

Batch Certificate Release for Market			
Production Site:	Catalent Germany Schorndorf GmbH Steinbeisstr.1-2 73614 Schorndorf - Germany	Manufacturing Authorisation No.:	DE BW 01 MIA 2019 0118
Product (Name / dosage form):		Duodart 0,5mg / 0,4mg capsules	
Customer:		Glaxo Smith Kline	
Item No. (Customer/Catalent):		P220287131	PCD287131CATALENT,CHE11
Importing Country:		Chile	
Marketing authorisation No.:		I.S.P.N° F-18.358	
Package size (contents/type of container):		Finished package of 30 hard capsules	
Packaging:			
Batch No. Packaging (Customer/Catalent):		4082719B	4136974
Expiry Date (Finished pack):		04/2022	
Yield (Packaging):		100.0 %	
Packaging date:		27.05.2020 - 28.05.2020	
Master batch record version:		10	
Manufacturing:			
Batch No. Bulk (Customer/Catalent):		4082719	4082719
Manufacturing date:		22.04.2020	
Yield (Bulk):		97.6 %	
Identity name / amount API per unit dose:		Dutasteride 0,5mg; Tamsulosin HCl 0,4mg	
Batch size (Bulk):		2773331 capsules	
Master batch record version:		4	
Order Details:			
Quantity delivered (excl. samples):		48600 finished packages	
Yield (commercial):		partial delivery	
Order No. (Customer/Catalent):		572207	195065
Customer Samples:		n.a.	
Quality Control (COA attached):		Release Testing performed by Catalent	
Remarks:			
Tamsulosin HCl Pellets Batch No.Customer 2000113/6471802			
Deviations:			
no			
I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with current / EU GMP requirements and with the requirements of the Marketing Authorisation(s) of the destination country/countries.			
Name of Qualified Person, Date		Signature of Qualified Person	
Thomas, Daniela/OP 03. JUNI 2020			

Certificate of Analysis - 100025544

Duodart Finished Pack

Customer: Glaxo Smith Kline
 Customer Lot: 4082719B
 Internal Lot: 4136974
 Internal Bulk-Lot: 4082719
 Item Number: PCD287131CATALENT,CHE11
 Order: 195065
 Manufacturing date: 22-APR-2020
 Expiry date: 30-APR-2022
 Date of Analysis: 02-JUN-2020
 Test Instruction: PA 465 / 505
 Specification: PA465-DUTAM-
 INTERNATIONAL-GLOBAL G 4

Test	Specification	Result
General		
Appearance	oblong Hard-shell capsule; orange cap imprinted with black GS 7CZ and brown body	complies -
Identity Dutasteride (HPLC)	Retention time must comply with reference	complies -
Identity Tamsulosin (HPLC)	Retention time must comply with reference	complies -
Assay		
Dutasteride (HPLC)	0.475 - 0.525 mg	0.508 mg
Dutasteride (HPLC)	95.0 - 105.0 %	101.7 %
Tamsulosin (HPLC)	0.380 - 0.420 mg	0.404 mg
Tamsulosin (HPLC)	95.0 - 105.0 %	101.0 %
Uniformity of dosage units		
Tamsulosin-HCL (HPLC)	complies	complies -
AV	<= 15.0	5.8 -
Dissolution Dutasteride		
Vessel 1	complies with USP<711> and Ph.Eur.2.9.3 with Q = 80%	106 %
Vessel 2		105 %
Vessel 3		102 %
Vessel 4		104 %
Vessel 5		103 %
Vessel 6		105 %
Mean value		104 %
Dissolution Tamsulosin 2h		
Vessel 1	complies with USP<711> and Ph.Eur.2.9.3 with <= 10 %	2 %
Vessel 1	complies with USP<711> and Ph.Eur.2.9.3 with <= 10 %	2 %
Vessel 2		2 %
Vessel 2		1 %
Vessel 3		2 %
Vessel 3		4 %
Vessel 4		2 %
Vessel 4		3 %

Certificate of Analysis - 100025544

Duodart Finished Pack

Test	Specification	Result	
Dissolution Tamsulosin 2h			
Vessel 5		2	%
Vessel 5		2	%
Vessel 6		2	%
Vessel 6		1	%
Mean value		2	%
Mean value		n.a.	%
Dissolution Tamsulosin 3h			
Vessel 1	40 - 70 %	51	%
Vessel 1	40 - 70 %	52	%
Vessel 2		50	%
Vessel 2		50	%
Vessel 3		54	%
Vessel 3		51	%
Vessel 4		50	%
Vessel 4		52	%
Vessel 5		52	%
Vessel 5		53	%
Vessel 6		55	%
Vessel 6		52	%
Mean value		52	%
Mean value		n.a.	%
Dissolution Tamsulosin 7h			
Vessel 1	>= 80%	92	%
Vessel 1	>= 80%	93	%
Vessel 2		90	%
Vessel 2		92	%
Vessel 3		93	%
Vessel 3		90	%
Vessel 4		91	%
Vessel 4		90	%
Vessel 5		92	%
Vessel 5		91	%
Vessel 6		93	%
Vessel 6		92	%
Mean value		92	%
Mean value		n.a.	%

The bulk-batch meets the specification and has been signed on 02.06.20 by André Weiß electronically.

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Duodart Finished Pack

Test**Specification****Result**

The batch conforms to the specification and was signed electronically by André Weiß on 02.06.20.