

Finasteride

CODE ARTICLE: 4178	BATCH: 0123999	Active pharmaceutical ingredient
TEST DATE: 14/12/2023	TEST: QC-00259555	
EXPIRY DATE: 27/05/2028	FABRICATION DATE: 28/05/2023	MR: 372,60
CAS: [98319-26-7]	FORMULA: C23H36N2O2	
SYNONYMS / BOTANICAL NAME: Finasteride		
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POWDER	PH.EUR.*
COLOUR	CONFORM	-		WHITE	PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN ABSOLUTE				PH.EUR.*
	ETHANOL				
SOLUBLE	FREELY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
INSOLUBLE	PRACTICALLY INSOLUBLE IN				PH.EUR.*
	WATER				
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
ROTACION OPTICA (SUST.SECA)	12,5 -		12	14	PH.EUR.*
LOSS ON DRYING	0,04 %		-	0,5	PH.EUR.*
SUSTANCIAS RELACIONADAS					
IMPURITY A	0,1 %		-	0,3	PH.EUR.*
IMPURITY C	<RT=0,05 -			<=0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,05 %		-	0,1	PH.EUR.*
TOTAL IMPURITIES	0,2 %		-	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,4 %		98	102	PH.EUR.*
RESIDUAL SOLVENTS					
ACETONE	N.D. MG/KG			5000	Manufacture's Standard
CHLOROFORM	N.D. MG/KG			60	Manufacture's Standard
THF	N.D. MG/KG			720	Manufacture's Standard
TOLUENE	N.D. MG/KG			890	Manufacture's Standard
METHANOL	6 MG/KG			3000	Manufacture's Standard
TERT-BUTANOL	N.D. MG/KG			1000	Manufacture's Standard
ETHYL ACETATE	N.D. MG/KG			5000	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS -				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS -				Manufacture's Standard

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer: 43238 H. Y. PHARMACEUTICAL CO., LTD. (China) Manufacturer Batch: FSD-230509 Manufacturer original CoA available under request

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Silvia Sancho-Tello Ripoll
Technical Director.

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