)	Impurezas desconocidas / ***Unknown impurities*** $\leq$ 0.5% Impurezas totales / ***Total impurities*** $\leq$ 1.0%	Impurezas desconocidas / ***Unknown impurities*** = ND* Impurezas totales / ***Total impurities*** = ND*
Microbiología / ***Microbiology***	-TAMC $\leq 10^3$ ufc/***cfu***/g -TYMC $\leq 10^2$ ufc/***cfu***/g *-E. Coli*: Ausencia en 1g / ***Absence in 1g***	N/A**

OBSERVACIONES / ***REMARKS:***
*ND: No Detectado / ***Not Detected***
N/A: No Aplica / ***Not Applicable*

This batch of product has been manufactured in compliance with GMP. Released for use in Chile.
GMP certificate:
Cyndea Pharma SL, Spain - 6358/19

Name, address and number of license for all sites of manufacture and quality control:
Cyndea Pharma SL, Spain (total manufacturer)
Number of license: **6358**

Declaration of certification
I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/ labeling and quality control at the above-mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

DECISION	**RELEASE DATE**	Visa of Qualified Person/
ACCEPTED	18 Jun 2020	Mar Sánchez

Cyndea PHARMA
CYNDEA PHARMA, S.L.
C. I. F. B-84363555
Pol. Ind. Emiliano Revilla Sanz
Avda. Ágreda, 31 42110 ÓLVEGA (Soria)
Tel.: 976 645 474 - Fax: 976 196 316

CERTIFICADO DE CONFORMIDAD
CERTIFICATE OF COMPLIANCE

PRODUCTO / ***PRODUCT***: DUTASVITAE GALENICUM 6OB 0,5 MG 30 C CHL

CÓDIGO Y LOTE INTERNO / ***INTERNAL CODE & BATCH No.:*** 001067 201424

CLIENTE / ***CUSTOMER***: GALENICUM

1. This batch of product has been fabricated /manufactured, including quality control at the above-mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specification of the Marketing Authorisation.
2. The batch processing and analysis records were reviewed and found to be in compliance with GMP.
3. All deviations have been evaluated and approved based on fixed internal procedures
   - ☒ no release relevant deviation
   - ☐ release relevant deviations according enclosure
   - ☐ additional quality relevant information for the mentioned batch is enclosed

   I hereby certify that the above information is authentic and accurate.

Fecha de fabricación/***Date of manufacture:*** Ver certificado de análisis adjunto/***See attached certificate of analysis***

Aprobado por / ***Approved by:***

Mar Sánchez
Directora técnica
Qualified Person

Firma y fecha /
Signature and date:

18/6/2020

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