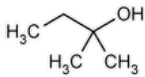


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# Amylene Hydrate



$C_5H_{12}O$  88.15  
2-Butanol, 2-methyl;  
*tert*-Pentyl alcohol CAS RN<sup>®</sup>: 75-85-4.

## DEFINITION

Amylene Hydrate contains NLT 99.0% and NMT 100.0% of  $C_5H_{12}O$ .

## IDENTIFICATION

*Change to read:*

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F ▲](#) (CN 1-MAY-2020)
- **B. PROCEDURE**  
**Sample solution:** 1 in 10  
**Analysis:** To 10 mL of the *Sample solution* quickly add 5 mL of a 1-in-100 solution of vanillin in sulfuric acid.  
**Acceptance criteria:** A violet-red color is produced.

## ASSAY

- **PROCEDURE**  
**Sample solution:** Amylene Hydrate  
**Chromatographic system**  
**Mode:** GC  
**Detector:** Thermal conductivity  
**Column:** 4-mm × 2-cm glass column; packed with chromatographic support S2 (under typical conditions)  
**Temperature**  
**Column:** 190°  
**Injector:** 200°  
**Detector block:** 200°  
**Carrier gas:** Helium  
**Flow rate:** 50 mL/min  
**Injection size:** 0.4 µL  
**Analysis**  
**Sample:** *Sample solution*  
From the area under the curve, calculate the percentage (a/a) of  $C_5H_{12}O$  in the Amylene Hydrate taken.  
**Acceptance criteria:** 99.0%–100.0%

## IMPURITIES

### Inorganic Impurities

- **LIMIT OF NONVOLATILE RESIDUE**  
**Sample:** 10 mL  
**Analysis:** Evaporate the *Sample* in a tared porcelain dish on a steam bath to a volume of about 1 mL, and allow it to evaporate spontaneously to dryness while protected from dust.  
**Acceptance criteria:** The residue, if any, is colorless, and when dried at 105° for 1 h, weighs NMT 2 mg (0.02%).

### Organic Impurities

- **PROCEDURE**  
**Sample solution:** 1 in 20  
**Analysis:** To 10 mL of the *Sample solution* add 0.10 mL of 0.10 N potassium permanganate.

**Acceptance criteria:** The pink color does not completely disappear within 10 min.

**SPECIFIC TESTS**

- **SPECIFIC GRAVITY (841):** 0.803–0.807
- **DISTILLING RANGE, Method I (721):** It distills completely at between 97° and 103°, a correction factor of 0.037°/mm being applied as necessary.
- **WATER:** The relative retention time of water on the gas chromatographic column used in the Assay is approximately 0.2 times that of Amylene Hydrate. From the area under the curve obtained in the Assay, calculate the percentage (a/a) of water in the Amylene Hydrate taken: NMT 0.5% is found.
- **ALDEHYDE**  
**Sample solution:** 1 in 20  
**Analysis:** To 10 mL of the *Sample solution* add 1 mL of silver–ammonium nitrate TS, and heat the mixture on a water bath at 60° for 10 min.  
**Acceptance criteria:** No darkening occurs.

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMYLENE HYDRATE	<a href="#">Documentary Standards Support</a>	SE2020 Simple Excipients

**Chromatographic Database Information:** [Chromatographic Database](#)

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