



## OPES HEALTHCARE PVT. LTD.

### ANALYTICAL DEVELOPMENT LABORATORY

#### IN USE STABILITY REPORT

#### 1.0 OBJECTIVE

The objective of in use stability is to establish a period of time during which multi dose product can be used whilst retaining quality within an accepted specification once the container is opened. The extent of drug product testing was established by assessing whether or not acceptable physicochemical changes.

#### 2.0 PRODUCT

Product Name	Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v
Generic Name	Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v
Batch No.	JW8001
Mfg. date	12-2018
Expiry Date	11-2020
Manufacturer	Lincoln Pharmaceuticals Limited
Storage condition	Do not store above 30°C. Protect from light. Do not freeze.

#### 3.0 SAMPLE STORAGE CONDITION

The product should be stored under the same condition as per recommended in the product literature/leaflet (SPC/PIL) throughout the in use stability period.

#### 4.0 TEST PARAMETERS

1. Description
2. pH
3. Assay
4. Related Substance

#### 5.0 ANALYTICAL PROCEDURE

##### **1. DESCRIPTION**

**Apparatus:** Test tube.

**Procedure:** Take sufficient number of bottles and remove solution from each bottle in a dry glass test tube and check against white background and observe against requirements.

**Requirement:** White colour suspension filled in bottle.



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#### **2. pH**

**Instrument:** pH meter.

**Procedure:**

Select about 10 to 15 containers for the test. Transfer the sufficient solution from bottles to previously dried 50 ml beaker to immerse the electrode. Mix well and then immerse the electrodes in the solution to be examined and take the reading.

**Requirement:** Between 5.0 and 6.0.

#### **3. ASSAY**

**(A) ASSAY OF PREDNISOLONE ACETATE:**

**Instrument:** HPLC.

**Preparation of mobile phase:** Prepare a filtered and degased mixture of water and acetonitrile (3: 2). Make adjustment if necessary.

**Diluent:** Prepare a mixture of acetonitrile and water (1: 1).

**Chromatographic conditions:**

Column	: Hypersil BDS (25 cm x 4.6 mm) packing L1 (C <sub>18</sub> ) (5 µm) OR Equivalent.
Flow rate	: 2.0 ml per minute
Wave length	: 254 nm
Injection volume	: 10 µl
Column temperature	: Ambient
Run time	: About 15 min
Retention time	: About 4 min

**Standard preparation:** Weigh accurately about 50 mg of Prednisolone Acetate WS in 100 ml of volumetric flask, add about 50 ml of diluent to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make volume with diluent. Transfer 10 ml of this solution to 50 ml of volumetric flask and make volume with diluent.

**System suitability preparation:** Weigh accurately about 10 mg of Prednisolone WS in 100 ml of volumetric flask, add about 50 ml of mixture of Acetonitrile and methanol (1: 1) to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make volume with mixture of Acetonitrile and methanol (1: 1). Mix equal volume of system suitability preparation and standard preparation.



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**Assay preparation:** Take 1 ml of ophthalmic suspension (Equivalent to about 10 mg of Prednisolone Acetate) in 100 ml volumetric flask, add about 50 ml of diluent, shake well and make volume 100 ml with diluent and mix. Filter the solution through 0.45-µm Nylon syringe filter.

**Procedure:** Follow the injection sequence of Blank, System suitability preparation, Standard preparation and Assay preparation in following order in to liquid chromatograph and record the chromatograph.

Sr. No.	Solution	No. of Injections
1	Blank	1
2	System suitability preparation	1
3	Standard preparation	5
4	Assay preparation	2
5	Bracketing System suitability preparation	1
6	Bracketing Standard preparation	1

**System suitability requirement:** Inject 10 µl of system suitability solution and standard preparation.

1. The relative retention times are 0.5 for Prednisolone and 1.0 for Prednisolone Acetate.
2. **Resolution:** The resolution R, between Prednisolone and Prednisolone Acetate is not less than 2.0, system suitability preparation.
3. **Column efficiency:** Not less than 7000.
4. **Tailing factor:** Not more than 2.0.

#### Calculation:

Calculate the amount of Prednisolone Acetate using following formula:

% w/v of Prednisolone Acetate per ml =

$$\frac{\text{Spl. Area}}{\text{Std. Area}} \times \frac{\text{Std. Wt. (in mg)}}{100 \text{ ml}} \times \frac{10 \text{ ml}}{50 \text{ ml}} \times \frac{100 \text{ ml}}{\text{Spl. Taken (in ml)}} \times \frac{\% \text{ Assay of Prednisolone Acetate on "as is" basis of Prednisolone Acetate WS}}{1000} \times \frac{1}{1000}$$





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**% of Prednisolone Acetate =**

% w/v of Prednisolone Acetate X 100

-----  
Claim (1 % w/v)

**Requirements:**

**IQC & RELEASE LIFE SPECIFICATION:** Between 95.0 % and 115.0 % of the label claim.

**SHELF LIFE SPECIFICATION:** Between 90.0 % and 115.0 % of the label claim.

**(B) ASSAY OF BENZALKONIUM CHLORIDE:**

**Instrument:** HPLC

**Preparation of Buffer:** Dissolve about 6.8 gm of potassium dihydrogen orthophosphate & 11.5 gm of 1-heptane sulfonic acid sodium salt in 1000 ml of water. Adjust pH 6.3 with dilute solution of sodium hydroxide. Filter through 0.45 µm nylon filter.

