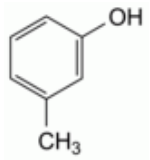
Edition: BP 2025 (Ph. Eur. 11.6 update)

Metacresol

General Notices

(Ph. Eur. monograph 2077)



C_7H_8O 108.1 *108-39-4*

Action and use

Antiseptic; antimicrobial preservative.

Ph Eur

DEFINITION

3-Methylphenol.

CHARACTERS

Appearance

Colourless or yellowish liquid.

Solubility

Sparingly soluble in water, miscible with ethanol (96 per cent) and with methylene chloride.

Relative density

About 1.03.

mp

About 11 °C.

bp

About 202 °C.

IDENTIFICATION

Infrared absorption spectrophotometry (*2.2.24*).

Comparison *Ph. Eur. reference spectrum of metacresol*.

TESTS

Solution S

Dissolve 1.5 g in *carbon dioxide-free water R* and dilute to 100 mL with the same solvent.

Appearance of solution

Freshly prepared solution S is not more opalescent than reference suspension III (*2.2.1*) and not more intensely coloured than reference solution BY_7 (*2.2.2, Method II*).

Acidity

To 25 mL of solution S add 0.15 mL of *methyl red solution R*. The solution is red. Not more than 0.5 mL of *0.01 M sodium hydroxide* is required to change the colour of the indicator to yellow.

Related substances

Gas chromatography (*2.2.28*): use the normalisation procedure.

Test solution Dissolve 1.00 g of the substance to be examined in *methanol R* and dilute to 100.0 mL with the same solvent.

Reference solution (a) Dissolve 0.10 g of *cresol R*, 0.10 g of *p-cresol R* and 0.10 g of the substance to be examined in *methanol R* and dilute to 20.0 mL with the same solvent.

Reference solution (b) Dilute 1.0 mL of the test solution to 100.0 mL with *methanol R*. Dilute 1.0 mL of this solution to 20.0 mL with *methanol R*.

Column:

— *material*: fused silica,

— *size*: *l* = 25 m, Ø = 0.25 mm,

— *stationary phase*: *cyanopropyl(25)phenyl(25)methyl(50)polysiloxane R* (0.2 µm).

Carrier gas *helium for chromatography R*.

Flow rate 1.8 mL/min.

Split ratio 1:30.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 35	100
	35 - 40	100 → 150
	40 - 50	150
Injection port		200
Detector		200

Detection Flame ionisation.

Injection 1.0 µL.

Relative retention With reference to metacresol (retention time = about 28 min): impurity B = about 0.75; impurity C = about 0.98.

System suitability Reference solution (a):

— *resolution*: minimum 1.4 between the peaks due to impurity C and metacresol.

Limits:

— *impurities B, C*: for each impurity, not more than 0.5 per cent,

— *any other impurity*: for each impurity, not more than 0.1 per cent,

— *total*: not more than 1.0 per cent.

— *disregard limit*: the area of the peak due to metacresol in the chromatogram obtained with reference solution (b) (0.05 per cent).

Residue on evaporation

Maximum 0.1 per cent.

Evaporate 2.0 g to dryness on a water-bath in a fume cupboard and dry at 100-105 °C for 1 h. The residue weighs a maximum of 2 mg.

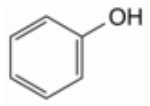
STORAGE

In an airtight container, protected from light.

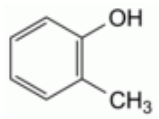
IMPURITIES

Specified impurities *B, C.*

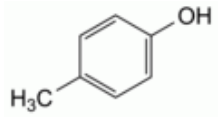
Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use) *A, D, E, F, G, H, I, J, K, L, M.*



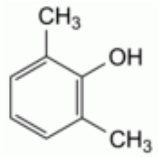
A. phenol,



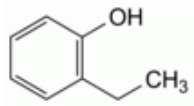
B. 2-methylphenol (*o*-cresol, cresol),



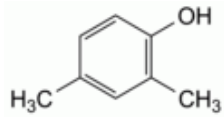
C. 4-methylphenol (*p*-cresol),



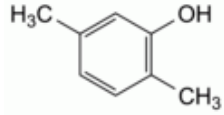
D. 2,6-dimethylphenol (2,6-xylenol),



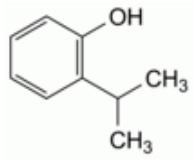
E. 2-ethylphenol (*o*-ethylphenol),



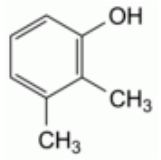
F. 2,4-dimethylphenol (2,4-xylenol),



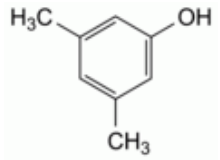
G. 2,5-dimethylphenol (2,5-xylenol),



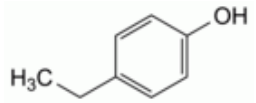
H. 2-(1-methylethyl)phenol,



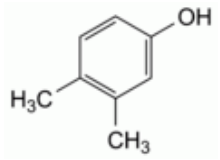
I. 2,3-dimethylphenol (2,3-xylenol),



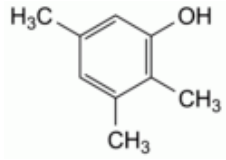
J. 3,5-dimethylphenol (3,5-xylenol),



K. 4-ethylphenol (*p*-ethylphenol),



L. 3,4-dimethylphenol (3,4-xylenol),



M. 2,3,5-trimethylphenol.

Ph Eur