



FENOL (ACIDO FENICO) (EUR. PH.)

PRODUCT CODE: 0056	CAS Nº: 108-95-2	ANALYSIS Nº: 193/24
MANUFACTURER BATCH: 0002476987	CERTIFICATE ID: 43.014	
SUPPLIER BATCH: 00024769	MANUFACTURING DATE: 18/03/2024	
METAPH BATCH: 0160724	RETEST DATE: 31/03/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or faintly pink or faintly yellowish, crystals or crystalline masses, deliquescent	Faintly pink crystals, deliquescent
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B6	Complies
Acidity	Complies	Complies (*)
Freezing point	=> 39.5 °C	40.5 °C (*)
Residue on evaporation	=< 0.05 %	< 0.01 % (*)
Assay	99.0 - 100.5 %	99.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Phenol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

(*) Data adapted from the supplier's certificate of analysis.

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 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.

STORAGE

Store it in an airtight container. Protect from light.

Analysis date: 28/08/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies

Manufacturer: 40000925