



## TECHNICAL DATA SHEET

002739-TDS-ENG-2024

<b>ITRACONAZOL (EUR. PH.)</b>		
DESCRIPTION DCI: itraconazole		DESCRIPTION DOE: ITRACONAZOL
CAS N°: 84625-61-6	EC N°: 617-596-9	AEMPS CODE: 2436A
MOL. WEIGHT: 705,63	MOL. FORMULA: C <sub>35</sub> H <sub>38</sub> Cl <sub>2</sub> N <sub>8</sub> O <sub>4</sub>	ARTICLE CODE: 002739

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

### COMPLIES WITH

European Pharmacopeia 11.0

### STORAGE

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

### REMARKS

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

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.