METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TECHNICAL DATA SHEET

5-TDS-ENG-2025

ORLISTAT USP		
DESCRIPTION DCI: orlistat	DESCRIPTION DOE: ORLISTAT	
CAS Nº: 96829-58-2	EC Nº: 639-755-1	AEMPS CODE: 1077A
MOL. WEIGHT: 495,73	MOL. FORMULA: C29H53NO5	ARTICLE CODE: 5

ATTRIBUTES	SHOULD BE
Description	White to off-white fine powder or fine powder with lumps
Identification A	Complies
Identification B	Complies
Assay	98.0 - 101.5 %
Residue on ignition	=< 0.1 %
Limit Related Compound A	=< 0.2 %
Limit Related Compound B	=< 0.05 %
Organic Impurities	
Formylleucine	=< 0.2 %
Related compound C	=< 0.05 %
Open ring epimer	=< 0.2 %
D-leucine	=< 0.2 %
Any individual unspecified impurity	=< 0.1 %
Total impurities	=< 1.0 %
Limit Related Compound D and Open ring amide	
Related Compound D	=< 0.2 %
Open ring amide	=< 0.1 %
Limit Related Compound E	=< 0.2 %
Water	=< 0.2 %
Specific optical rotation	-48º / -51º

COMPLIES WITH

USP 2024

STORAGE

Protect from light and heat. Transport temperature 2 - 8 ºC

REMARKS

Orlistat 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.