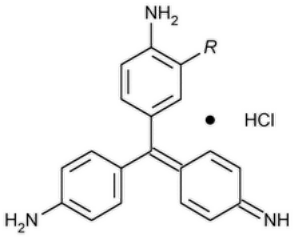
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Aug-2022
Document Type: USP Monographs
DocId: GUID-DB501C7B-8174-4B68-A94F-7937E0D23388_2_en-US
DOI: https://doi.org/10.31003/USPNF_M34440_02_01
DOI Ref: t1lfa

Basic Fuchsin



	R
Rosaniline	CH_3
Pararosaniline	H

Benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl-2-methyl]-, monohydrochloride;
C.I. Basic Violet 14 monohydrochloride

CAS RN®: 632-99-5.

DEFINITION

Basic Fuchsin is a mixture of rosaniline and pararosaniline hydrochlorides. It contains the equivalent of NLT 88.0% of rosaniline hydrochloride ($C_{20}H_{19}N_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A.**

  Sample solution: 1 mg/mL

  Analysis: To 5 mL of the *Sample solution*, add a few drops of hydrochloric acid.

  Acceptance criteria: A yellow color is produced (distinction from acid fuchsin).

- **B.**

  Sample solution: 2 mg/mL

  Analysis: To 5 mL of the *Sample solution*, add a few drops of tannic acid TS.

  Acceptance criteria: A red precipitate is formed.

- **C.**

  Sample solution: 2 mg/mL

  Analysis: To 10 mL of the *Sample solution*, add 10 mL of ammonia TS and 500 mg of zinc dust, and agitate the mixture. The solution becomes decolorized. Place a few drops of the decolorized solution on filter paper, and nearby on the same paper, place a few drops of 3 N hydrochloric acid.

  Acceptance criteria: A red color develops at the zone of contact.

ASSAY

- **Procedure**

  Solution A: 300 mg/mL of sodium tartrate in water

  Solution B: 200 mg/mL of titanium trichloride in water

  Solution C: Prepare 500 mL of a mixture of water, *Solution B*, and hydrochloric acid (400:40:40) to which about 10 mg of safranin O has been added.

  Sample: 100 mg

  Titrimetric system

  Mode: Direct titration

  Titrant: 0.05 N titanium trichloride VS

  Endpoint detection: Visual

  Analysis: Dissolve the *Sample* in 175 mL of water in a 500-mL closed system titration vessel fitted with a gas inlet tube, a gas outlet tube, an upright reflux condenser, and a buret. Add about 25 mL of *Solution A* and a polytef-coated magnetic stirring bar, and heat to boiling. Flush this titration vessel for 15 min with nitrogen that has been passed through two successive gas washing bottles, each containing 500 mL of *Solution C*. Continue the heating and nitrogen flow, and while stirring, titrate with titrant to a yellow endpoint.

  Calculate the percentage of rosaniline hydrochloride ($C_{20}H_{19}N_3 \cdot HCl$) in the portion of Basic Fuchsin taken:

$$\text{Result} = [(V \times N \times F)/W] \times 100$$

V = *Titrant* volume consumed by the *Sample* (mL)

N = *Titrant* normality (mEq/mL)

F = equivalency factor, 67.58 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NLT 88.0% on the dried basis

IMPURITIES

• **Alcohol-Insoluble Substances**

Sample: 1 g

Analysis: Boil the *Sample* with 50 mL of alcohol under a reflux condenser for 15 min, and filter through a tared filtering crucible. Wash the residue on the filter with hot alcohol until the washings cease to be colored violet, and dry the crucible at 105° for 1 h.

Acceptance criteria: The amount of insoluble residue is NMT 1.0%.

• **Residue on Ignition** ⟨281⟩

Sample: 1 g

Analysis: Ignite the *Sample* with 0.5 mL of sulfuric acid.

Acceptance criteria: NMT 0.3%.

Delete the following:

▲• **Arsenic** ⟨211⟩, *Procedures, Method II*: 8 ppm▲ (USP 1-Aug-2022)

Delete the following:

▲• **Lead** ⟨251⟩

Sample solution: Place 1 g of Basic Fuchsin in a small Kjeldahl flask, add 5 mL of sulfuric acid, and insert a small funnel into the flask. Gently rotate the flask until the sulfuric acid has completely wetted the Basic Fuchsin, then heat with a small flame until carbonization is complete. Allow to cool, and add, in small quantities, 5 mL of nitric acid. Again heat gently until fumes of sulfur trioxide are evolved. Allow to cool, add another 5 mL of nitric acid, and heat to the evolution of sulfur trioxide. Allow to cool, add about 25 mL of water, and boil for a few min. Cool, neutralize with stronger ammonia water, using litmus paper as the indicator, and add 5 mL of nitric acid. Transfer the solution to a 100-mL volumetric flask, and dilute to volume.

Analysis: Proceed as directed, using a 20-mL portion of the *Sample solution*.

Acceptance criteria: NMT 30 ppm of lead▲ (USP 1-Aug-2022)

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° to constant weight.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 47(2)

Current DocID: GUID-DB501C7B-8174-4B68-A94F-7937E0D23388_2_en-US

DOI: https://doi.org/10.31003/USPNF_M34440_02_01

DOI ref: t1lfa