**Mobile phase:** Prepare a mixture of Buffer and Acetonitrile in the ratio of 35:65. Mix well and degas for 15 minutes.

**Chromatographic conditions:**

Column	: Agela Venusil XBP, C18 (150 mm X 3.9 mm) 5 µm <b>OR</b> Equivalent.
Column temperature	: 40°C
Wavelength	: 215 nm
Flow rate	: 1.8 ml / minute
Injection volume	: 20 µl
Run Time	: About 15 minutes
Retention Time	: For Benzalkonium chloride C12: About 4.0 minutes For Benzalkonium chloride C14: About 8.0 minutes

**Note:** The two peaks are found, Benzalkonium chloride (C12) and Benzalkonium chloride (C14). The elution order is, first peak is for Benzalkonium chloride (C12) and the second peak is for Benzalkonium chloride (C14).

**Standard Solution:** Weigh accurately about 20 mg of Benzalkonium chloride solution 50% (equivalent to about 10 mg of Benzalkonium chloride) into 100 ml volumetric flask, Add about 50 ml of Mobile Phase to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make up volume with Mobile Phase to 100 ml. Transfer 10 ml of this solution into 100 ml of volumetric flask and make up volume with Mobile Phase.



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**Sample Solution:** Transfer 5.0 ml of sample solution in to 25 ml of volumetric flask, make volume with Mobile Phase and mix well.

**Procedure:** Separately inject Blank (Mobile phase), Standard Solution and Sample Solution in to the chromatograph, record the chromatograms and measure the peak responses for the analyte peak. Follow the injection sequence as mentioned below.

Sr. No.	Sample	No. of Injections
1.	Blank (Mobile phase)	1
2.	Standard Solution	5
3.	Sample Solution	2
4.	Bracketing (Standard Solution)	1

**System suitability requirement:** Inject 20 µl of standard preparation.

- Tailing factor:** Not more than 2.5 for Benzalkonium chloride (C12) and (C14) peaks.
- Theoretical plates:** Not less than 1000 for Benzalkonium chloride (C12) and (C14) peaks.
- Relative standard deviation:** Not more than 2.0 % for Benzalkonium chloride (C12) and (C14) peaks.

#### Calculation:

Calculate the amount of **Benzalkonium Chloride** using following formula:

% w/v of **Benzalkonium Chloride** in Ophthalmic Suspension =

$$\frac{\text{AU}}{\text{AS}} \times \frac{\text{Std. taken (in mg)}}{100 \text{ ml}} \times \frac{10 \text{ ml}}{25 \text{ ml}} \times \frac{\% \text{ Assay of Benzalkonium Chloride in solution}}{100} \times \frac{100}{1} = \text{Result}$$

(in ml)

Where,

AU = Average area of sum of benzalkonium chloride (C12) and (C14) in sample preparation.

AS = Average area of sum of benzalkonium chloride (C12) and (C14) in standard preparation.



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**% of Benzalkonium Chloride in Ophthalmic Suspension =**

**% w/v of Benzalkonium Chloride in Ophthalmic suspension X 100**

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Claim (0.006% w/v)

**Requirements:**

**RELEASE SPECIFICATION:** Between 90.0 % and 110.0 % of the label claim.

**SHELF LIFE SPECIFICATION:** Between 50.0 % and 110.0 % of the label claim.

**4. RELATED SUBSTANCES**

**Instrument:** HPLC

**Note:** Use the sample Solution within 3 hours after preparation.

**Mobile phase:** Prepare a mixture of Water and Acetonitrile in the ratio of (650:350). Filter through 0.45µm PVDF membrane filter and degas for about 10 min.

**Preparation of Dilute Hydrochloric acid:** Weigh and transfer about 20 gm of Hydrochloric acid in 100 ml volumetric flask & make up volume with water.

**Preparation of Sodium Acetate Solution:** Weigh and transfer about 6.8 gm of Sodium Acetate anhydrous in 100 ml of water.

**Preparation of Potassium chloride (KCL) Solution:** Weigh and transfer about 7.46 gm Potassium chloride (KCL) in 200 ml of Water.

**Buffer Preparation (pH 4.0):** Transfer 10 ml of Dilute Hydrochloric acid, 50 ml of Sodium Acetate Solution, 150 ml of Potassium chloride (KCL) Solution and 790 ml of water.

**Solvent Mixture:** Prepare a mixture of Buffer preparation (pH 4.0) and Acetonitrile in the ratio of (500: 500).

**Chromatographic conditions:**

Column	: Waters, Sunfire-C18 (250 mm X 4.6 mm); 5 µm <b>OR</b> Equivalent.
Column temperature	: 40°C
Wavelength	: 254 nm
Flow rate	: 1.0 ml / minute
Injection volume	: 10 µl
Retention time	: About 17 minutes of Prednisolone Acetate
Run Time	: 60 minutes for Sample Solution & 35 minutes for Standard Solution





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**System suitability Solution:** Weigh and transfer about 2 mg of Prednisolone Acetate & 2 mg of Hydrocortisone Acetate in 100 ml volumetric flask, add 50 ml of Solvent Mixture to dissolve with aid of sonication for about 5 minutes with occasional shaking and make volume 100 ml with Solvent Mixture.

