

**TECHNICAL DATA SHEET**

0510-TDS-ENG-2025

| <b>DILTIAZEM HCL (EUR. PH.)</b>          |                                                                                 |                                         |
|------------------------------------------|---------------------------------------------------------------------------------|-----------------------------------------|
| DESCRIPTION DCI: DILTIAZEM HYDROCHLORIDE |                                                                                 | DESCRIPTION DOE: DILTIAZEM HIDROCLORURO |
| CAS Nº: 33286-22-5                       | EC Nº: 251-443-3                                                                | AEMPS CODE: 3735CH                      |
| MOL. WEIGHT: 451,00                      | MOL. FORMULA: C <sub>22</sub> H <sub>27</sub> CIN <sub>2</sub> O <sub>4</sub> S | ARTICLE CODE: 0510                      |

| ATTRIBUTES                | SHOULD BE                                                                                             |
|---------------------------|-------------------------------------------------------------------------------------------------------|
| Appearance                | White or almost white, crystalline powder                                                             |
| Solubility                | Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol |
| Identification A          | Complies                                                                                              |
| Identification D          | Complies                                                                                              |
| Appearance of solution    | Clear and colourless                                                                                  |
| pH                        | 4.3 - 5.3                                                                                             |
| Specific optical rotation | +115 / +120                                                                                           |
| Related substances        |                                                                                                       |
| Impurity F                | =< 0.3 %                                                                                              |
| Unspecified impurities    | =< 0.10 %                                                                                             |
| Total impurities          | =< 0.3 %                                                                                              |
| Loss on drying            | =< 0.5 %                                                                                              |
| Sulfated ash              | =< 0.1 %                                                                                              |
| Assay                     | 98.5 - 101.0 %                                                                                        |

**COMPLIES WITH**

European Pharmacopoeia 11.0

**STORAGE**

Store the container in a fresh, dry and well-ventilated place.

**REMARKS**

Diltiazem Hydrochloride 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.