GUINAMA
ABSOLUTA CALIDAD

Certificate of Analysis

Finasteride

CODE ARTICLE: 4175	**BATCH:** 0131546 **Active pharmaceutical ingredient**
TEST DATE: 25/10/2024	**TEST:** QC-00269222
EXPIRY DATE: 02/05/2029 **FABRICATION DATE:** 03/05/2024	**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	PASS				PH.EUR.*
ROTACION OPTICA (SUST.SECA)	12,5	-	12	14	PH.EUR.*
LOSS ON DRYING	0,03	%	-	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	%		0,10	PH.EUR.*
TOTAL IMPURITIES	0,2	%	-	0,5	PH.EUR.*
ASSAY (DRY SUBSTANCE)	101,5	%	98	102	PH.EUR.*
RESIDUAL SOLVENTS					
ACETONE	N.D.	ppm		5000	Manufacture's Standard
CHLOROFORM	N.D.	ppm		60	Manufacture's Standard
THF	N.D.	ppm		720	Manufacture's Standard
TOLUENE	N.D.	ppm		890	Manufacture's Standard
METHANOL	N.D.	ppm		3000	Manufacture's Standard
TERT-BUTANOL	N.D.	ppm		1000	Manufacture's Standard
ETHYL ACETATE	N.D.	ppm		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-240419 Manufacturer original CoA available under request

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GOOD MANUFACTURING PRACTICE GMP

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Silvia Sancho-Tello Ripoll
Technical Director.

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