METAPHARMACEUTICAL IND SL
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TALIDOMIDA USP

PRODUCT CODE: 002797	CAS Nº: 50-35-1	ANALYSIS Nº: 335/24	
MANUFACTURER BATCH:	NPBX-065	CERTIFICATE ID:	44.614
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/09/2022
METAPH BATCH:	0221224	RETEST DATE:	30/09/2027

ATTRIBUTES	SHOULD BE	IS
Description	White or almost white powder	White crystalline powder
Identification A	Complies	Conmplies
Identification B	Complies	Complies
Assay	98.0 - 101.5 %	99.6 %
Organic impurities		
Individual impurities	=< 0.1 %	< 0.05 %
Total impurities	=< 0.3 %	< 0.05 %
Limit of glutamine	=< 0.1 %	< 0.1 %
Microbial contamination		
TAMC	< 1000 CFU/g	< 10 CFU/g
TYMC	< 100 CFU/g	< 10 CFU/g
Water	=< 0.5 %	0.1 %

COMPLIES WITH

USP 2025

REMARKS

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

Thalidomide 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

Preserve in tight container, protected from light, and store at room temperature.

Analysis date: 24/01/2025
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000771
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