

## TECHNICAL DATA SHEET

011164-TDS-ENG-2025

| <b>GLICERINA (GLICEROL) (EUR. PH.)</b> |                      |                            |
|----------------------------------------|----------------------|----------------------------|
| DESCRIPTION DCI: GLYCERIN              |                      | DESCRIPTION DOE: GLICERINA |
| CAS Nº: 56-81-5                        | EC Nº: 200-289-5     | AEMPS CODE: 1651B          |
| MOL. WEIGHT: 92,1                      | MOL. FORMULA: C3H8O3 | ARTICLE CODE: 011164       |

| ATTRIBUTES                                           | SHOULD BE                                                                                                                                  |
|------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance                                           | Clear, colourless or almost colourless, very hygroscopic, syrupy liquid, unctuous to the touch                                             |
| Solubility                                           | Miscible with water and with ethanol (96 per cent), slightly soluble in acetone, practically insoluble in fatty oils and in essential oils |
| Identification A                                     | Complies                                                                                                                                   |
| Identification B                                     | Complies                                                                                                                                   |
| Appearance of solution                               | Clear and colourless                                                                                                                       |
| Acidity or alkalinity                                | =< 0.2 mL of 0.1M NaOH                                                                                                                     |
| Refractive index                                     | 1.470 - 1.475                                                                                                                              |
| Aldehydes                                            | =< 10 ppm                                                                                                                                  |
| Esters                                               | => 8.0 mL of 0.1M HCl                                                                                                                      |
| Impurity A and related substances                    |                                                                                                                                            |
| Impurity A                                           | =< 0.1 %                                                                                                                                   |
| Cualquier otra impureza con RT menor que el glicerol | =< 0.1 %                                                                                                                                   |
| Impurezas totales con RT mayor al del glicerol       | =< 0.5 %                                                                                                                                   |
| Halogenated compounds                                | =< 35 ppm                                                                                                                                  |
| Azucars                                              | Complies                                                                                                                                   |
| Chlorides                                            | =< 10 ppm                                                                                                                                  |
| Water                                                | =< 2.0 %                                                                                                                                   |
| Sulfated ash                                         | =< 0.01 %                                                                                                                                  |
| Assay                                                | 98.0 - 101.0 %                                                                                                                             |

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

### REMARKS

Product suitable as a pharmaceutical excipient.