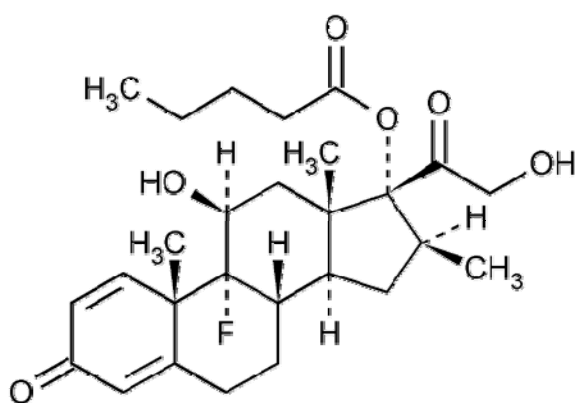


Betamethasone

USP Method Betamethasone Valerate Assay



Original Manufacturer:	-
Original Brand Name:	-
Generic Names:	Betamethasone dipropionate: Diprosone, Diprolene, Celestamine and others) Betamethasone sodium phosphate: Bentelan, Betamethasone valerate Betnovate, Celestone and others).
Combination Drugs:	Lotrisone (Betamethasone and clotrimazole) Lotriderm (Betamethasone and clotrimazole)

Betamethasone is a glucocorticoid steroid with anti-inflammatory and immunosuppressive properties. It is applied as a topical cream, ointment, foam, lotion or gel to treat itching.



Betamethasone Valerate

USP34 – NF29 S1

USP Columns

MicroBondapak C18 (Assay)

Equivalent Column:

Purospher®STAR RP-18 endcapped (5 µm) 250x4.0 mm (1.50252.0001)

Optional Scaled Column:

Purospher®STAR RP-18 endcapped (5 µm) 250x3.0 mm (1.50254.0001)

Recommended Solvents and Reagents:

Methanol for liquid chromatography LiChrosolv® (1.06018)

Acetonitrile isocratic grade for liquid chromatography LiChrosolv® (1.14291)

Water Water for chromatography LiChrosolv® (1.15333)
or freshly purified water from Milli-Q water purification system

Acetic Acid Acetic acid (glacial) 100% . Use ACS reagent grade

USP Standards

Betamethasone Valerate (200 mg) USP Product Number: 1069007

Beclomethasone Dipropionate (200 mg) USP Product Number: 1048506

USP Method Betamethasone Valerate Assay

Mobile phase

Prepare a filtered and degassed mixture of acetonitrile and water (3:2).
Make adjustments if necessary (see System Suitability under Chromatography 621).

Internal standard solution

Transfer about 40 mg of beclomethasone dipropionate to a 100-mL volumetric flask, add a solution of glacial acetic acid in methanol (1 in 1000) to volume, and mix.

Standard preparation

Transfer about 30 mg of USP Betamethasone Valerate RS, accurately weighed, to a 50-mL volumetric flask, add a solution of glacial acetic acid in methanol (1 in 1000) to volume, and mix. Transfer 5.0 mL of this solution to a suitable stoppered vial, add 10.0 mL of Internal standard solution, and mix to obtain a solution having a known concentration of about 0.2 mg of USP Betamethasone Valerate RS per mL.

Assay preparation

Transfer about 60 mg of Betamethasone Valerate, accurately weighed, to a 100-mL volumetric flask, add a solution of glacial acetic acid in methanol (1 in 1000) to volume, and mix. Transfer 5.0 mL of this solution to a suitable stoppered vial, add 10.0 mL of Internal standard solution, and mix.

Chromatographic system

The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the relative retention times are about 1.7 for beclomethasone dipropionate and 1.0 for betamethasone valerate; the resolution, R, between betamethasone valerate and beclomethasone dipropionate is not less than 4.5; and the relative standard deviation for replicate injections is not more than 2.0%.

