

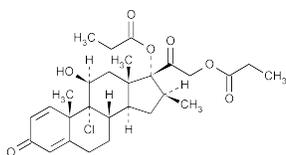
dose, of tuberculin-negative persons results in an acceptable tuberculin conversion rate. It is free from other organisms, and contains a suitable stabilizer. It contains no antimicrobial agent.

**NOTE**—Use the Vaccine immediately after its constitution, and discard any unused portion after 2 hours.

**Packaging and storage**—Preserve in hermetic containers, preferably of Type I glass, at a temperature between 2 ° and 8 °.

**Expiration date**—The expiration date is not later than 6 months after date of issue, or not later than 1 year after date of issue if stored at a temperature below 5 °.

## Beclomethasone Dipropionate



$C_{28}H_{37}ClO_7$  521.04

Pregna-1,4-diene-3,20-dione, 9-chloro-11-hydroxy-16-methyl-17,21-bis(1-oxopropoxy)-, (11 $\beta$ ,16 $\beta$ )-.

9-Chloro-11 $\beta$ ,17,21-trihydroxy-16 $\beta$ -methylpregna-1,4-diene-3,20-dione 17,21-dipropionate [5534-09-8].

Monohydrate 539.07.

» Beclomethasone Dipropionate is anhydrous or contains one molecule of water of hydration. It contains not less than 97.0 per cent and not more than 103.0 per cent of  $C_{28}H_{37}ClO_7$ , calculated on the dried basis.

**Packaging and storage**—Preserve in well-closed containers.

**USP Reference standards** (11)—

USP Beclomethasone Dipropionate RS

USP Testosterone Propionate RS

**Identification**, *Infrared Absorption* (197M).

**Specific rotation** (781S): between +88 ° and +94 °.

*Test solution*: 10 mg per mL, in dioxane.

**Loss on drying** (731)—Dry it at 105 ° for 3 hours: the anhydrous form loses not more than 0.5% of its weight; the monohydrate form loses between 2.8% and 3.8% of its weight.

**Residue on ignition** (281): not more than 0.1%.

**Assay**—

*Mobile phase*—Prepare a suitable degassed solution of 3 volumes of acetonitrile in 2 volumes of water, such that the retention time of beclomethasone dipropionate is approximately 6 minutes and that of testosterone propionate is approximately 10 minutes.

*Internal standard solution*—Dissolve a suitable quantity of USP Testosterone Propionate RS, accurately weighed, in methanol to obtain a solution having a concentration of about 1.2 mg per mL.

*Standard preparation*—Dissolve a suitable quantity of USP Beclomethasone Dipropionate RS, accurately weighed, in methanol to obtain a solution having a concentration of about 1.4 mg per mL. Transfer 4.0 mL of this solution to a suitable vial, and add 4.0 mL of *Internal standard solution* to obtain a solution having a known concentration of about 0.7 mg per mL with respect to the Reference Standard and 0.6 mg per mL with respect to the internal standard.

*Assay preparation*—Weigh accurately about 70 mg of Beclomethasone Dipropionate, transfer to a 50-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 4.0 mL of this solution to a suitable vial, and add 4.0 mL of *Internal standard solution*.

*Procedure*—Separately inject equal volumes (between 5  $\mu$ L and 25  $\mu$ L) of the *Assay preparation* and the *Standard preparation* into a high-performance liquid chromatograph (see *Chromatography* (621)) operated at room temperature, adjusting the specimen size and other operating parameters such that the peak obtained with the internal standard in the *Standard preparation* is about 0.6 to 0.9 full-scale. Typically, the apparatus is fitted with a 4-mm  $\times$  30-cm column that contains packing L1 and is equipped with an UV detector capable of monitoring absorption at 254 nm, a suitable recorder, and a pump capable of operating at a column pressure of up to 3500 psi. In a suitable chromatogram, the coefficient of variation for five replicate injections of the *Standard preparation* is not more than 3.0%. Calculate the quantity, in mg, of  $C_{28}H_{37}ClO_7$  in the portion of Beclomethasone Dipropionate taken by the formula:

$$100C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Beclomethasone Dipropionate RS in the *Standard preparation*; and  $R_U$  and  $R_S$  are the peak height ratios of beclomethasone dipropionate to the internal standard obtained from the *Assay preparation* and the *Standard preparation*, respectively.

## Belladonna Leaf

» Belladonna Leaf consists of the dried leaf and flowering or fruiting top of *Atropa belladonna* Linné or of its variety *acuminata* Royle ex Lindley (Fam. Solanaceae). Belladonna Leaf yields not less than 0.35 percent of the alkaloids of belladonna leaf.

**Packaging and storage**—Preserve in well-closed containers and avoid long exposure to direct sunlight. Preserve powdered Belladonna Leaf in light-resistant containers.

**USP Reference standards** (11)—

USP Atropine Sulfate RS

USP Homatropine Hydrobromide RS

USP Scopolamine Hydrobromide RS

**Botanic characteristics**—

*Belladonna Leaf*—Usually partly matted together, crumpled or broken leaves, together with some smaller stems and a number of flowers and fruits. The leaves are thin and brittle, mostly light green to moderate olive-green. The lamina is mostly from 5 to 25 cm in length and from 4 to 12 cm in width and possesses an ovate-lanceolate to broadly ovate outline, an acute to acuminate apex, an entire margin, an acute to somewhat decurrent base and slightly hairy surface, the hairs being more abundant along the veins; when broken transversely, it shows numerous light-colored dots (crystal cells) visible with a lens. The petiole is slender and usually up to 4 cm in length. The flowers possess a campanulate corolla with 5 small, reflexed lobes, purplish to yellowish purple, becoming faded to brown or dusky yellow or yellow, a green, 5-lobed calyx, 5 epipetalous stamens, and a superior, bilocular ovary with numerous ovules. The fruit is subglobose, dark yellow to yellowish brown to dusky red or black, up to about 12 mm in width and sometimes subtended by the persistent calyx and containing numerous flattened, somewhat reniform seeds, the latter up to about 2 mm in width. The stems are more or less flattened and hollow and finely hairy when young.

*Histology—Leaf*: The epidermis of the lamina possesses wavy anticlinal walls and a distinctly striated cuticle. Stomata