METAPHARMACEUTICAL IND SL
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ORLISTAT USP

PRODUCT CODE: 5	CAS Nº: 96829-58-2	ANALYSIS Nº: 05/23R	
MANUFACTURER BATCH:	T12B-A010-220201	CERTIFICATE ID:	38.928
SUPPLIER BATCH:	----	MANUFACTURING DATE:	18/02/2022
METAPH BATCH:	0110622	EXPIRY DATE:	17/02/2026

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 %	99.7 %
Residue on ignition	=< 0.1 %	0.03 %
Limit Related Compound A	=< 0.2 %	< 0.2 %
Limit Related Compound B	=< 0.05 %	< 0.05 %
Organic Impurities		
Formylleucine	=< 0.2 %	Not Detected
Related compound C	=< 0.05 %	< 0.01 %
Open ring epimer	=< 0.2 %	Not Detected
D-leucine	=< 0.2 %	Not Detected
Any individual unspecified impurity	=< 0.1 %	Not Detected
Total impurities	=< 1.0 %	< 0.01 %
Limit Related Compound D and Open ring amide		
Related Compound D	=< 0.2 %	0.01 %
Open ring amide	=< 0.1 %	0.02 %
Limit Related Compound E	=< 0.2 %	< 0.2 %
Water	=< 0.2 %	0.12 %
Specific optical rotation	-48 / -51	-50

COMPLIES WITH

USP 2023

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: 20/07/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001013
CHONGQING ZEIN PHARMACEUTICAL CO.,LTD
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