USP Method for Betamethasone Valerate Assay

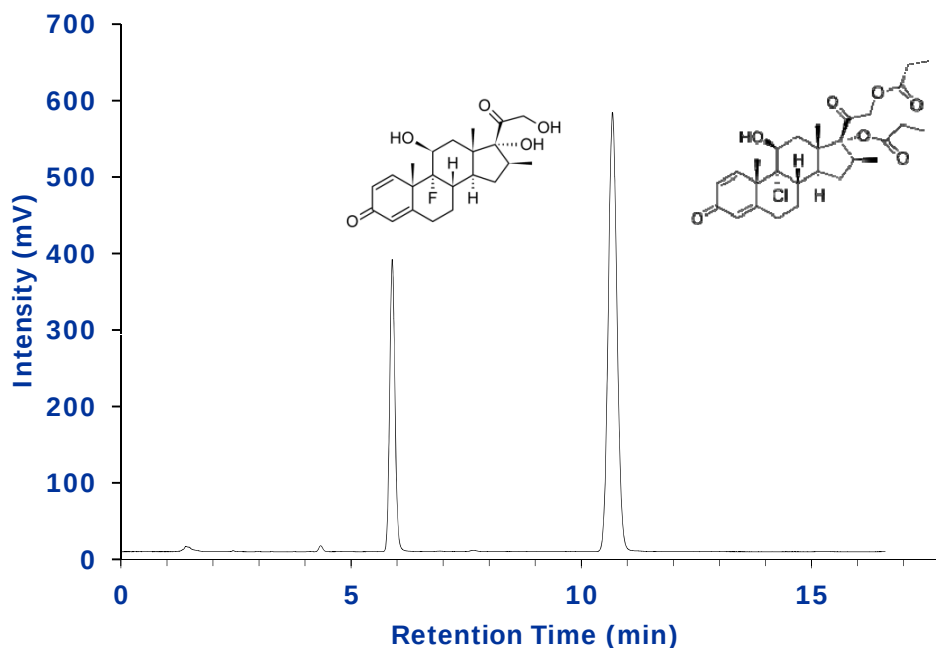
Purospher®STAR RP-18 endcapped

Chromatographic Conditions

Column: Purospher®STAR RP-18 endcapped (5 µm) 250x4.0 mm 1.50252.0001
Injection: 10 µL
Detection: Shimadzu Prominence 2010, UV 254 nm
Cell: 8 µL
Flow Rate: 1.2 mL/min

Mobile Phase (v/v): Acetonitrile and water 60:40

Temperature: Ambient
Diluent: Methanol with 0.1 % glacial acetic acid
Sample: 200 ppm Betamethasone Valerate RS and 267 ppm Beclomethasone Dipropionate
Pressure Drop: 172 Bar (2494 psi)



Chromatographic Data

No.	Compound	Time (min)	Resolution	Relative Retention Time (RRT)	Tailing Factor (T _{USP})
1	Betamethasone Valerate RS	5.9	-	1.0	1.10
2	Beclomethasone Dipropionate	10.7	17.1	1.8	1.07

USP Method for Betamethasone Valerate Assay

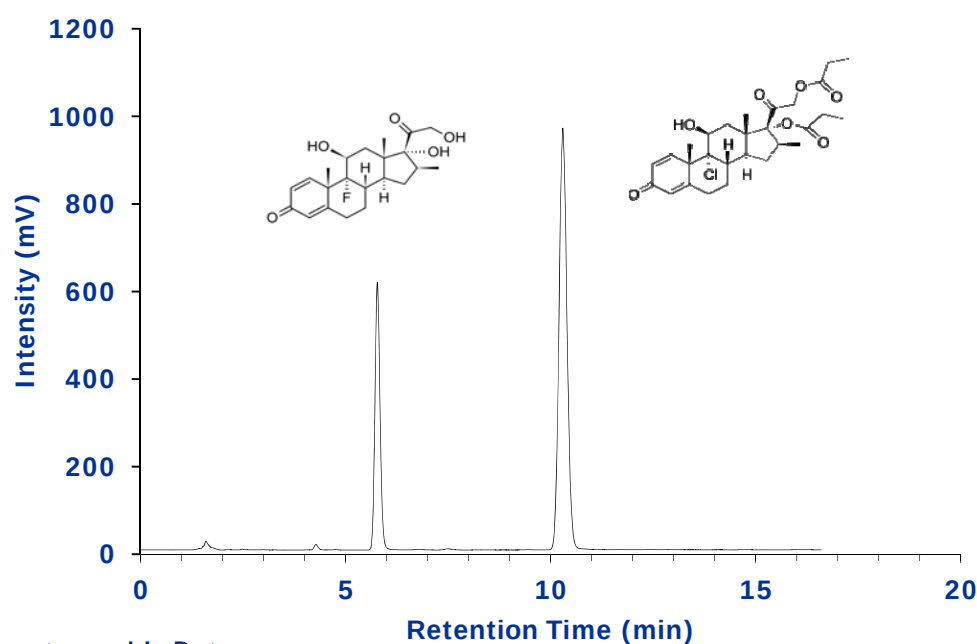
Purospher®STAR RP-18 endcapped

Chromatographic Conditions

Column: Purospher®STAR RP-18 endcapped (5 µm) 250x3.0 mm 1.50254.0001
 Injection: 10 µL
 Detection: Shimadzu Prominence 2010, UV 254 nm
 Cell: 8 µL
 Flow Rate: 0.7 mL/min

Mobile Phase (v/v): Acetonitrile and water 60:40

Temperature: Ambient
 Diluent: Methanol with 0.1 % glacial acetic acid
 Sample: 200 ppm Betamethasone Valerate RS and 267 ppm Beclomethasone Dipropionate
 Pressure Drop: 164 Bar (2378 psi)



Chromatographic Data

No.	Compound	Time (min)	Resolution	Relative Retention Time (RRT)	Tailing Factor (T _{USP})
1	Betamethasone Valerate RS	5.8	–	1.0	1.12
2	Beclomethasone Dipropionate	10.3	15.5	1.8	1.09