

Ketoconazole

CODE ARTICLE: 93891	BATCH: 0122049	Active pharmaceutical ingredient
TEST DATE: 26/09/2023	TEST: QC-00257055	
EXPIRY DATE: 30/08/2027	FABRICATION DATE: 01/09/2022	MR: 531,40
CAS: [65277-42-1]	FORMULA: C ₂₆ H ₂₈ Cl ₂ N ₄ O ₄	
STORAGE: Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM	-		POLVO	PH.EUR.*
COLOUR	CONFORM	-		BLANCO	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	MODERADAMENTE SOLUBLE EN				PH.EUR.*
	ETANOL 96				
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
MELTING POINT	150,7 °C		148	152	PH.EUR.
IR IDENTIFICATION	CONFORM				PH.EUR.*
TLC	CONFORM				PH.EUR.
IDENTIFICATION, CHLORIDES REACTION	CONFORM				PH.EUR.
SPECIFIC ROTATION	0 DEGREES		-0,1	0,1	PH.EUR.*
DISSOLUTION ASPECT	CONFORM	-		Límpida y color <BY4	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	0,2 %			<=0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,07 %			<=0,10	PH.EUR.*
IMPURITY D	0,1 %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,3 %		-	0,5	PH.EUR.*
SULPHATED ASHES	0,04 %		-	0,1	PH.EUR.*
ASSAY	100,6 %		99	101	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	74,28 ppm		-	3.000	Manufacture's Standard
ACETONE	622,43 ppm		-	5.000	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	CONFORM				
Elemental Impurities ICHQ3D	CONFORM				

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.



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Silvia Sancho-Tello Ripoll
Technical Director.

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