METAPHARMACEUTICAL

TECHNICAL DATA SHEET

006997-TDS-ENG-2026

OXIBUTININA HCL (EUR. PH.)		
DESCRIPTION DCI: OXYBUTININ HYDROCHLORIDE	DESCRIPTION DOE: OXIBUTININA HIDROCLORURO	
CAS Nº: 5633-20-5	EC Nº: 630-332-7	AEMPS CODE: 366CH
MOL. WEIGHT: 357,49	MOL. FORMULA: C22H31NO3	ARTICLE CODE: 006997

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %), soluble in acetone, practically insoluble in cyclohexane
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution BY5
Optical rotation	-0.10 º / +0.10º
Related substances	
Impurity A	=< 1.5 %
Impurity C	=< 0.15 %
Impurity D	=< 0.15 %
Impurity F	=< 0.15 %
Unspecified impurities	=< 0.10 %
Sum of impurities other than A	=< 0.5 %
Loss on drying	=< 3.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Oxybutynin HCl is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.

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