

ORLISTAT USP

PRODUCT CODE: 5	CAS Nº: 96829-58-2	ANALYSIS Nº: 074/24
MANUFACTURER BATCH: T12B-A010-240101	CERTIFICATE ID: 41.536	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 19/01/2024	
METAPH BATCH: 0270324	RETEST DATE: 18/01/2026	

ATTRIBUTES	SHOULD BE	IS
Description	White to off-white fine powder or fine powder with lumps	White to off-white fine powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Assay	98.0 - 101.5 %	99.5 %
Residue on ignition	=< 0.1 %	0.08 %
Limit Related Compound A	=< 0.2 %	< 0.2 %
Limit Related Compound B	=< 0.05 %	Not Detected
Organic Impurities		
Formylleucine	=< 0.2 %	Not Detected
Related compound C	=< 0.05 %	Not Detected
Open ring epimer	=< 0.2 %	Not Detected
D-leucine	=< 0.2 %	Not Detected
Any individual unspecified	=< 0.1 %	Not Detected
impurity		
Total impurities	=< 1.0 %	Not Detected
Limit Related Compound D and		
Open ring amide		
Related Compound D	=< 0.2 %	Not Detected
Open ring amide	=< 0.1 %	Not Detected
Limit Related Compound E	=< 0.2 %	< 0.2 %
Water	=< 0.2 %	0.1 %
Specific optical rotation	-48° / -51°	-50°

COMPLIES WITH

USP 2024

REMARKS

Orlistat is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

Protect from light and heat.

Analysis date: 25/04/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001013
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