**Dexamethasone Sodium Phosphate Cream**

Dexamethasone Sodium Phosphate Cream contains an amount of dexamethasone sodium phosphate \( \text{C}_{22}\text{H}_{28}\text{FN}_{3}\text{O}_{8}\text{P} \) equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of dexamethasone phosphate \( \text{C}_{22}\text{H}_{30}\text{FO}_{8}\text{P} \).

**Packaging and storage**—Preserve in collapsible tubes or tight containers.

**USP Reference standards** (11)—

USP Dexamethasone RS
USP Dexamethasone Phosphate RS

**Identification**—Prepare a pH 9.0 buffer solution by dissolving 3.1 g of boric acid, 203 mg of magnesium chloride, and 860 mg of sodium hydroxide in water to make 1000 mL. Dissolve 50 mg of alkaline phosphatase enzyme in 50 mL of the pH 9.0 buffer solution, and transfer 5 mL of the resulting solution to a glass-stoppered, 50-mL tube containing 5 mL of the **Assay preparation**, prepared as directed in the **Assay**. Incubate at 37° for 45 minutes, then add 25 mL of methylene chloride, and shake for 2 minutes. The methylene chloride extract so obtained responds to the **Identification** test under **Dexamethasone Sodium Phosphate Injection**, beginning with “Evaporate 15 mL of the methylene chloride extract.”

**Microbial enumeration tests** (61) and **Tests for specified microorganisms** (62)—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

**Minimum fill** (755): meets the requirements.

**Assay**—

**Alcohol-aqueous phosphate buffer**—Dissolve 0.29 g of dibasic sodium phosphate in 450 mL of water, add 550 mL of alcohol, and mix.

**0.05 M Phosphate buffer**—In a 1-L volumetric flask, dissolve 6.9 g of monobasic sodium phosphate in 500 mL of water, dilute with water to volume, and mix.

**Mobile phase**—Prepare a suitable degassed solution of methanol and 0.05 M Phosphate buffer (52:48) which, at ambient temperature and at a flow rate of 1.5 mL per minute, gives a retention time of about 8.5 minutes for dexamethasone phosphate.

**Standard preparation**—Using an accurately weighed quantity of USP Dexamethasone Phosphate RS, prepare a solution in Alcohol-aqueous phosphate buffer having a known concentration of about 30 µg per mL. Prepare this solution fresh.

**Assay preparation**—Transfer an accurately weighed quantity of USP Dexamethasone Phosphate RS, preferably of Type I glass, protected from light, into a 1-L volumetric flask, add water to volume, and mix. Pipet 5 mL of this solution into a 125-mL separator, and wash with two 10-mL portions of water-washed methylene chloride, discarding the washings. Transfer the solution into a glass-stoppered, 50-mL tube, and add 5 mL of alkaline phosphatase solution, prepared by dissolving 50 mg of alkaline phosphatase enzyme in 50 mL of pH 9 Buffer with magnesium (prepared as directed in Identification test A under Dexamethasone Sodium Phosphate). Incubate at 37° for 45 minutes, and extract with 25 mL of methylene chloride. Evaporate 15 mL of the methylene chloride extract on a steam bath to dryness, and dissolve the residue in 1 mL of methylene chloride. Apply 5 µL of this solution and 5 µL of a solution of USP Dexamethasone RS in methylene chloride containing 300 µg per mL to a 20- × 20-cm, thin-layer chromatographic plate (see Chromatography (621)) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a tank completely lined with a strip of filter paper, using a solvent system consisting of a mixture of 50 parts of chloroform, 50 parts of acetone, and 1 part of water. The radioactive spot obtained from the test specimen corresponds to that obtained from the Reference Standard.

