

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

PRODUCT CODE: 001279	CAS Nº: 108-46-3	ANALYSIS Nº: 081/24
MANUFACTURER BATCH: 0002346675	CERTIFICATE ID: 41.573	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 12/09/2023	
METAPH BATCH: 0340324	RETEST DATE: 12/09/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly pinkish-grey, crystalline powder or crystals, turning red on exposure to light and air	Slightly pinkish-grey crystals, turning red on exposure to light and air
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Melting point	109 - 112 °C	111 °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	Complies (*)
Related substances		(*)
Any impurity	=< 0.5 %	< 0.5 %
Pyrocatechol	Complies	Complies (*)
Loss on drying	=< 1.0 %	0.7 %
Sulfated ash	=< 0.1 %	< 0.1 %
Assay	98.5 - 101.0 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Resorcinol is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer'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 in a cool, dry and well-ventilated place. Store protected from light.

Analysis date: 08/05/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000925

