

## PHARMACEUTICAL GLYCEROL 99,5%

### TECHNICAL SPECIFICATIONS

No. 000022/01/2023

**PRODUCT NAME:** Pharmaceutical Glycerol 99,5%

**CHEMICAL NAME:** Pharmaceutical Glycerol 99,5%

**CAS:** 56-81-5

**Origin:** Plant (rapeseed oil)

**Date:** 11.01.2023

**Shelf Life:** 365 days from the production date

**Solubility:** Miscible with water and with alcohol, slightly soluble in acetone, practically insoluble in fatty oils and in essential oils.

#### Organoleptic requirements

Appearance	Syrupy liquid, unctuous to the touch, colourless or almost colourless, clear, very hygroscopic; solution S is clear*
Odour	Characteristic
Taste	-

\*There is a possibility of air bubbles or foam on the glycerin surface. This is a natural process that should disappear over time.

#### Physicochemical requirements

PARAMETERS	SPECIFICATION	Methodology
Refractive index (1,470-1,475)	Compatible	Ph. Eur. 10th Edit. 2019
Infrared absorption spectroscopy	Compatible	Ph. Eur. 10th Edit. 2019
Relative density (1,258-1,268)	Compatible	Ph. Eur. 10th Edit. 2019
Glycerol content [% (m/m)]	99,5-101,0	Ph. Eur. 10th Edit. 2019
Acidity / alkalinity [ml (0,1M NaOH)]	≤ 0,20	Ph. Eur. 10th Edit. 2019
Aldehydes content [ppm]	≤ 10	Ph. Eur. 10th Edit. 2019
Esters content [ml (0,1 M HCl)]	≥ 8,00	Ph. Eur. 10th Edit. 2019
Halogenated compounds content [ppm]	≤ 35	Ph. Eur. 10th Edit. 2019
Sugars content	Compatible	Ph. Eur. 10th Edit. 2019
Chlorides content [ppm]	≤ 10	Ph. Eur. 10th Edit. 2019
Water content [% (m/m)]	≤ 0,500	Ph. Eur. 10th Edit. 2019
Refractive index	1,470-1,475	Ph. Eur. 10th Edit. 2019
Sulphated ash content [% (m/m)]	≤ 0,01	Ph. Eur. 10th Edit. 2019
Diethylene glycol content [% (m/m)]	≤ 0,1	Ph. Eur. 10th Edit. 2019
Content of any other impurity with a retention time less than the retention time of glycerol [% (m/m)]	≤ 0,1 %	Ph. Eur. 10th Edit. 2019
Content of impurities with a retention times greater than the retention time of glycerol [% (m/m)]	≤ 0,5 %	Ph. Eur. 10th Edit. 2019
Colour in Pt-Co Colour Scale	≤ 10	ASTM D 1209-00
Density at 20°C [g/cm <sup>3</sup> ]	1,258 – 1,268	-

## Allergens

No.	Allergens	Presence in the product
1.	Cereals containing gluten (i.e. wheat, rye, barley, regular oats, unhusked wheat/spelt, kamut or their hybridised strains) and products thereof	NO
2.	Crustaceans and products thereof	NO
3.	Eggs and products thereof	NO
4.	Fish and products thereof	NO
5.	Peanuts and products thereof	NO
6.	Soybeans and products thereof	NO
7.	Milk and products thereof (including lactose)	NO
8.	Nuts i.e. Almond, Hazelnut, Walnut, Cashew nut, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut and products thereof)	NO
9.	Celery and products thereof	NO
10.	Mustard and products thereof	NO
11.	Sesame seeds and products thereof	NO
12.	Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg	NO
13.	Lupin and products thereof	NO
14.	Molluscs and products thereof	NO

### Additional Information:

#### 1. Storage and Transport

Store in original closed packaging in hygienic conditions. Provide protection against contamination, pests and atmospheric conditions.

#### 2. GMO

The raw material is not genetically modified.

#### 3. Irradiation

Product has not been treated with irradiated.

#### 4. Vegan and vegetarian

The raw material is not suitable for vegans and vegetarians.

The certificate was made on the basis of the supplier's certificate. The data contained in this certificate were prepared on the basis of certificates and quality standards of suppliers or manufacturers and on the basis of tests in the factory laboratory.

Prepared by

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An electronic document does not require a seal or signature.