



TECHNICAL DATA SHEET

0281-TDS-ENG-2025

| COLODION 4 % (USP) FARMA | | | | | |
|--------------------------|---------------|------------------|--------------------|--|--|
| DESCRIPTION DCI: | | DESCRIPTION DOE: | | | |
| CAS Nº: | EC Nº: | | AEMPS CODE: | | |
| MOL. WEIGHT: | MOL. FORMULA: | | ARTICLE CODE: 0281 | | |

| ATTRIBUTES | SHOULD BE | | |
|-----------------------|--------------------|--|--|
| Identification A | Complies | | |
| Identification B | Complies | | |
| Assay | => 5.0 % | | |
| Alcohol determination | 22.0 - 26.0 % | | |
| Specific gravity | 0.765 - 0.775 g/mL | | |
| Acidity | Complies | | |
| | | | |

COMPLIES WITH

USP 2024

STORAGE

Keep tightly closed. In a well ventilated, cool and dry place.

REMARKS

ORIGIN CERTIFICATE

Product is obtained by a synthetic manufacturing process.

BSE/TSE CERTIFICATE

Product and raw materials from which this product was obtained are not of animal origin. For thus, this is not subjected to BSE regulations, according to EMEA/410/01, final Rev. 03. In addition, we confirm that no material of animal origin is present at any time during production.

GMO CERTIFICATE

Product and raw materials from which this product has been obtained do not contain genetically modified organisms (GMO). For thus, it complies with applicable European regulations (EC) 1829/2003 and (EC) 1830/2003 of the Spanish state and European Directive 2001/18/EC.

RESIDUAL SOLVENTS CERTIFICATE

Product fulfils the requirements for residual solvents according to guide CPMP/ICH/283/95-ICH Q3C(R3).

ALLERGENS CERTIFICATE

Product and raw materials from which this product has been obtained do not contain allergenic agents, according to Directive 2003/89/EC (amended by 2003/89/EC, 2006/142/EC and 2007/68/EC).

LATEX CERTIFICATE

We state that, to the best of our knowledge, Latex is not present in product. We hereby declare that we don't use any Latex.

LACTOSE & MILK DERIVATIVES CERTIFICATE

Product and raw materials from which this product has been obtained do not contain milk and/or its derivatives (including lactose), according to the relevant EU legislation. We state that, to the best of our knowledge, lactose is not present in this product.

NON ANIMALS TESTING CERTIFICATE

We state that it has not been tested in animals.

IONIZATION CERTIFICATE

All methods are validated by the official pharmacopoeias and/or by the authorized manufacturer





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Product is not treated with ionizing radiation (Directive 1999/2/EC an 1999/3/EC).

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.