

## Finasteride

<b>CODE ARTICLE:</b> 4178	<b>BATCH:</b> 0127780	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 17/05/2024	<b>TEST:</b> QC-00264441	
<b>EXPIRY DATE:</b> 29/12/2028	<b>FABRICATION DATE:</b> 30/12/2023	<b>MR:</b> 372,60
<b>CAS:</b> [98319-26-7]	<b>FORMULA:</b> C23H36N2O2	
<b>SYNONYMS / BOTANICAL NAME:</b> Finasteride		
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			CRYSTALLINE WHITE POWDER	PH.EUR.*
<b>SOLUBILITY</b>					
SOLUBLE	FREELY SOLUBLE IN ABSOLUTE				PH.EUR.*
	ETHANOL				
SOLUBLE	FREELY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
INSOLUBLE	PRACTICALLY INSOLUBLE IN				PH.EUR.*
	WATER				
<b>IDENTIFICATION</b>					
IR IDENTIFICATION	PASS				PH.EUR.*
ROTACION OPTICA (SUST.SECA)	12,5 -		12	14	PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
<b>SUSTANCIAS RELACIONADAS</b>					
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.*
<b>RESIDUAL SOLVENTS</b>					
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

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**Silvia Sancho-Tello Ripoll**  
Technical Director.

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