

Finasteride

CODE ARTICLE: 4176	BATCH: 0125086	Active pharmaceutical ingredient
TEST DATE: 29/01/2024	TEST: QC-00260825	
EXPIRY DATE: 29/12/2028	FABRICATION DATE: 30/12/2023	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	PASS -			CRYSTALLINE WHITE POWDER	PH.EUR.*
SOLUBILITY					
SOLUBLE	FREELY SOLUBLE IN ABSOLUTE ETHANOL				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
IDENTIFICATION					
IR IDENTIFICATION	CONFORM				PH.EUR.*
ROTACION OPTICA (SUST.SECA)	12,5 -		12	14	PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
SUSTANCIAS RELACIONADAS					
IMPURITY A	0,1 %		-	0,3	PH.EUR.*
IMPURITY C	0,1 %		-	0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,06 %		-	0,1	PH.EUR.*
TOTAL IMPURITIES	0,2 %		-	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,9 %		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	8	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
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				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-231211 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain
Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



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Silvia Sancho-Tello Ripoll
Technical Director.

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