

**Itraconazol**

<b>CODE ARTICLE:</b> 11470	<b>BATCH:</b> 0120359	<b>Active pharmaceutical ingredient</b>
<b>TEST DATE:</b> 30/06/2023	<b>TEST:</b> QC-00254823	
<b>EXPIRY DATE:</b> 30/09/2026	<b>FABRICATION DATE:</b> 01/10/2022	<b>MR:</b> 706,00
<b>CAS:</b> 84625-61-6	<b>FORMULA:</b> C35H38CI2N8O4	
<b>STORAGE:</b> Store in tightly closed containers in a cool, dry place.		

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	CONFORM			POWDER	PH.EUR.*
COLOUR	CONFORM			White	PH.EUR.*
<b><u>SOLUBILITY</u></b>					
SOLUBLE	FREELY SOLUBLE IN				PH.EUR.*
	DICHLOROMETHANE				
SOLUBLE	VERY SLIGHTLY SOLUBLE IN				PH.EUR.*
	ETHANOL				
INSOLUBLE	WATER				PH.EUR.*
<b><u>IDENTIFICATION</u></b>					
IR IDENTIFICATION	CONFORM				PH.EUR.*
DISSOLUTION ASPECT	CONFORM -			Limpid and color <BY6	PH.EUR.*
<b><u>RELATED SUBSTANCES (HPLC)</u></b>					
TOTAL IMPURITIES	0,2% (PASS) -			<=0,8% (<= 8xArea SR A)	PH.EUR.*
UNSPECIFIED IMPURITIES	0,08% (PASS) -			<= 0.10% (<= Progesterone area RS A)	PH.EUR.*
IMPURITY B	0,1% (PASS) -			<=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	0,03 %		0,0	0,5	PH.EUR.*
SULPHATED ASHES	0,1 %		0,0	0,1	PH.EUR.*
ASSAY (DRY SUBSTANCE)	100,7 %		99	101	PH.EUR.*
<b><u>RESIDUAL SOLVENTS</u></b>					
METHANOL	BDL MG/KG			<=3000	Manufacture's Standard
METHYL ISOBUTYL KETONE	16 MG/KG		-	4.500	Manufacture's Standard
DICHLOROMETHANE	91 MG/KG		-	600	Manufacture's Standard
TOLUENE	BDL MG/KG			<=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				

**NON-sterile**

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/2301001 Manufacturer original CoA available under request  
 GUINAMA S.L. C/ OSLO,3 (before C/Praga) POL.IND. GUTENBERG 46185 La Pobra 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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**Este producto ha sido manipulado en sala NO estéril, para lotes aptos uso estéril consultar disponibilidad.**

**Silvia Sancho-Tello Ripoll**  
Technical Director.

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