

**TECHNICAL DATA SHEET**

002797-TDS-ENG-2026

| <b>TALIDOMIDA USP</b>        |                                                                             |                             |
|------------------------------|-----------------------------------------------------------------------------|-----------------------------|
| 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: C <sub>13</sub> H <sub>10</sub> N <sub>2</sub> O <sub>4</sub> | 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 2026

**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.