**Standard solution:** Weigh and transfer about 20 mg of Prednisolone Acetate WS in 200 ml volumetric flask, add about 100 ml of Methanol to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make volume with Methanol. Transfer 5 ml of standard solution in 100 ml volumetric flask and make volume with Methanol.

**Placebo solution:** Transfer about 5 ml of Placebo in 20 ml of volumetric flask, add about 10 ml of methanol to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make volume with Methanol. Filter the solution through 0.45- $\mu$ m Nylon syringe filter.

**Sample solution:** Transfer about 5 ml of Sample (equivalent to about 50 mg) of Prednisolone Acetate in 20 ml of volumetric flask, add about 10 ml of methanol to dissolve with the aid of sonication for about 5 minutes with occasional shaking and make volume with Methanol. Filter the solution through 0.45- $\mu$ m Nylon syringe filter.

**Procedure:** Follow the injection sequence of Blank (Methanol), Placebo solution, System suitability solution, & Standard Solution and Sample Solution in following order in to liquid chromatography and record the chromatograph.

Sr. No.	Solution	No. of Injections
1.	Blank (Methanol)	1
2.	Placebo solution	1
3.	System suitability solution	1
4.	Standard Solution	1
5.	Sample Solution	1

#### **Identification of impurity**

Relative Retention with reference to Prednisolone Acetate (RT about 17 minutes)

Prednisolone (Impurity B) = About 0.4,

Hydrocortisone Acetate (Impurity A) = About 1.1,

**System suitability requirement:** Inject 10  $\mu$ l of System Suitability Solution.

1. **Resolution:** Not less than 2.0 between Prednisolone Acetate & Hydrocortisone Acetate (impurity A) for System Suitability Solution.



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##### Disregard limit:

1. Disregard any peak obtains due to interference of placebo and Blank (Methanol).
2. Disregard any Peak with an area less than 0.05% of the Principle peak in the chromatogram obtain in sample solution.

##### Calculation:

**(A) Hydrocortisone Acetate (Impurity A):** Not more than 1.0 %.

$$= \frac{\text{Area of Hydrocortisone Acetate (Impurity A) in sample solution}}{\text{Total area of all Peaks in the sample Solution}} \times 100$$

**(B) Prednisolone (Impurity B):** Not more than 2.0 %.

$$= \frac{\text{Area of Prednisolone (Impurity B) in sample solution}}{\text{Total area of all Peaks in the sample Solution}} \times 100$$

**(C) Any other Unspecified Impurity:** Not more than 0.5 %.

$$= \frac{\text{Area of unspecified impurity in sample solution}}{\text{Total area of all Peaks in the sample Solution}} \times 100$$


**(D) Total impurities:** Not more than 3.0 %.

$$= \frac{\text{Sum of area of all impurities in sample solution}}{\text{Total area of all Peaks in the sample Solution}} \times 100$$

**Requirement:** For both, release specification and shelf life specification:

- A) Hydrocortisone Acetate (Impurity A): Not more than 1.0 %.
- B) Prednisolone (Impurity B): Not more than 2.0 %
- C) Any other Unspecified Impurity: Not more than 0.5 %.
- D) Total impurities: Not more than 3.0 %.



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## 5.0 TEST DESIGN

As per the recommendation printed on container the solution is used within one month after open the container. The study is carried out for 28 days for the mentioned test parameters.

The physicochemical analysis is performed after 7, 14, 21 and 28 days. The sample for specified batch no are consumed every day about 2 to 3 drops from each container. Use set of five containers for each time point of analysis. Analysis should perform as per following table.

Sample exposure schedule is as per follow.

Container No.	Days	Date of Exposure
1	Initial	27-01-2019
2	After 7 days	20-01-2019
3	After 14 days	13-01-2019
4	After 21 days	06-01-2019
5	After 28 days	30-12-2018




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#### Test Performance Design As Per Follow:-

Day	Test to be perform			
	Description	pH	Assay	Related Substance
1	Not required			
2				
3				
4				
5				
6				
7	To be perform	To be perform	To be perform	To be perform
8	Not required			
9				
10				
11				
12				
13				
14	To be perform	To be perform	To be perform	To be perform
15	Not required			
16				
17				
18				
19				
20				
21	To be perform	To be perform	To be perform	To be perform
22	Not required			
23				
24				
25				
26				
27				
28	To be perform	To be perform	To be perform	To be perform

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## 6.0 RESULTS

AS THE ANALYSIS ARE PERFORMED THE RESULTS ARE FIND AS PER BELOW TABLE.

Day	Test to be perform			
	Batch No.: JW8001			
	Description	pH	Assay	
			Prednisolone acetate	Benzalkonium Chloride
<b>Initial</b>	White colour suspension filled in bottle	5.22	101.7 %	102.8 %
<b>7</b>	White colour suspension filled in bottle	5.21	101.3 %	102.6 %
<b>14</b>	White colour suspension filled in bottle	5.19	101.3 %	100.5 %
<b>21</b>	White colour suspension filled in bottle	5.19	100.2 %	100.3 %
<b>28</b>	White colour suspension filled in bottle	5.15	100.5 %	98.2 %
<b>limit</b>	White colour suspension filled in bottle	Between 5.0 and 6.0.	Between 90.0 % and 115.0 % of the label claim	Between 50.0 % and 110.0 % of the label claim





