Ophthalmic Ointment Monographs: Hydrocortisone Acetate Ophthalmic Ointment

Type of Posting	Revision Bulletin
Posting Date	29–Jul–2016
Official Date	01–Aug–2016
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).

Hydrocortisone Acetate Ophthalmic Ointment

DEFINITION

Hydrocortisone Acetate Ophthalmic Ointment is Hydrocortisone Acetate in a suitable ophthalmic ointment base. It contains NLT 90.0% and NMT 110.0% of the labeled amount of total steroids, calculated as hydrocortisone acetate ($C_{23}H_{32}O_6$). It is sterile.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test** ⟨**201**⟩

Sample solution: Transfer a quantity of Ophthalmic Ointment nominally equivalent to 5 mg of hydrocortisone acetate to a flask, add 5 mL of methanol, and heat on a steam bath for 5 min with frequent mixing. Cool to solidify the Ophthalmic Ointment base, and filter. Use the filtrate.

Spray reagent: 70% Methanolic sulfuric acid solution

Analysis: Proceed as directed in the chapter. Locate the spots by spraying the dried plate with *Spray reagent*. Heat the plate for 20–30 min at 90°, allow to cool, and view under long-wavelength UV light.

Acceptance criteria: The R_F value and fluorescence of the principal spot of the *Sample solution* correspond to those of the *Standard solution*.

ASSAY

• **Assay for Steroids** ⟨**351**⟩

Standard solution: Prepare as directed in the chapter for *Standard Preparation* using USP Hydrocortisone Acetate RS.

Sample solution: Transfer a portion of Ophthalmic Ointment nominally equivalent to 10 mg of hydrocortisone acetate to a flask, and add 30 mL of alcohol. Heat on a steam bath to melt the Ophthalmic Ointment base. Cool to solidify the Ophthalmic Ointment base, and filter the alcohol solution into a 100-mL volumetric flask. Repeat the extraction with three 20-mL portions of alcohol, and add alcohol to volume. Pipet 10 mL of this solution into a 100-mL volumetric flask, and add alcohol to volume. Pipet 20 mL of the resulting solution into a glass-stoppered, 50-mL conical flask.

Analysis: Proceed as directed in the chapter. Calculate the percentage of the labeled amount of total steroids, as hydrocortisone acetate ($C_{23}H_{32}O_6$), in the portion of Ophthalmic Ointment taken:

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

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 hydrocortisone acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

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

Delete the following:

▲• **Particulate Matter:** It meets the requirements of the test for *Metal Particles in Ophthalmic Ointments* ⟨751⟩. ▲*USP39*

Change to read:

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

Delete the following:

▲• **Minimum Fill** ⟨**755**⟩**:** Meets the requirements▲*USP39*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in collapsible ophthalmic ointment tubes.

• **USP Reference Standards** ⟨**11**⟩
USP Hydrocortisone Acetate RS