

Testosterone

CODE ARTICLE: 10856	BATCH: 0126731	Active pharmaceutical ingredient
TEST DATE: 28/02/2024	TEST: QC-00261853	
EXPIRY DATE: 15/12/2026	FABRICATION DATE: 16/12/2023	MR: 288,40
CAS: [58-22-0]	FORMULA: C19H28O2	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		crystalline powder	PH.EUR.*
COLOUR	CONFORM			white, almost white, colorless or slightly yellow	PH.EUR.*
MELTING POINT		155 DEGREES		Sobre 155	PH.EUR.*
<u>SOLUBILITY</u>					
INSOLUBLE	PRACTICALLY INSOLUBLE IN FATTY ACIDS				PH.EUR.
INSOLUBLE	PRACTICALLY INSOLUBLE IN WATER				PH.EUR.*
SOLUBLE	FFREELY SOLUBLE IN METHYLENE CHLORIDE				PH.EUR.*
SOLUBLE	FREELY SOLUBLE IN ETHANOL				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
ROTACION OPTICA (SUST.SECA)	110 DEGREES		106	114	PH.EUR.*
LOSS ON DRYING	0,2 %		-	1	PH.EUR.*
<u>RELATED SUBSTANCES (HPLC)</u>					
TOTAL IMPURITIES	0,2 %			0,6	PH.EUR.*
UNSPECIFIED IMPURITIES	0,05 %			0,10	PH.EUR.*
IMPURITY C	0,1 %			0,3	PH.EUR.*
IMPURITY I	<DL (0,05) %			0,2	PH.EUR.*
IMPURITY K	0,05 %			0,15	PH.EUR.*
ASSAY (DRY SUBSTANCE)	99,2 %		98	102	PH.EUR.*
<u>PARTICLE SIZE</u>					
PARTICLE SIZE 90%	CONFORM MICRONS			50	Manufacture's Standard
PARTICLE SIZE 99%	CONFORM MICRONS			100	Manufacture's Standard
<u>RESIDUAL SOLVENTS</u>					
ETHYL ACETATE	29 MG/KG			<5000	Manufacture's Standard
ETHYL FORMATE	N.D. MG/KG			<5000	Manufacture's Standard
METHANOL	N.D. MG/KG			<3000	Manufacture's Standard
PYRIDINE	N.D. MG/KG			<200	Manufacture's Standard
ETHANOL	N.D. MG/KG			<5000	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				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: 56057 H. Z. H. PHARMACEUTICAL CO., LTD. (China) Manufacturer Batch: GT231206W Manufacturer original CoA available under request

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TEST	RESULTS	Units	MIN	MAX	METHOD
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				Manufacture's Standard
Elemental Impurities ICHQ3D	PASS				Manufacture's Standard



Silvia Sancho-Tello Ripoll
Technical Director.

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