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**Batch no: JW8001**

	Related Substances			
	Hydrocortisone Acetate (Imp.A)	Prednisolone (Imp.B)	Any other Unspecified impurity	Total Impurities
Initial	0.74 %	0.73 %	0.24 %	1.76 %
After 07 Days	0.74 %	0.79 %	0.21 %	1.84 %
After 14 Days	0.74 %	0.86 %	0.18 %	1.89 %
After 21 Days	0.73 %	0.92 %	0.16 %	1.89 %
After 28 Days	0.74 %	1.04 %	0.12 %	1.99 %
Limit	Not more than 1.0 %	Not more than 2.0 %	Not more than 0.5%	Not more than 3.0%

#### 7.0 CONCLUSION

Commencing results of in use stability study conducted at normal defined storage condition the physicochemical parameters such as Description, pH, Assay, and Related Substance are complies within the shelf life specification up to expose the sample for 28 days. As a result of absorption of moisture fro atmosphere during repeated opening and closing of container in routine use the value of physicochemical parameters are not significantly impacted. However, by reason of repeated exposure of temperature, moisture and light the quality of product remains stable as per recommended exposure time.

Prepared by:

*Dr. Arvind*  
01/02/19

Checked by:

*Dr. Arvind*  
01/02/19

**Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v**

Batch NO: JUS601 (Initial)

**Hydrocortisone Acetate(Impurity A) :**

$$= \frac{\text{Area of Hydrocortisone Acetate(Imp.A) in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{250761}{3206187} \times 100$$

$$= 0.781 \text{ (N.M.T. 1.0 \%)}$$

**Prednisolone(Impurity B) :**

$$= \frac{\text{Area of Prednisolone(Imp B.) in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{217721}{3206187} \times 100$$

$$= 0.731 \text{ (N.M.T. 2.0 \%)}$$

**Any other Unspecified Impurity :**

$$= \frac{\text{Area of unspecified impurity in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{83221}{3206187} \times 100$$

$$= 0.26 \text{ (N.M.T. 0.5 \%)}$$

**Total Impurities :**

$$= \frac{\text{Sum of area of all Impurities in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{397707}{3206187} \times 100$$

$$= 1.761 \text{ (N.M.T. 3.0 \%)}$$

*GAH*  
26/11/19

*Lu*  
28/01/19

**Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v**

Batch NO: *JW 8001 (AFA) 07/01/19*  
Hydrocortisone Acetate(Impurity A) :

$$\begin{aligned} & \frac{\text{Area of Hydrocortisone Acetate(Imp.A) in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{262062}{31236281} \times 100 \\ &= 0.71\% \text{ (N.M.T. 1.0 \%)} \end{aligned}$$

**Prednisolone(Impurity B) :**

$$\begin{aligned} & \frac{\text{Area of Prednisolone(Imp B.) in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{271837}{31236281} \times 100 \\ &= 0.79\% \text{ (N.M.T. 2.0 \%)} \end{aligned}$$

**Any other Unspecified Impurity :**

$$\begin{aligned} & \frac{\text{Area of unspecified impurity in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{73317}{31236281} \times 100 \\ &= 0.21\% \text{ (N.M.T. 0.5 \%)} \end{aligned}$$

**Total Impurities :**

$$\begin{aligned} & \frac{\text{Sum of area of all Impurities in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{631225}{31236281} \times 100 \\ &= 1.81\% \text{ (N.M.T. 3.0 \%)} \end{aligned}$$

*hacat*  
28/01/19

*lu*  
28/01/19



**Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v**

Batch NO: JW80.1 (AHS 1N2015)  
Hydrocortisone Acetate(Impurity A) :

$$= \frac{\text{Area of Hydrocortisone Acetate(Imp.A) in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{251254}{31022027} \times 100$$
$$= \underline{0.71\%} \text{ (N.M.T. 1.0 \%)}$$

**Prednisolone(Impurity B) :**

$$= \frac{\text{Area of Prednisolone(Imp B.) in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{232761}{31022027} \times 100$$
$$= \underline{0.66\%} \text{ (N.M.T. 2.0 \%)}$$

**Any other Unspecified Impurity :**

$$= \frac{\text{Area of unspecified impurity in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{62697}{31022027} \times 100$$
$$= \underline{0.14\%} \text{ (N.M.T. 0.5 \%)}$$

**Total Impurities :**

$$= \frac{\text{Sum of area of all Impurities in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{611252}{31022027} \times 100$$
$$= \underline{1.89\%} \text{ (N.M.T. 3.0 \%)}$$

*GAH*  
28/11/19

*En*  
28/01/19

**Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v**

Batch NO: *JW 8501 (Aty 21 Dns)*  
Hydrocortisone Acetate(Impurity A) :

$$\begin{aligned} &= \frac{\text{Area of Hydrocortisone Acetate(Imp.A) in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{250166}{3112111} \times 100 \\ &= 0.73\% \text{ (N.M.T. 1.0 \%)} \end{aligned}$$

**Prednisolone(Impurity B) :**

$$\begin{aligned} &= \frac{\text{Area of Prednisolone(Imp B.) in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{313617}{3112111} \times 100 \\ &= 0.92\% \text{ (N.M.T. 2.0 \%)} \end{aligned}$$

