

**TALIDOMIDA USP**

PRODUCT CODE: 002797		CAS Nº: 50-35-1	ANALYSIS Nº: 002/23
MANUFACTURER BATCH:	TDM20221003	CERTIFICATE ID:	36.897
SUPPLIER BATCH:	----	MANUFACTURING DATE:	22/10/2022
METAPH BATCH:	0010123	EXPIRY DATE:	21/10/2025

ATTRIBUTES	SHOULD BE	IS
Description	White or almost white powder	Almost white powder
Identification	Complies	Complies
Assay	98.0 - 101.5 %	100.7 %
Organic impurities		
Individual impurities	=< 0.1 %	< 0.10 % (#)
Total impurities	=< 0.3 %	0.08 %
Limit of glutamine	=< 0.1 %	< 0.10 %
Microbial contamination		
TAMC	< 1000 CFU/g	30 CFU/g
TYMC	< 100 CFU/g	< 10 CFU/g
Water	=< 0.5 %	0.06 %

**COMPLIES WITH**

USP 2023

**REMARKS**

(# ) Individual impurities detailed underneath:

RT (1.697 min) = 0.03 %

RT (7.890 min) = 0.04 %

RT (13.503 min) = 0.01 %

All data controlled by Metapharmaceutical Industrial SL.

Thalidomide is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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: 09/02/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000349

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