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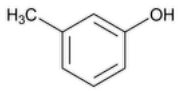
Metacresol



C_7H_8O 108.14
3-Methylphenol;
3-Hydroxytoluene CAS RN®: 108-39-4; UNII: GGO4Y809LO.

DEFINITION
Metacresol contains NLT 98.0% and NMT 102.0% of metacresol (C_7H_8O).

IDENTIFICATION
Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F**▲ (CN 1-May-2020)

Change to read:

• **B.** The retention time of the ▲metacresol▲ (ERR 1-Jan-2019) peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Internal standard solution: 1 mg/mL of USP Phenol RS in methanol
System suitability solution: 5 mg/mL each of metacresol, orthocresol, and paracresol in methanol
Standard solution: 1 mg/mL of USP Metacresol RS in the *Internal standard solution*
Sample solution: 1 mg/mL of Metacresol in the *Internal standard solution*
Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: GC
Detector: Flame-ionization
Column: 0.25-mm × 30-m; 0.25-µm coating of G7
Temperatures
Injection port: 200°
Detector: 200°
Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
90	0	90	10
90	2	120	0
120	10	150	3

Carrier gas: Helium
Flow rate: 1.8 mL/min
Injection type: Split ratio of 1:40
Injection volume: 1 µL
System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for phenol, orthocresol, paracresol, and metacresol are about 0.77, 0.85, 0.99, and 1.00, respectively.]

Suitability requirements

Resolution: NLT 1.4 between the paracresol and metacresol peaks, *System suitability solution*

Relative standard deviation: NMT 1.0% for the peak ratio of metacresol to phenol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of metacresol (C_7H_8O) in the portion of Metacresol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = ratio of the metacresol peak response to the phenol peak response from the *Sample solution*

R_S = ratio of the metacresol peak response to the phenol peak response from the *Standard solution*

C_S = concentration of USP Metacresol RS in the *Standard solution* (mg/mL)

C_U = concentration of Metacresol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **ORGANIC IMPURITIES**

System suitability solution: 5 mg/mL each of metacresol, orthocresol, and paracresol in methanol

Sensitivity solution: 5 µg/mL of USP Metacresol RS in methanol

Sample solution: 10 mg/mL of Metacresol in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame-ionization

Column: 0.25-mm × 30-m; 0.25-µm coating of G7

Temperatures

Injection port: 200°

Detector: 200°

Column: See *Table 2*.

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
90	0	90	10
90	2	150	15

Carrier gas: Helium

Flow rate: 1.8 mL/min

Injection type: Split ratio of 1:40

Injection volume: 1 µL

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 1.4 between the paracresol and metacresol peaks, *System suitability solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Sample: *Sample solution*

Calculate the percentage of each individual impurity in the portion of Metacresol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of each individual impurity from the *Sample solution*

r_T = sum of all the peak areas from the *Sample solution*

Acceptance criteria: See *Table 3*. Disregard any peak less than 0.05%.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Orthocresol	0.85	0.5
Paracresol	0.99	0.5
Metacresol	1.00	—
Any unspecified impurity	—	0.1
Total impurities	—	1.0

SPECIFIC TESTS

• **Clarity of Solution**

A.

Analysis: Add 10 mL of Metacresol to 10 mL of hexane, and mix.

Acceptance criteria: A clear solution is obtained.

B.

Analysis: Add 1.0 mL of Metacresol to 20 mL of 1 N sodium hydroxide, and mix.

Acceptance criteria: A clear solution is obtained.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Metacresol RS

USP Phenol RS

Phenol.
C_6H_6O 94.11

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METACRESOL	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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