**Any other Unspecified Impurity :**

$$\begin{aligned} &= \frac{\text{Area of unspecified impurity in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{55437}{3112111} \times 100 \\ &= 0.16\% \text{ (N.M.T. 0.5 \%)} \end{aligned}$$

**Total Impurities :**

$$\begin{aligned} &= \frac{\text{Sum of area of all Impurities in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100 \\ &= \frac{615721}{3112111} \times 100 \\ &= 1.89\% \text{ (N.M.T. 3.0 \%)} \end{aligned}$$

*Aty*  
28/01/19

*lu*  
28/01/19

**Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v**

Batch NO: JW5001 (Oph 25 Dose)

**Hydrocortisone Acetate(Impurity A) :**

$$= \frac{\text{Area of Hydrocortisone Acetate(Imp.A) in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{251221}{31125880} \times 100$$

$$= 0.79\% \text{ (N.M.T. 1.0 \%)}$$

**Prednisolone(Impurity B) :**

$$= \frac{\text{Area of Prednisolone(Imp B.) in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{353828}{31125880} \times 100$$

$$= 1.14\% \text{ (N.M.T. 2.0 \%)}$$

**Any other Unspecified Impurity :**

$$= \frac{\text{Area of unspecified impurity in Sam. Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{11877}{31125880} \times 100$$

$$= 0.12\% \text{ (N.M.T. 0.5 \%)}$$

**Total Impurities :**

$$= \frac{\text{Sum of area of all Impurities in Sam.Sol.}}{\text{Total area of all Peaks in the Sam. Sol.}} \times 100$$

$$= \frac{0.99\%}{31125880} \times 100$$

$$= 1.99\% \text{ (N.M.T. 3.0 \%)}$$

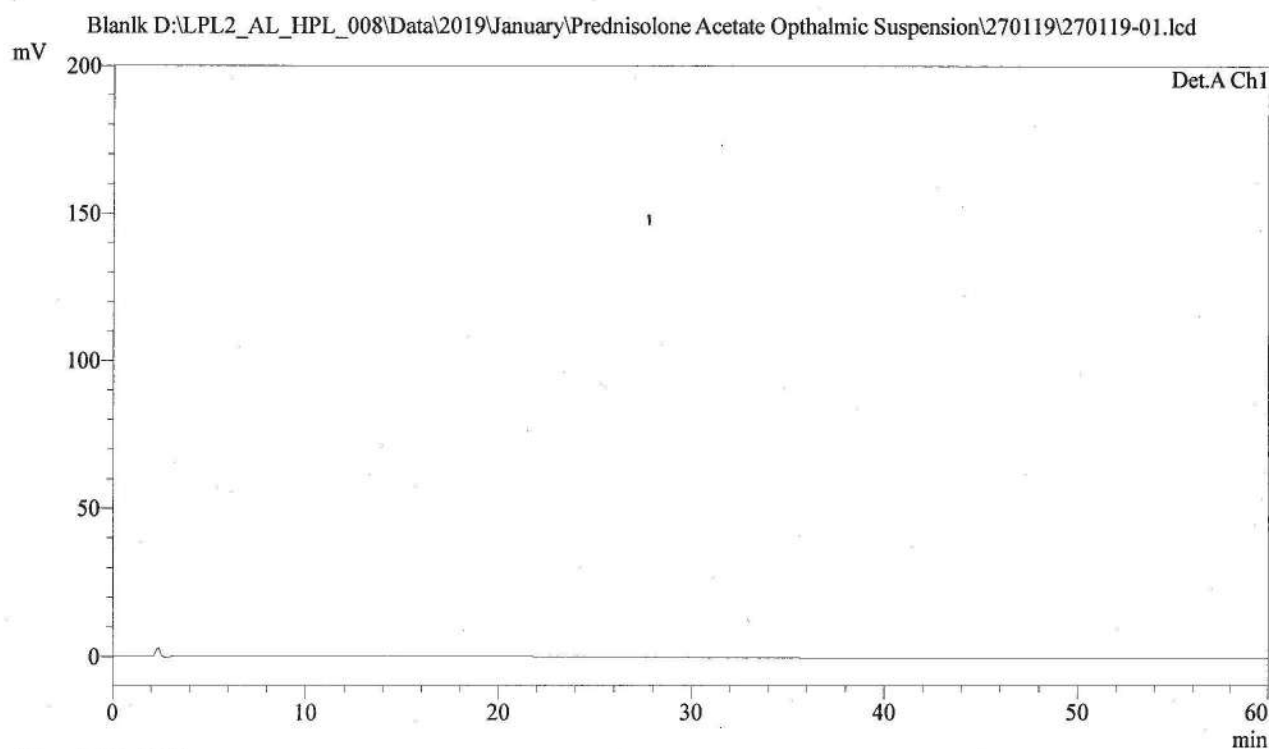


## Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-01.lcd

Acquired by : Sunil Patel.  
Sample Name : Blank  
Sample ID : Methanol  
Description : RS  
Vial : 1  
Injection Volume : 10  
Data Filename : 270119-01.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
Batch Filename : 270119.lcb  
Date Acquired : 27/01/19 12:28:05

