Ophthalmic Ointment Monographs: Idoxuridine Ophthalmic Ointment

Type of Posting	Revision Bulletin
Posting Date	29–Jul–2016
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Expert Committee	Chemical Medicines Monographs 1 to 6
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Chemical Medicines Expert Committees 1 to 6 has revised the monographs listed below. The purpose of the revision is to replace the requirement to comply with the entire content of the USP general chapter *Ophthalmic Products—Quality Tests* <771> with a requirement to comply only with the subsection for *Particulate and Foreign Matter* in *Ophthalmic Products—Quality Tests* <771>, and with the section for *Container Content* for those monographs where the requirement for Minimum Fill was deleted.

- Atropine Sulfate Ophthalmic Ointment
- Bacitracin Ophthalmic Ointment
- Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment
- Bland Lubricating Ophthalmic Ointment
- Chloramphenicol and Polymyxin B Sulfate Ophthalmic Ointment
- Chloramphenicol Ophthalmic Ointment
- Chlortetracycline Hydrochloride Ophthalmic Ointment
- Ciprofloxacin Ophthalmic Ointment
- Dexamethasone Sodium Phosphate Ophthalmic Ointment
- Erythromycin Ophthalmic Ointment
- Gentamicin and Prednisolone Acetate Ophthalmic Ointment
- Gentamicin Sulfate Ophthalmic Ointment
- Hydrocortisone Acetate Ophthalmic Ointment
- Idoxuridine Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Acetate Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates and Bacitracin Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment
- Neomycin and Polymyxin B Sulfates, Bacitracin, and Hydrocortisone Acetate Ophthalmic Ointment
- Neomycin Sulfate and Dexamethasone Sodium Phosphate Ophthalmic Ointment
- Neomycin Sulfate Ophthalmic Ointment
- Oxytetracycline Hydrochloride and Polymyxin B Sulfate Ophthalmic Ointment
- Sodium Chloride Ophthalmic Ointment
- Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Ointment
- Sulfacetamide Sodium Ophthalmic Ointment
- Tetracycline Hydrochloride Ophthalmic Ointment
- Tobramycin and Dexamethasone Ophthalmic Ointment
- Tobramycin Ophthalmic Ointment

The Revision Bulletins for the monographs listed above supersede the currently official version of these monographs. The Revision Bulletin will be incorporated in the *First Supplement to USP 40–NF 35*.

Should you have any questions, please contact Margareth R. C. Marques, M.Sc., Ph.D. (301-816-8106 or mrm@usp.org).

Idoxuridine Ophthalmic Ointment

DEFINITION

Idoxuridine Ophthalmic Ointment is Idoxuridine in a petrolatum base. It contains NLT 0.45% and NMT 0.55% of idoxuridine ($C_9H_{11}IN_2O_5$). It is sterile.

IDENTIFICATION

• **A.**

Standard solution and **Sample solution:** Prepare as directed in the *Assay*.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*.

ASSAY

• **PROCEDURE**

Chromatographic column: Mix 4 g of chromatographic siliceous earth with 4 mL of 0.1 N hydrochloric acid in a glass mortar until the mixture is fluffy. Transfer to a 19-mm × 250-mm chromatographic tube (see *Chromatography* ⟨621⟩) that contains a pledget of glass wool and is fitted with a stopcock at the bottom. Tamp gently to compress to a uniform mass.

Mobile phase: Butyl alcohol and chloroform (1:5)

Standard stock solution: 0.5 mg/mL of USP Idoxuridine RS in methanol

Standard solution: 25 µg/mL of USP Idoxuridine RS in *Mobile phase* from *Standard stock solution*

Sample solution: Nominally 25 µg/mL of idoxuridine in eluant obtained from the *Chromatographic column* prepared as follows. Mix 4 g of chromatographic siliceous earth with 2 mL of 0.1 N hydrochloric acid in a glass mortar until the mixture is fluffy. Add an equivalent to 5 mg of idoxuridine from Ophthalmic Ointment to the mixture, and transfer to the prepared *Chromatographic column*. Transfer 2 g of chromatographic siliceous earth and 2 mL of 0.1 N hydrochloric acid to the glass mortar, and mix until fluffy. Use this material to rinse the mortar and pick up any remaining Ophthalmic Ointment. Transfer half of this mixture to the tube, and tamp gently until the column appears uniform. Transfer the remaining portion to the *Chromatographic column*, and tamp as before. Wipe the walls of the mortar with a small pledget of glass wool, and insert the pledget in the top of the column. Pass 50 mL of chloroform through the column at a flow rate of approximately 1 mL/min, and discard the chloroform. Elute with 200 mL of *Mobile phase* at the same flow rate, discarding the first 20 mL of the eluate. Collect the remainder of the eluate in a 200-mL volumetric flask, and dilute with *Mobile phase* to volume.

Instrumental conditions

Mode: UV

Analytical wavelengths: 320 and 283 nm

Cell: 1 cm

Blank: *Mobile phase*

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the absorbances of the *Sample solution* and the *Standard solution*.

Calculate the percentage of idoxuridine ($C_9H_{11}IN_2O_5$) in the portion of Ophthalmic Ointment taken:

$$\text{Result} = (A_{U283} - A_{U320}/A_{S283} - A_{S320}) \times (C_S/C_U) \times 100$$

A_{U283} = absorbance of the *Sample solution* at 283 nm
A_{U320} = absorbance of the *Sample solution* at 320 nm
A_{S283} = absorbance of the *Standard solution* at 283 nm
A_{S320} = absorbance of the *Standard solution* at 320 nm
C_S = concentration of USP Idoxuridine RS in the *Standard solution* (µg/mL)
C_U = nominal concentration of idoxuridine in the *Sample solution* (µg/mL)

Acceptance criteria: 0.45%–0.55%

SPECIFIC TESTS

• **STERILITY TESTS ⟨71⟩:** Meets the requirements

Delete the following:

▲• **METAL PARTICLES IN OPHTHALMIC OINTMENTS ⟨751⟩:** Meets the requirements ▲*USP39*

Change to read:

▲• **OTHER REQUIREMENTS:** It meets the requirements •for *Particulate and Foreign Matter*• (RB 1-Aug-2016) in *Ophthalmic Products—Quality Tests* ⟨771⟩, •*Drug Product Quality, Universal Tests, Particulate and Foreign Matter.*• (RB 1-Aug-2016) ▲*USP39*

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in collapsible ophthalmic ointment tubes in a cool place.

• **USP REFERENCE STANDARDS ⟨11⟩**
USP Idoxuridine RS