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# Hydroxypropyl Cellulose Ocular System

## DEFINITION

Hydroxypropyl Cellulose Ocular System contains NLT 85.0% and NMT 115.0% of the labeled amount of Hydroxypropyl Cellulose. It contains no other substance. It is sterile.

## IDENTIFICATION

• **Infrared Absorption**

**Sample solution:** A 10-mg/mL solution in methanol, based on the labeled amount of Hydroxypropyl Cellulose. Evaporate 2 drops of the solution on a silver chloride plate so that it forms a thin film.

**Acceptance criteria:** The infrared absorption spectrum of the film exhibits maxima only at the same wavelengths as that of a similar preparation of USP Hydroxypropyl Cellulose RS.

## ASSAY

• **Procedure**

**Standard stock solution:** 0.25 mg/mL of USP Hydroxypropyl Cellulose RS prepared as follows: Weigh 25 mg of USP Hydroxypropyl Cellulose RS into a 100-mL volumetric flask. Dissolve in 80 mL of water. Mix well by agitating on a mechanical shaker until completely dissolved. Add one drop of methanol to dispel the foam and dilute with water to volume. [Note—Stirring overnight before diluting to volume is recommended.]

**Standard solution:** 0.05 mg/mL of hydroxypropyl cellulose in water, from *Standard stock solution*

**Sample stock solution:** 0.25 mg/mL of hydroxypropyl cellulose prepared using the same procedure as the *Standard stock solution*

**Sample solution:** 0.05 mg/mL of hydroxypropyl cellulose in water, from *Sample stock solution*

**Spectrometric conditions**

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

**Mode:** UV-Vis

**Analytical wavelength:** 620 nm

**Cell length:** 1.0 cm, quartz

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Separately pipet 2 mL of the *Standard solution*, the *Sample solution*, and water, to provide a blank, into individual 50-mL centrifuge tubes. Add to each tube, 6.0 mL of a 0.5 mg/mL solution of anthrone in sulfuric acid, and mix on a vortex mixer. Let the centrifuge tubes cool for approximately 40 min and remix. Concomitantly determine the absorbances of the *Standard solution* and the *Sample solution*. [Note—Prepare anthrone in sulfuric acid solution just before use in low-actinic glassware, and mix well before adding to the tube. Use it within 12 h of preparation. Avoid contact between the glassware and the paper products during analysis; the cellulose in the paper will react with the sulfuric acid and alter the results.]

Calculate the percentage of hydroxypropyl cellulose in the Ocular System:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

$A_U$ = absorbance of the *Sample solution*

$A_S$ = absorbance of the *Standard solution*

$C_S$ = concentration of the *Standard solution* (mg/mL)

$C_U$ = nominal concentration of hydroxypropyl cellulose in the *Sample solution* (mg/mL)

**Acceptance criteria:** 85.0%–115.0%

## PERFORMANCE TESTS

• **Weight Variation**

**Analysis:** Determine the weight of each of a sufficient number of Systems.

**Acceptance criteria:** NMT 1 out of 20 Systems varies more than 25% from the average or, failing that, NMT 6 out of 60 (including the original 20) vary more than 25% (but none more than 35%) from the average weight.

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**SPECIFIC TESTS**

• **Sterility Tests ⟨71⟩:** Meets the requirements

**ADDITIONAL REQUIREMENTS**

• **Packaging and Storage:** Preserve in single-dose containers, at a temperature not exceeding 30°.

• **USP Reference Standards ⟨11⟩**

USP Hydroxypropyl Cellulose RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| HYDROXYPROPYL CELLULOSE OCULAR SYSTEM | Documentary Standards Support | SM32020 Small Molecules 3 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM32020 Small Molecules 3 |

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