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Fluorescein Sodium Ophthalmic Strips

DEFINITION

Fluorescein Sodium Ophthalmic Strips contain NLT 100.0% and NMT 160.0% of the labeled amount of fluorescein sodium ($C_{20}H_{10}Na_2O_5$).

IDENTIFICATION

- A.

Sample solution: Cut the colored tip from 1 Ophthalmic Strip, place it in a small test tube containing 1 mL of water, and agitate for 1 min.

Acceptance criteria: *Sample solution* is strongly fluorescent, even in extreme dilution. The fluorescence disappears when the *Sample solution* is made acid and reappears when it is again made alkaline.

- B.

Sample solution: Cut the colored tip from 1 Ophthalmic Strip, place it in a small test tube containing 1 mL of water, and agitate for 1 min.

Place 1 drop of solution upon a piece of filter paper.

Acceptance criteria: A yellow spot is produced, and when exposed while moist to the vapor of bromine for 1 min and then to ammonia vapor, it becomes deep pink in color.

ASSAY

- PROCEDURE

Standard stock solution: 1 μ g/mL of fluorescein sodium from [USP Diacetylfluorescein RS](#) in water prepared as follows. Dissolve [USP](#)

[Diacetylfluorescein RS](#) in 10 mL of alcohol contained in a 100-mL volumetric flask, add 2 mL of 2.5 N sodium hydroxide, and heat on a steam bath at the boiling temperature for 20 min, with frequent swirling. Cool, and dilute with water to volume. Transfer a suitable aliquot to a volumetric flask, and dilute with water to volume. [NOTE—110.7 mg of anhydrous [USP Diacetylfluorescein RS](#) is equivalent to 100.0 mg of fluorescein sodium.]

Standard solution: 0.03 μ g/mL of fluorescein sodium in water prepared as follows. Transfer 3 mL of *Standard stock solution* to a 100-mL volumetric flask containing 20 mL of pH 9.0 alkaline borate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)), and dilute with water to volume.

Sample stock solution: Remove 1 Ophthalmic Strip from its package, taking care not to allow any portion of the tip to adhere to the packaging material. Transfer to a 100-mL volumetric flask, add 50 mL of water, shake the flask vigorously, and dilute with water to volume. Shake occasionally, and after 1 h, mix the contents of the flask. Transfer an aliquot (V) of this solution, equivalent to 100 μ g of fluorescein sodium, to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Transfer 3 mL of the *Sample stock solution* to a 100-mL volumetric flask containing 20 mL of pH 9.0 alkaline borate buffer (see [Reagents, Indicators, and Solutions—Buffer Solutions](#)), and dilute with water to volume.

Instrumental conditions

Mode: Fluorescence

Excitation wavelength: 485 nm

Emission wavelength: 515 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the fluorescence intensities, I , of the *Standard solution* and the *Sample solution*.

Calculate the percentage of the labeled amount of fluorescein sodium ($C_{20}H_{10}Na_2O_5$) in the Ophthalmic Strip taken:

$$\text{Result} = (I_U/I_S) \times (C_S/C_U) \times 100$$

I_U = fluorescence value of the *Sample solution*

I_S = fluorescence value of the *Standard solution*

C_S = concentration of fluorescein sodium in the *Standard solution* (μ g/mL)

C_U = nominal concentration of fluorescein sodium in the *Sample solution* (μg/mL)

Acceptance criteria: 100.0%–160.0% on the average content calculated from the individual assays of NLT 10 Ophthalmic Strips

PERFORMANCE TESTS

- **CONTENT UNIFORMITY:** The content of fluorescein sodium ($C_{20}H_{10}Na_2O_5$) in each of NLT 10 Ophthalmic Strips, determined as directed in the Assay, is 85.0%–175.0% of the labeled amount.

SPECIFIC TESTS

- **STERILITY TESTS (71):** Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package NMT 2 Ophthalmic Strips in a single-unit container in such a manner as to maintain sterility until the package is opened. Package individual packages in a second protective container.
- **LABELING:** The label of the second protective container bears a statement that the contents may not be sterile if the individual package has been damaged or opened previously. The label states the amount of fluorescein sodium in each Ophthalmic Strip.

- **USP REFERENCE STANDARDS (11):**

[USP Diacetylfluorescein RS](#)

Spiro(isobenzofuran-1(3H), 9-(9H)xanthen)-3-one, 3',6'-bis(acetyloxy)-
 $C_{24}H_{16}O_7$ 416.39

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

Topic/Question	Contact	Expert Committee
FLUORESCEIN SODIUM OPHTHALMIC STRIPS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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