SAG MANUFACTURING for life

CERTIFICATE OF ANALYSIS/CONFORMANCE/RELEASE

PRODUCT:	Dutamsuvitae 0,5/0,4MG 30CAP GH CL DUTAS/TAMSU 0,5/0,4MG 30CAP GH CL			**Bulk/Batch:**	**DPB2049**
Dosage form:	Capsules			**Local Code:**	203344
Package size/type	30 capsules			**Final Quantity (units)**	31.228
Strength/Potency:	Dustasteride/Tamsulosin (0,5 /0,4mg/capsule)			**Manufacturing date:**	30/JUN/2020
API Lot (SAG/Manufacturer):	Dutasteride: 204075/204075 Tamsulosin: 27987/AB57044 - 27988/AB62466			**Expiration date:**	05.2022
Importing Country:	Chile			**Date of analysis:**	NOV/2020
Manufacturing Autorisation Nº:	6540E	**Certificate GMP Compliance Nº:**	ES/118HVI/19	**Product Marketing Autorisation Nº:**	F-25373
Manufacturing Bulk/Packaging /Quality Control site			SAG MANUFACTURING S.L.U Km. 36 A-I, 28750. San Agustin de Guadalix. Madrid (ESP)		

REQUIREMENTS/ TESTS	SPECIFICATIONS / ACCEPTANCE LIMITS	RESULTS
Description	Orange cap and brown body hard capsules size 00 containing white to off-white pellets and one yellow soft gelatin capsule with an oily and yellowish liquid.	Complies
Identification Dutasteride		
- UV	The UV spectrum of the Dutasteride peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Dutasteride and BHT Assay.	Complies
- HPLC	The retention time of the Dutasteride peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Dutasteride and BHT Assay.	Complies
Identification BHT		
- UV	The UV spectrum of the BHT peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Dutasteride and BHT Assay.	Complies
- HPLC	The retention time of the BHT peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Dutasteride and BHT Assay	Complies
Identification Tamsulosin HCl		
- UV	The UV spectrum of the Tamsulosin peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Tamsulosin Assay.	Complies
- HPLC	The retention time of the Tamsulosin peak in the chromatogram of the Assay preparation corresponds to that the reference standard preparation obtained as directed in the Tamsulosin Assay.	Complies
Uniformity of dosage units (content uniformity) - Dutasteride - Tamsulosin hydrochloride	 AV NMT 15.0 AV NMT 15.0	 Complies Complies
Water content of pellets of Tamsulosin hydrochloride (by KF)	NMT 8.5 %	4.3 %

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REQUIREMENTS/ TESTS	SPECIFICATIONS / ACCEPTANCE LIMITS	RESULTS
Dutasteride dissolution test	NLT 80% (Q=75) in 60 minutes	96 %
Tamsulosin hydrochloride dissolution test Stage 1 (0.1 N HCl): 2 h Stage 2 (Buffer Phosphate pH 6.8) 1h 6h	 NMT 10% 25% - 60% NLT 75%	 0 % 35 % 89 %
Assay (by HPLC) - Dutasteride assay - BHT assay - Tamsulosin hydrochloride assay	 95% to 105% 90% to 110% 95% to 105%	 99 % 97 % 99 %
Dutasteride related substances (by HPLC) - Any individual impurity - Total impurities	 NMT 0.5% NMT 1.0%	 0.0 % 0.0 %
Tamsulosin hydrochloride related substances (by HPLC) - Any individual impurity - Total impurities	 NMT 0.8 % NMT 1.5 %	 0.1 % 0.2 %
Microbial examination (*) - TAMC - TYMC - *Escherichia coli*	 NMT 10^3 CFU/g NMT 10^2 CFU/g Absence in 1 g	 NP NP NP

(*)non-routine test; NP = Not Performed

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 in full compliance with GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country and in compliance with Quality Agreement with customer.

No significant deviations are related to this batch.

26 nov 2020

Approved by: ***Sonia Valverde***
Date of issue: Qualified Person