

Itraconazol

CODE ARTICLE: 11474	BATCH: 0133229	Active pharmaceutical ingredient
TEST DATE: 21/05/2024	TEST: QC-00264536	
EXPIRY DATE: 30/01/2028	FABRICATION DATE: 01/02/2023	MR: 706,00
CAS: 84625-61-6	FORMULA: C35H38Cl2N8O4	
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				PH.EUR.*
	DICHLOROMETHANE				
SOLUBLE	VERY SLIGHTLY SOLUBLE IN				PH.EUR.*
	ETHANOL				
INSOLUBLE	WATER				PH.EUR.*
<u>IDENTIFICATION</u>					
IR IDENTIFICATION	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Limpid and color <BY6	PH.EUR.*
<u>RELATED SUBSTANCES (HPLC)</u>					
TOTAL IMPURITIES	0,1% (PASS) -			<=0,8% (<= 8xArea SR A)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,07% (PASS) -			<= 0.10% (<= Progesterone area RS A)	PH.EUR.*
IMPURITY B	<DL=0,05% (CONFORM) -			<=0,3% (<= 3xArea SR A)	PH.EUR.*
IMPURITY G	< DL=0,05% (PASS) -			<=0,3% (<= 3xArea SR A)	PH.EUR.*
IMPURITY E	< DL=0,05% (PASS) -			<=0,2% (<= 2xArea SR A)	PH.EUR.*
SUMA IMPUREZAS C+D	0,1% (PASS) -			<=0,3% (<= 3xArea SR A)	PH.EUR.*
LOSS ON DRYING	0,2 %		0,0	0,5	PH.EUR.*
SULPHATED ASHES	0,04 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,7 %		99	101	PH.EUR.*
<u>RESIDUAL SOLVENTS</u>					
METHANOL	BQL ppm			<=3000	Manufacture's Standard
METHYL ISOBUTYL KETONE	19 ppm		-	4.500	Manufacture's Standard
DICHLOROMETHANE	47 ppm		-	600	Manufacture's Standard
TOLUENE	BDL ppm			<=890	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	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.

Manufacturer: 43330 V. P. C. LIMITED (India) Manufacturer Batch: CIZL/2310002 Manufacturer original CoA available under request

GUINAMA S.L. Calle Oslo, 3 46185 La Pobla de Vallbona (Valencia) Spain

Phone: +34 96 186 90 90 / 902 11 98 16 Fax: 96 185 03 52 E-mail: ventas@guinama.com - www.guinama.com



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TEST	RESULTS	Units	MIN	MAX	METHOD
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NON-sterile



The product has been handled in NON-sterile rooms, therefore this product
IS NOT STERILE

Silvia Sancho-Tello Ripoll
Technical Director.

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