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

TECHNICAL DATA SHEET

002797-TDS-ENG-2023

TALIDOMIDE USP		
DESCRIPTION DCI: THALIDOMIDE	DESCRIPTION DOE: TALIDOMIDA	
CAS Nº: 50-35-1	EC Nº: 200-031-1	AEMPS CODE: 7064A
MOL. WEIGHT: 258.23	MOL. FORMULA: C13H10N2O4	ARTICLE CODE: 002797

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

COMPLIES WITH

USP 2023

STORAGE

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

REMARKS

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

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.

Contraindications

THALIDOMIDE should not be used by people who are breast feeding or pregnant, trying to conceive a child, or cannot or will not follow the risk management program to prevent pregnancies. The prescribing doctor is required to ensure that contraception is being used, and regular pregnancy tests must be administered. Some people are allergic to THALIDOMIDE and should not take it. It should be used with caution in people with chronic infections like HIV or hepatitis B.