

A080.02.ENG

TECHNICAL DATA SHEET

0027-TDS-ENG-2023

ACEITE RICINO VIRGEN PH. EUR.					
DESCRIPTION DCI:		DESCRIPTION DOE:			
CAS N°: 8001-79-4	EC N°: 232-293-8		AEMPS CODE:		
MOL. WEIGHT:	MOL. FORMULA:		ARTICLE CODE: 0027		

ATTRIBUTES	SHOULD BE			
Appearance	Clear at 40 °C, 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	+3.5° / +6.0°			
Specific absorbance				
Maximum 270 nm	=< 0.7			
Acid value	=< 1.5			
Hydroxyl value	=> 160			
Peroxide value	=< 10.0			
Unsaponifiable matter	=< 0.8 %			
Composition of fatty acids				
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 11.0

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

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer,



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which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.