

Ketoconazole

CODE ARTICLE: 93892	BATCH: 0120468	Active pharmaceutical ingredient
TEST DATE: 17/06/2022	TEST: QC-00243863	
EXPIRY DATE: 30/07/2026	FABRICATION DATE: 30/08/2021	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	POWDER				PH.EUR.*
COLOUR	WHITE				PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	SPARINGLY SOLUBLE IN ETHANOL				PH.EUR.*
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
MELTING POINT	149,7 °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	0,25 %			<=0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,10 %			<=0,10	PH.EUR.*
IMPURITY D	0,15 %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,02 %		-	0,5	PH.EUR.*
SULPHATED ASHES	0,1 %		-	0,1	PH.EUR.*
ASSAY	100,58 %		99	101	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	146,21 ppm		-	3.000	Manufacture's Standard
ACETONE	641,09 ppm		-	5.000	Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
SPECIFICATION	PH.EUR 10				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				

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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