Synthon Hispania S.L.

Synthon

Certificate of Conformance

Local trade name:	Tamsin Forte
Marketing Authorization number:	UA/14197/01/01
Synthon item number:	339963
Batch number:	2400949A
Strength:	0.4 mg / Tamsulosin
Dosage form:	prolonged release tablets
Packaging size and type:	10 tablets per blister, 3 blisters per carton box
Manufacturing site API	Synthon s.r.o., Brnenska 32/cp. 597, Blansko, 67801, Czech Republic
Authorization number of manufacturing site API:	sukls 132091/2021 (GMP)
Manufacturing site Bulk Drug Product:	Synthon Hispania, S.L. C/Castello, n°1, Sant Boi de Llobregat, Barcelona, 08830, Spain
Authorization number of manufacturing site Bulk Drug Product:	0438 (ML)/ NCF/2344/002/CAT (GMP)
Primary and secondary Packaging site:	GE Pharmaceuticals, Ltd Industrial zone, Chekanitza-South area, Botevgrad, 2140, Bulgaria
Manufacturing Authorization number of Primary and secondary Packaging site:	BG/MIA-0433 (ML) / BG/GMP/2022/197 (GMP)
Batch Release site:	Synthon Hispania, S.L. C/Castello, n°1, Sant Boi de Llobregat, Barcelona, 08830, Spain
Authorization number of batch release site:	0438 (ML)/ NCF/2344/002/CAT (GMP)
Batch size finished product:	47427 packs
Number of relevant deviations:	/NA
Remarks / comment:	/NA

By.doc 25/7/11

23.05.2024

Synthon Hispania S.L. | CIF: ES-61739645
C/ Castelló 1 | P.I. Las Salinas | 08830 Sant Boi de Llobregat | Barcelona | Spain | Tel +34 936 401 516 | Fax +34 936 401 146
www.synthon.com | Inscrita en el Registro Mercantil de Barcelona en la hoja número B-184.023, folio 43, tomo 30.987, inscripción 1

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

This batch of product has been manufactured including packaging (if applicable) and quality control at the above mentioned site(s) in full compliance with EU GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the Importing country, and any additional requirements as agreed upon in a Quality Agreement.

The Drug Substance Tamsulosin hydrochloride is produced according to current GMP.

The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU GMP.

The Drug Product complies with the current BSE/TSE guidelines.

Any deviation has been assessed and documented. For any deviation that might have an influence on the quality, safety and/or efficacy of the product (relevant deviation), a deviation report is added to the CoC.

The batch complies with CFPS.NUS.38374 (1.0) and is released for shipment to Mega Lifesciences Pty Ltd by a Qualified Person of Synthon Hispania S.L. for sale by Mega Lifesciences Pty Ltd.

In combination with the corresponding Certificate of Analysis this document forms the Quality Batch release certification for the above detailed product batch. This document is an integral part of the relevant Certificate of Analysis.

Signature: _____ Anna Martínez Qualified Person Synthon Hispania, S.L.

Date: 13 MAY 2024

Qualified Person Synthon Hispania S.L.

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Certificate of Analysis

TAMSIN FORTE 0.4mg Prolonged-release tablet

Lot Number : 2400949A

Item Number : 339963

Date of Manufacture : 09-Feb-2024

Expiry Date : Feb-2027

Manufacturing Site : Synthon Hispania S.L.

Tests	Results	Acceptance Criteria
Appearance	Complies	White, un-scored, round biconvex tablets debossed on one side with "T9SL" and "0.4" on the other side
Hardness		
Minimum	152 N	
Maximum	195 N	
Average	171 N	≥ 90 N
Friability	0.0 %	≤ 1.0 %
Water content	2.5 %	≤ 6.0 %
Dissolution in 4 hours		
Minimum	38 %	
Maximum	42 %	
Average	40 %	27 - 47% in 4 hours
Dissolution in 12 hours		
Minimum	71 %	
Maximum	75 %	
Average	73 %	63 - 83% in 12 hours
Dissolution in 20 hours		
Minimum	87 %	
Maximum	90 %	
Average	88 %	≥ 80% in 20 hours
Number of units tested	6	
Conclusion	Complies, L1	.
Identification (tamsulosin)		
HPLC retention time	Complies	The same as standard prep.
TLC retardation factor	Complies	The same as standard prep.
Assay (tamsulosin hydrochloride)		
HPLC	0.40 mg/tablet	0.38 - 0.42 mg/tablet
HPLC (% label claim)	100.1 %	(95.0 - 105.0 %)

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Certificate of Analysis

TAMSIN FORTE 0.4mg Prolonged-release tablet

Lot Number: 2400949A

Tests	Results	Acceptance Criteria
Uniformity of dosage units	Complies	Complies with Ph. Eur. 2.9.40
Minimum (% of label claim)	98.1 %	
Maximum (% of label claim)	103.9 %	
Average (% of label claim)	100.8 %	
RSD	1.6 %	
Acceptance Value	4.0	≤ 15.0
Number of Units Tested	10	
Impurities HPLC		
Y#043 (Desethoxytamsulosin)	≤ 0.1 %	≤ 0.5 %
Y#060 (Methyl-tamsulosin)	≤ 0.1 %	≤ 0.5 %
Largest unspecified impurity	≤ 0.1 %	≤ 0.2 %
Total impurities	≤ 0.1 %	≤ 1.5 %
Microbial contamination		
Total aerobic microbial count (TAMC)	Not Performed	≤ 1000 CFU/g
Total combined yeasts/moulds count (TYMC)	Not Performed	≤ 100 CFU/g
Escherichia coli	Not Performed	Not present/g

This batch complies with the specification set in CFPS.NUS.38374 (1.0).

Issued by : Andrea Lopez Ibañez
QA CMO Specialist

Date of Issue : 13/May/2024
This is an electronic signature