

ITRACONAZOL (EUR. PH.)

PRODUCT CODE: 002739	CAS Nº: 84625-61-6	ANALYSIS Nº: 133/24
MANUFACTURER BATCH: CIZL/2310002	CERTIFICATE ID: 42.210	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/02/2023	
METAPH BATCH: 0170524	RETEST DATE: 30/01/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, very slightly soluble in ethanol (96 %)	Complies (*)
Identification	Complies	Complies
Appearance of solution	Clear and not more coloured than ref. sol. R6 or B6.	Complies
Related substances		
Impurity B	=< 0.3 %	Not Detected
Impurity G	=< 0.3 %	Not Detected
Impurity E	=< 0.2 %	< 0.05 %
Sum of impurities C and D	=< 0.3 %	0.07 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.8 %	0.07 %
Loss on drying	=< 0.5 %	0.2 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	99.6 %

COMPLIES WITH

European Pharmacopeia 11.0

REMARKS

Itraconazole is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

Analysis date: 28/05/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000715

