

TECHNICAL DATA SHEET

0056-TDS-ENG-2026

FENOL (ACIDO FENICO) (EUR. PH.)		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS Nº: 108-95-2	EC Nº: 203-632-7	AEMPS CODE: ---
MOL. WEIGHT: 94,11	MOL. FORMULA: C6H6O	ARTICLE CODE: 0056

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	Colourless or faintly pink or faintly yellowish, crystals or crystalline masses, deliquescent
Solubility	Soluble in water, very soluble in ethanol (96 %), in glycerol and in methylene chloride
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6
Acidity	Complies
Freezing point	=> 39.5 °C
Residue on evaporation	=< 0.05 %
Assay	99.0 - 100.5 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Store it in an airtight container. Protect from light.

REMARKS

Product suitable as a pharmaceutical excipient.

ORIGIN CERTIFICATE

The product is obtained by chemical process, derived from petroleum raw materials.

BSE/TSE CERTIFICATE

The 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 MEA/410/01, final Rev. 03. In addition, we confirm that no material of animal origin is present at any time during production.

GMO CERTIFICATE

The 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

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

JATROPHA OIL & DERIVATIVES STATEMENT

Based on the production process as well as on the type of raw materials used and the information received from the raw material suppliers, we can exclude that the product contains any derivative from Jatropha oil. We also confirm that no

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Jatropha oil is used for the manufacture of above-mentioned product.

RESIDUAL METALS CERTIFICATE

The product fulfils the requirements for residual metals (by ICP) according to guideline EMEA/CHMP/SWP/4446/2000).

LACTOSE & MILK DERIVATIVES CERTIFICATE

The 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.

AFLATOXINES, MICOTOXINES CERTIFICATE

We hereby declare that, to the best of our knowledge, the product doesn't contain any aflatoxines or micotoxines, based on the production process.

LATEX CERTIFICATE

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

MELAMINE CERTIFICATE

Based on the production process as well as on the type of raw materials used, we can exclude that the product contains any Melamine.

IONIZATION CERTIFICATE

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

GLUTEN CERTIFICATE

The product and raw materials from which this product has been obtained do not contain any gluten, according to the relevant EU legislation. We state that, to the best of our knowledge, gluten is not present at no stage during production.