

## RESORCINOL (RESORCINA) (EUR. PH. / USP / BRIT. PH.)

PRODUCT CODE: 001279	CAS Nº: 108-46-3	ANALYSIS Nº: 267/22
MANUFACTURER BATCH: 0002242032	CERTIFICATE ID: 36.716	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 02/12/2022	
METAPH BATCH: 0061222	RETEST DATE: 01/11/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly pinkish-grey, crystalline powder or crystals, turning red on exposure to light and air	Colourless crystals, turning red on exposure to light and air
Solubility	Very soluble in water and in alcohol	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Melting point	109 - 111 °C	110 °C
Appearance of solution	Clear and not more intensely coloured than ref. sol. B5 or R5	Complies (*)
Acidity or alkalinity	= < 0.05 mL of 0.1 M NaOH or 0.1 M HCl	< 0.05 mL of 0.1 M NaOH or 0.1 M HCl (*)
Related substances		(*)
Any impurity	= < 0.5 %	< 0.50 %
Pyrocatechol	Complies	Complies (*)
Loss on drying	= < 1.0 %	0.05 %
Sulfated ash	= < 0.1 %	< 0.01 %
Assay	98.5 - 101.0 %	98.7 %

### COMPLIES WITH

European Pharmacopoeia 10.0

### REMARKS

Resorcinol 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.

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

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 in a cool, dry and well-ventilated place. Store protected from light.

Analysis date: 14/12/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Manufacturer: 40000925