## Chromatogram



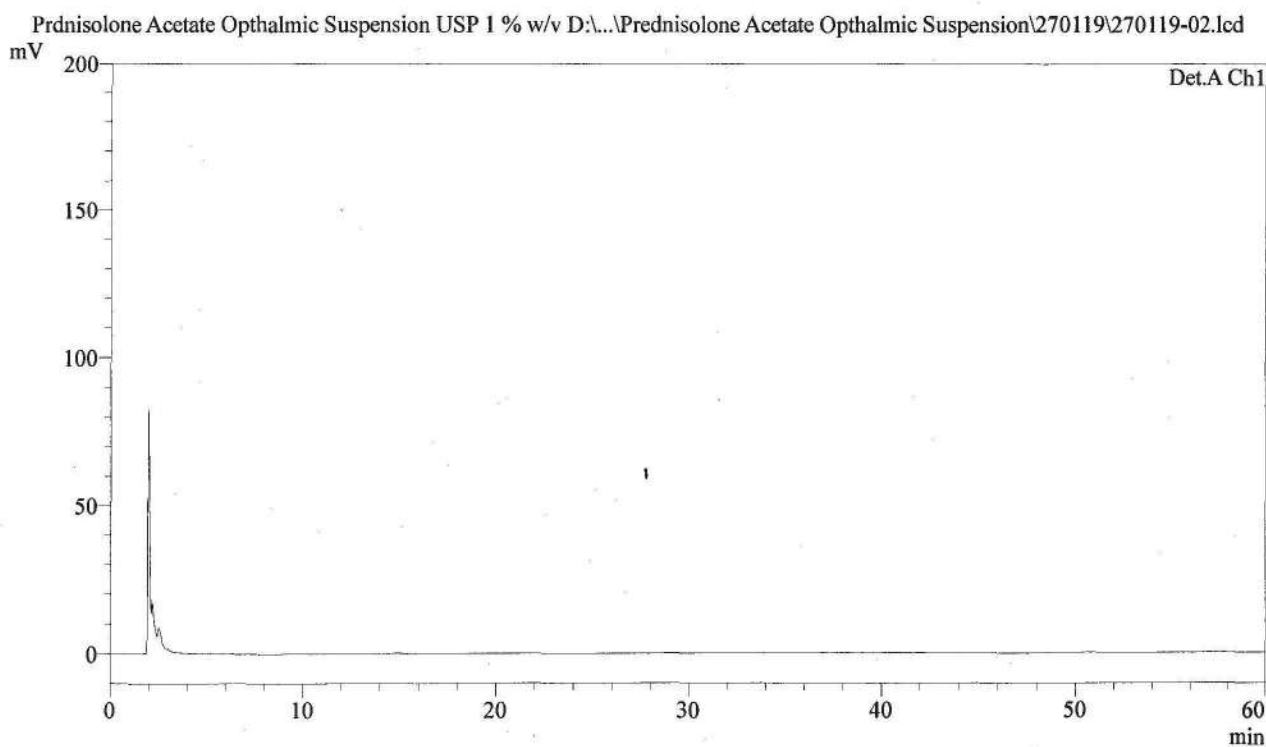
PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-01.lcd  
Detector A Ch1 254nm

OPES HEALTHCARE PVT. LTD.  
Analytical Development Laboratory

## Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-02.lcd  
Acquired by : Sunil Patel.  
Sample Name : Prdnisolone Acetate Ophthalmic Suspension USP 1 % w/v  
Sample ID : Placebo  
Description : RS  
Vail : 2  
Injection Volume : 10  
Data Filename : 270119-02.lcd  
Method Filename : Prednisolone Acatate Ophthalmic Suspension\_RS.lcm  
Batch Filename : 270119.lcb  
Date Acquired : 27/01/19 13:28:41

## Chromatogram



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-02.lcd  
Detector A Ch1 254nm

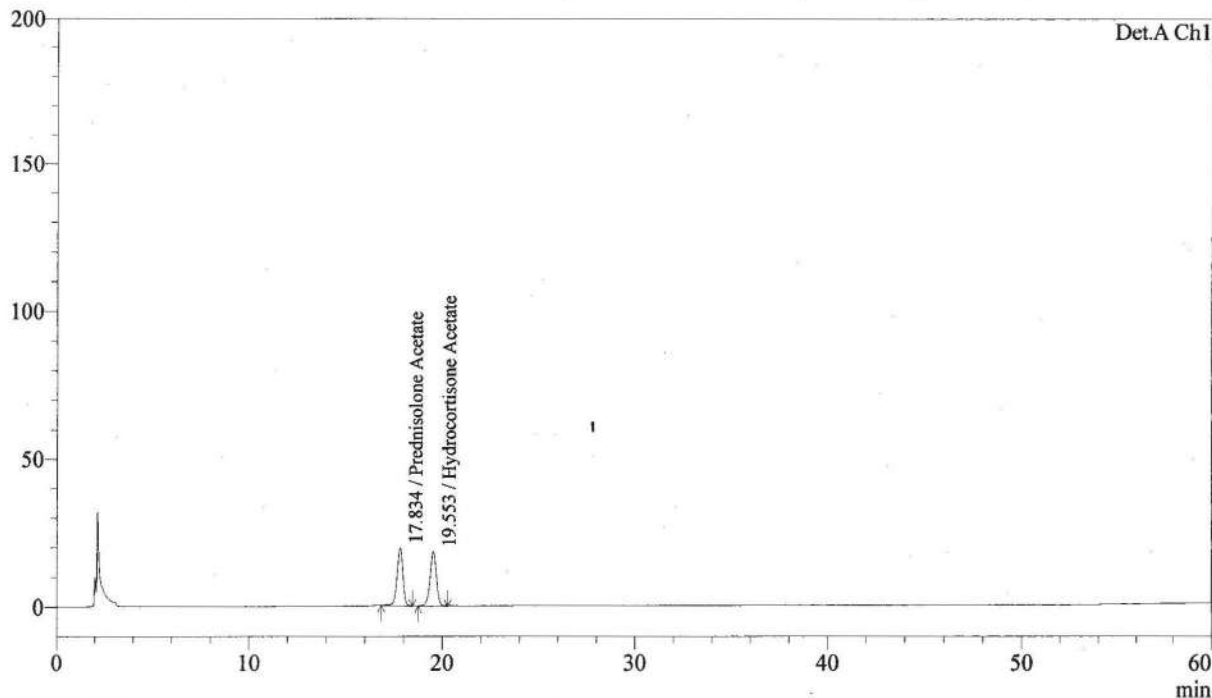
**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**

### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-03.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate+Hydrocortisone Acetate  
 Sample ID : System Suitability Solution  
 Description : RS  
 Vial : 3  
 Injection Volume : 10  
 Data Filename : 270119-03.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 14:29:20

### Chromatogram

Prednisolone Acetate+Hydrocortisone Acetate D:\...\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-03.lcd  
 mV



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-03.lcd  
 Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical Plattive Retention	Resolution
1	Prednisolone Acet	17.834	399904	19304	49.23	17273	0.000
2	Hydrocortisone A	19.553	412351	18238	50.77	17306	0.000
Total			812255	37542	100.00		

*Sunil Patel*  
 28/01/19

Analysed By: Sunil Patel.

1 / 1

Checked By:

*Sunil Patel*  
 28/01/19

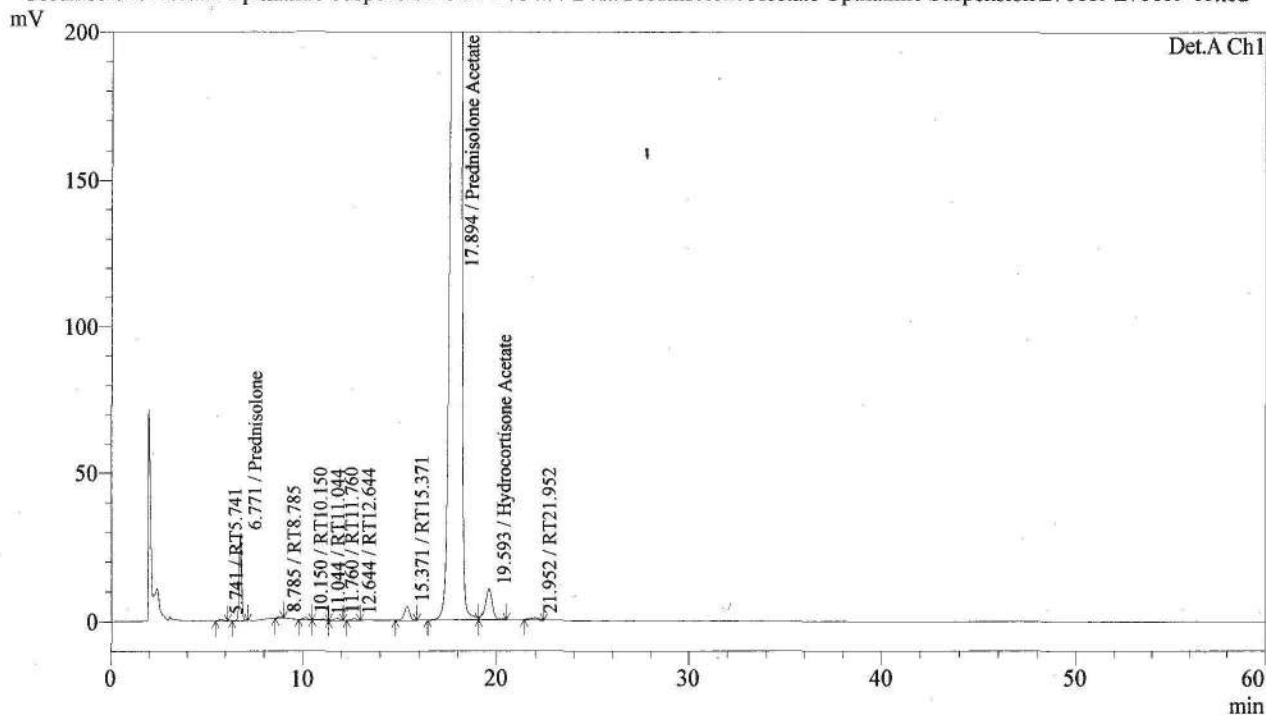


### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-05.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v  
 Sample ID : # JW8001\_Sam.Sol.  
 Description : RS\_Initial  
 Vial : 5  
 Injection Volume : 10  
 Data Filename : 270119-05.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 16:30:35

### Chromatogram

Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v D:\...\Prednisolone Acetate Ophthalmic Suspension\270119\270119-05.lcd



