

Ketoconazole

CODE ARTICLE: 93892	BATCH: 0130704	Active pharmaceutical ingredient
TEST DATE: 12/09/2024	TEST: QC-00267912	
EXPIRY DATE: 30/03/2029	FABRICATION DATE: 01/04/2024	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	PASS -			POWDER	PH.EUR.*
COLOUR	PASS -			WHITE	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	FREELY SOLUBLE IN DICHLOROMETHANE				PH.EUR.*
SOLUBLE	METHANOL				PH.EUR.*
SOLUBLE	MODERATELY SOLUBLE IN ETHANOL 96				PH.EUR.*
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
MELTING POINT	150,1 °C		148	152	PH.EUR.
IR IDENTIFICATION	PASS				PH.EUR.*
SPECIFIC ROTATION	0 DEGREES		-0,1	0,1	PH.EUR.*
DISSOLUTION ASPECT	PASS -			Clear and <BY4	PH.EUR.*
<u>RELATED SUBSTANCES</u>					
TOTAL IMPURITIES	0,2 %			<=0,3	PH.EUR.*
UNSPECIFIED IMPURITIES	0,05 %			<=0,10	PH.EUR.*
IMPURITY D	0,1 %			<=0,2	PH.EUR.*
LOSS ON DRYING	0,1 %		-	0,5	PH.EUR.*
SULPHATED ASHES	0,1 %		-	0,1	PH.EUR.*
ASSAY	99,9 %		99	101	PH.EUR.*
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11				Manufacture's Standard
Risk Assessment Evaluation for Nitrosamines	PASS				
Elemental Impurities ICHQ3D	PASS				



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.

