METAPHARMACEUTICAL IND SL
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KETOCONAZOL (EUR. PH.)

PRODUCT CODE: 1165	CAS Nº: 65277-42-1	ANALYSIS Nº: 162/24	
MANUFACTURER BATCH:	KET/124040204	CERTIFICATE ID:	42.523
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/04/2024
METAPH BATCH:	0080624	EXPIRY DATE:	30/03/2029

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	-0.10º / +0.10º	+0.0º
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 %	0.1 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	99.0 - 101.0 %	99.7 %

COMPLIES WITH

European Pharmacopoeia 11.4

REMARKS

Ketoconazole 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.

STORAGE

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

Analysis date: 22/07/2024
Signature: Cristina Borrell Olea (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000297