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

ORLISTAT USP

PRODUCT CODE: 5	CAS Nº: 96829-58-2	ANALYSIS Nº: 127/25	
MANUFACTURER BATCH:	202504002	CERTIFICATE ID:	46.504
SUPPLIER BATCH:	----	MANUFACTURING DATE:	02/04/2025
METAPH BATCH:	0140525	EXPIRY DATE:	01/04/2028

ATTRIBUTES	SHOULD BE	IS
Description	White to off-white fine powder or fine powder with lumps	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Assay	98.0 - 101.5 %	99.9 %
Residue on ignition	=< 0.1 %	0.08 %
Limit Related Compound A	=< 0.2 %	< 0.2 %
Limit Related Compound B	=< 0.05 %	< 0.003 %
Organic Impurities		
Formylleucine	=< 0.2 %	Not Detected
Related compound C	=< 0.05 %	< 0.001 %
Open ring epimer	=< 0.2 %	0.08 %
D-leucine	=< 0.2 %	Not Detected
Any individual unspecified impurity	=< 0.1 %	< 0.1 % (#)
Total impurities	=< 1.0 %	0.1 %
Limit Related Compound D and Open ring amide		
Related Compound D	=< 0.2 %	0.03 %
Open ring amide	=< 0.1 %	0.02 %
Limit Related Compound E	=< 0.2 %	< 0.2 %
Water	=< 0.2 %	0.03 %
Specific optical rotation	-48º / -51º	-50º

COMPLIES WITH

USP 2025

REMARKS

(#) Unspecified impurities detailed underneath:
RT 6.1 min) = 0.03 %
RT (6.7 min) = 0.02 %

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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.

Analysis date: 10/09/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001546
ARGUS PHARMACEUTICALS LTD.
Linyu Road, 178
Changsha National High-Tech Industrial Development Zone

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STORAGE

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

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