

**KETOCONAZOL (EUR. PH.)**

PRODUCT CODE: 1165	CAS Nº: 65277-42-1	ANALYSIS Nº: 295/21
MANUFACTURER BATCH: KET/12108345	CERTIFICATE ID: 33.259	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/08/2021	
METAPH BATCH: 0191121	EXPIRY DATE: 30/07/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 %)	Complies (*)
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. solution BY4	Complies
Optical rotation	-0.10° / +0.10°	0.0°
Related substances		
Impurity D	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	< 0.05 %
Loss on drying	=< 0.5 %	0.10 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	99.0 - 101.0 %	99.2 %
Residual solvents		(*) (**)
Acetone	=< 5000 ppm	641.09 ppm
Methanol	=< 3000 ppm	146.21 ppm

COMPLIES WITH

European Pharmacopoeia 10.3

REMARKS

Ketoconazole is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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

Store in a cool and dry place. Protect from light.

Analysis date: 10/03/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000297

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