

Ketoconazole

CODE ARTICLE: 93891	BATCH: 0125800	Active pharmaceutical ingredient
TEST DATE: 22/02/2024	TEST: QC-00261662	
EXPIRY DATE: 30/11/2028	FABRICATION DATE: 30/12/2023	MR: 531,40
CAS: [65277-42-1]	FORMULA: C26H28Cl2N4O4	
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	MODERATELY SOLUBLE IN				PH.EUR.*
	ETHANOL 96				
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
MELTING POINT	150,1 °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	0,07 %			<=0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,07 %			<=0,10	PH.EUR.*
IMPURITY D	<RT=0,05 %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
SULPHATED ASHES	0,03 %		-	0,1	PH.EUR.*
ASSAY	99,3 %		99	101	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	64,86 ppm		-	3.000	Manufacture's Standard
ACETONE	748,65 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				



Silvia Sancho-Tello Ripoll
Technical Director.

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: 43296 A. D. LIMITED (India) Manufacturer Batch: KET/123120663 Manufacturer original CoA available under request
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