**Bacterial endotoxins** (85)—It contains not more than 31.3 USP Endotoxin Units per mg of dexamethasone phosphate.

**pH** (791): between 7.0 and 8.5.

**Other requirements**—It meets the requirements under **Injections** (1).

**Assay**—

**Mobile phase**—Prepare a suitable degassed solution of 0.01 M monobasic potassium phosphate in a mixture of methanol and water (1:1) which, at ambient temperature and at a flow

and the **Assay preparation** into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of \( \text{C}_{22}\text{H}_{30}\text{FO}_{8}\text{P} \) in the portion of Cream taken by the formula:

\[
0.1 \frac{C(I)/C(U)}{C(I)/C(A)}
\]

in which \( C \) is the concentration, in µg per mL, of USP Dexamethasone Phosphate RS in the **Standard preparation**, and \( C(I) \) and \( C(U) \) are the peak responses at equivalent retention times obtained from the **Assay preparation** and the **Standard preparation**, respectively.

**Dexamethasone Sodium Phosphate Injection**

Dexamethasone Sodium Phosphate Injection is a sterile solution of Dexamethasone Sodium Phosphate in Water for Injection. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of dexamethasone phosphate \( \text{C}_{22}\text{H}_{30}\text{FO}_{8}\text{P} \), present as the disodium salt.

**Packaging and storage**—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

**USP Reference standards** (11)—

USP Dexamethasone RS
USP Dexamethasone Phosphate RS
USP Endotoxin RS

**Identification**—Pipe a volume of Injection, equivalent to 10 mg of dexamethasone phosphate, into a 100-mL volumetric flask, add water to volume, and mix. Pipet 5 mL of this solution into a 125-mL separator, and wash with two 10-mL portions of water-washed methylene chloride, discarding the washings. Transfer the solution into a glass-stoppered, 50-mL tube, and add 5 mL of alkaline phosphatase solution, prepared by dissolving 50 mg of alkaline phosphatase enzyme in 50 mL of Buffer with magnesium (prepared as directed in Identification test A under Dexamethasone Sodium Phosphate). Allow to stand at 37° for 45 minutes, and extract with 25 mL of methylene chloride. Evaporate 15 mL of the methylene chloride extract on a steam bath to dryness, and dissolve the residue in 1 mL of methylene chloride. Apply 5 µL of this solution and 5 µL of a solution of USP Dexamethasone RS in methylene chloride containing 300 µg per mL to a 20- × 20-cm, thin-layer chromatographic plate (see Chromatography (621)) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a tank completely lined with a strip of filter paper, using a solvent system consisting of a mixture of 50 parts of chloroform, 50 parts of acetone, and 1 part of water, until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing tank, mark the solvent front, and allow the spots to dry. Spray the plate with dilute sulfuric acid (1 in 2), and heat at 105° until brown or black spots appear: the \( R_f \) value of the principal spot obtained from the test specimen corresponds to that obtained from the Reference Standard.

**Bacterial endotoxins** (85)—It contains not more than 31.3 USP Endotoxin Units per mg of dexamethasone phosphate.

**pH** (791): between 7.0 and 8.5.

**Other requirements**—It meets the requirements under **Injections** (1).

**Assay**—

**Mobile phase**—Prepare a suitable degassed solution of 0.01 M monobasic potassium phosphate in a mixture of methanol and water (1:1) which, at ambient temperature and at a flow
rate of about 1.6 mL per minute, gives a retention time of about 5 minutes for dexamethasone phosphate.

Standard preparation—[NOTE—Prepare this solution at the time of use.] Dissolve an accurately weighed quantity of USP Dexamethasone Phosphate RS in Mobile phase to obtain a solution having a known concentration of about 80 µg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 8 mg of dexamethasone phosphate, to a 100-mL volumetric flask. Dilute with Mobile phase to volume, and mix.

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. Chromatograph five replicate injections of the Standard preparation, and record the peak responses as directed under Procedure: the relative standard deviation is not more than 1.5%.

