METAPHARMACEUTICAL

TECHNICAL DATA SHEET

0027-TDS-ENG-2026

ACEITE RICINO VIRGEN (EUR. PH.)		
DESCRIPTION DCI: ---	DESCRIPTION DOE: ---	
CAS Nº: 8001-79-4	EC Nº: 232-293-8	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 0027

ATTRIBUTES	SHOULD BE
Appearance	Clear at 40 ºC, slightly yellow, viscous, hygroscopic liquid
Solubility	Slightly soluble in light petroleum, miscible with ethanol (96 %) and with glacial acetic acid
Relative density	About 0.958
Refractive index	About 1.479
Identification B	Complies
Identification C	Complies
Optical rotation	+3.5º / +6.0º
Specific absorbance	
Maximum 270 nm	=< 0.7
Acidity index	=< 1.5
Hydroxyl value	=> 160
Peroxide value	=< 10.0
Unsaponifiable matter	=< 0.8 %
Fatty acids composition	
Palmitic acid	=< 2.0 %
Stearic acid	=< 2.5 %
Oleic acid	2.5 - 6.0 %
Linoleic acid	2.5 - 7.0 %
Linolenic acid	=< 1.0 %
Eicosenoic acid	=< 1.0 %
Ricinoleic acid	85.0 - 92.0 %
Any other fatty acids	=< 1.0 %
Water	=< 0.3 %

COMPLIES WITH

European Pharmacopoeia 12.3

STORAGE

Store the container tightly closed. Avoid direct sunlight.

REMARKS

Castor Oil Virgin 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

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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.

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