

RESORCINOL (RESORCINA) (EUR. PH. / USP / BRIT. PH.)			
PRODUCT CODE: 001279		CAS Nº: 108-46-3	ANALYSIS Nº: 269/24
MANUFACTURER BATCH:	0002526936	CERTIFICATE ID:	43.952
SUPPLIER BATCH:	----	MANUFACTURING DATE:	11/06/2024
METAPH BATCH:	0231024	RETEST DATE:	30/06/2030

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless or slightly pinkish-grey, crystalline powder or crystals, turning red on exposure to light and air	Slightly 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 %	0.1 % (*)
Sulfated ash	=< 0.1 %	0.07 % (*)
Assay	98.5 - 101.0 %	99.4 % (*)

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analysed inside the EU.

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

(*) Data controlled by Metapharmaceutical Industrial SL.

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

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

Release date: 20/11/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies



Manufacturer: 40000925