Procedure—By means of a suitable sampling valve, separately inject equal volumes (about 20 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P in each mL of the injection taken by the formula:

\[0.1(C / V)(t_0 / r)\]

in which \(C\) is the concentration, in µg per mL, of USP Dexamethasone Phosphate RS in the Assay preparation, \(V\) is the volume, in mL, of Injection taken, and \(t_0\) and \(r\) are the peak responses at equivalent retention times obtained from the Assay preparation and the Standard preparation, respectively.

**Dexamethasone Sodium Phosphate Ophthalmic Ointment**

Dexamethasone Sodium Phosphate Ophthalmic Ointment is a sterile, oily ointment containing an amount of dexamethasone sodium phosphate (C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P) equivalent to not less than 90.0 percent and not more than 115.0 per cent of the labeled amount of dexamethasone phosphate (C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P).

**Packaging and storage**—Preserve in collapsible ophthalmic ointment tubes.

**USP Reference standards** (11)—

USP Dexamethasone RS
USP Dexamethasone Phosphate RS

**Identification**—The Assay preparation, prepared as directed in the Assay, responds to the Identification test under Dexamethasone Sodium Phosphate Cream.

**pH** (791): between 6.6 and 7.8.

**Sterility** (71): meets the requirements.

**Assay**—

Mobile phase, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Dexamethasone Sodium Phosphate Injection.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 8 mg of dexamethasone phosphate, to a 100-mL volumetric flask, dilute with Mobile phase to volume, and mix.

Procedure—Proceed as directed for Procedure in the Assay under Dexamethasone Sodium Phosphate Injection. Calculate the quantity, in mg, of C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P in each mL of the Ophthalmic Solution taken by the formula:

\[0.1(C / V)(t_0 / r)\]

in which \(V\) is the volume, in mL, of Ophthalmic Solution taken.

**Dexamethasone Sodium Phosphate Ophthalmic Solution**

Dexamethasone Sodium Phosphate Ophthalmic Solution is a sterile, aqueous solution of Dexamethasone Sodium Phosphate. It contains an amount of dexamethasone sodium phosphate (C\textsubscript{22}H\textsubscript{28}FN\textsubscript{3}O\textsubscript{8}P) equivalent to not less than 90.0 percent and not more than 115.0 per cent of the labeled amount of dexamethasone phosphate (C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P).

**Packaging and storage**—Preserve in tight, light-resistant containers.

**USP Reference standards** (11)—

USP Dexamethasone RS
USP Dexamethasone Phosphate RS

**Identification**—The Assay preparation, prepared as directed in the Assay, responds to the Identification test under Dexamethasone Sodium Phosphate Cream.

**pH** (791): between 6.6 and 7.8.

**Sterility** (71): meets the requirements.

**Assay**—

Mobile phase, Standard preparation, and Chromatographic system—Prepare as directed in the Assay under Dexamethasone Sodium Phosphate Injection.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 8 mg of dexamethasone phosphate, to a 100-mL volumetric flask, dilute with Mobile phase to volume, and mix.

Procedure—Proceed as directed for Procedure in the Assay under Dexamethasone Sodium Phosphate Injection. Calculate the quantity, in mg, of C\textsubscript{22}H\textsubscript{30}FO\textsubscript{8}P in each mL of the Ophthalmic Solution taken by the formula:

\[0.1(C / V)(t_0 / r)\]

in which \(V\) is the volume, in mL, of Ophthalmic Solution taken.

**Dexbrompheniramine Maleate**

\[C_{18}H_{19}BrN_2 \cdot C_6H_4O_4 \quad \text{435.32} \]

2-Pyridinepropanamine, \(\gamma\)-(4-bromophenyl)-N,N-dimethyl- \(, (\delta)-, (\beta)-2\)-butenedioate (1:1).

Dexbrompheniramine Maleate contains not less than 98.0 percent and not more than 100.5 per cent of \(C_{18}H_{19}BrN_2 \cdot C_6H_4O_4\), calculated on the dried basis.