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Purified Honey

DEFINITION

Purified Honey is obtained by purification of honey from the comb of the bee, *Apis mellifera* L. and all subspecies of *Apis mellifera*. The honey is extracted by centrifugation, pressure, or other suitable procedures.

IDENTIFICATION

• A.

Sample solution: 1 in 20 solution

Standard solution: A 7.5 µg/mL solution of [USP L-Proline RS](#)

Analysis

Samples: *Standard solution* and *Sample solution*

Place 0.5 mL of the *Sample solution* and the *Standard solution* in separate reaction vials, and add 0.25 mL of formic acid and 1.0 mL of freshly prepared 3% solution of ninhydrin in peroxide-free ethylene glycol monomethyl ether to each vial. Cap the reaction vials tightly, shake well, and place in boiling water for 15 min. Cool for 5 min in a 22° water bath, remove the caps, and add 5.0 mL of 5% aqueous isopropanol solution.

Acceptance criteria: The *Sample solution* shows a purple color similar to, or more intense than that of the *Standard solution*. If necessary, scan the solutions being compared using a suitable spectrophotometer against a water blank. The two solutions each exhibit a maximum at the same wavelength, at about 520 nm. The absorbance of the *Sample solution* should be at least as high as that of the *Standard solution*.

IMPURITIES

- [CHLORIDE AND SULFATE, Chloride \(221\)](#): A 1-g portion shows no more chloride than corresponds to 0.5 mL of 0.020 N hydrochloric acid (0.035%).
- [CHLORIDE AND SULFATE, Sulfate \(221\)](#): A 2-g portion shows no more sulfate than corresponds to 0.5 mL of 0.020 N sulfuric acid (0.024%).
- [ARTICLES OF BOTANICAL ORIGIN, Total Ash \(561\)](#): NMT 0.3%

SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total bacterial count does not exceed 10³ cfu/g. The total combined molds and yeasts count does not exceed 100 cfu/g.
- [SPECIFIC GRAVITY \(841\)](#): 1.400–1.435 at 20°
- [REFRACTIVE INDEX \(831\)](#): 1.4900–1.4992 at 20°
- [WATER DETERMINATION, Method I \(921\)](#): 15.0%–18.6%
- [MICROBIOLOGICAL PROCEDURES FOR ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Where it is intended for use in preparations for infants under one year of age, it meets the requirements of the *Test for Absence of Clostridium Species*.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. No storage requirements specified.
- **LABELING:** Label it to indicate that it is not intended for use in preparations for infants under one year of age, unless it meets the requirements of the *Test for Absence of Clostridium Species*.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP L-Proline RS](#)

Topic/Question	Contact	Expert Committee
PURIFIED HONEY	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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