METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1357-TDS-ENG-2021

OXANDROLONA USP		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: 53-39-4	EC Nº: 200-172-9	AEMPS CODE: ---
MOL. WEIGHT: 306.43	MOL. FORMULA: C19H30O3	ARTICLE CODE: 1357

ATTRIBUTES	SHOULD BE
Description	White, crystalline powder. Is stable in air but darkens on exposure to light
Identification A	Complies
Identification B	Complies
Melting range	215 - 225 ºC
Polymorph form	Complies
Specific rotation	-18º / -24º
Loss on drying	=< 1.0 %
Residue on ignition	=< 0.2 %
Related Compounds	
Secodicarboxylic acid	=< 0.1 %
Related compound A	=< 0.1 %
Retaled compound B	=< 0.3 %
Open lactone methyl ester	=< 0.1 %
Secoacid anhydride	=< 0.1 %
Methyltestosterone	=< 0.1 %
17-epi-Oxandrolone	=< 0.3 %
D1-Mestalone	=< 0.1 %
4-Oxa-isomer (beta epimer)	=< 0.3 %
Specified unknown impurity 1	=< 0.1 %
Oxandrolone-17-acetate	=< 0.1 %
Related compound C	=< 0.5 %
Individual impurities	=< 0.1 %
Total impurities	=< 1.0 %
Assay	98.0 - 102.0 %
Related substances TLC	
OXAN 5	=< 0.15 %
Residual solvents	
Methanol	=< 3000 ppm
Methylene Chloride	=< 600 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/g

COMPLIES WITH

USP 43

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STORAGE

Store in a ventilated place, in well-sealed containers, out of direct sunlight, light and moisture.

REMARKS

Oxandrolone 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.