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-05.lcd

Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical	Plattive Retention	Resolution
1	RT5.741	5.741	7978	519	0.02	3334	0.321	0.00
2	Prednisolone	6.771	247721	28881	0.73	13438	0.378	3.26
3	RT8.785	8.785	4153	414	0.01	15834	0.491	7.85
4	RT10.150	10.150	10999	709	0.03	8479	0.567	3.79
5	RT11.044	11.044	6286	244	0.02	4461	0.617	1.62
6	RT11.760	11.760	14105	826	0.04	13954	0.657	1.35
7	RT12.644	12.644	9698	575	0.03	12713	0.707	2.09
8	RT15.371	15.371	83221	4535	0.24	16170	0.859	5.85
9	Prednisolone Acetate	17.894	33408706	1553204	98.09	16169	1.000	4.82
10	Hydrocortisone A	19.593	250761	10217	0.74	15814	1.095	2.86
11	RT21.952	21.952	15778	600	0.05	15466	1.227	3.55
Total			34059407	1600726	100.00			

# OPES HEALTHCARE PVT. LTD.

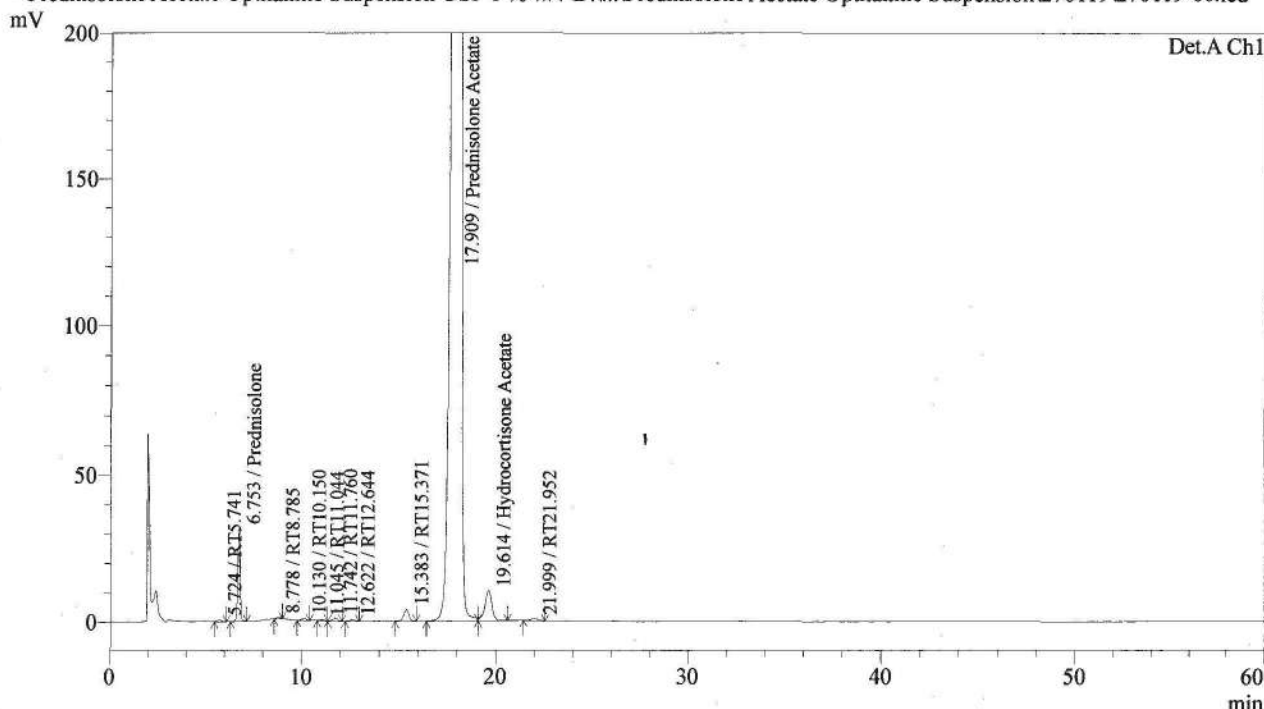
## Analytical Development Laboratory

### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-06.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v  
 Sample ID : # JW8001\_Sam.Sol.  
 Description : RS\_After 07 Days  
 Vial : 6  
 Injection Volume : 10  
 Data Filename : 270119-06.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 17:31:14

### Chromatogram

Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v D:\...\Prednisolone Acetate Ophthalmic Suspension\270119\270119-06.lcd



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-06.lcd

Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical Plate	Retention	Resolution
1	RT5.741	5.724	7994	511	0.02	3234	0.320	0.00
2	Prednisolone	6.753	271807	31799	0.79	13408	0.377	3.23
3	RT8.785	8.778	4905	446	0.01	14677	0.490	7.74
4	RT10.150	10.130	10540	717	0.03	9889	0.566	3.88
5	RT11.044	11.045	5338	257	0.02	5556	0.617	1.83
6	RT11.760	11.742	18272	1125	0.05	13805	0.656	1.41
7	RT12.644	12.622	10442	595	0.03	11789	0.705	2.03
8	RT15.371	15.383	73317	3956	0.21	15748	0.859	5.78
9	Prednisolone Acetate	17.909	33605056	1552826	98.04	16001	1.000	4.78
10	Hydrocortisone A	19.614	252062	10204	0.74	15624	1.095	2.86
11	RT21.952	21.999	15767	593	0.05	15315	1.228	3.56
Total			34275500	1603030	100.00			

*Sunil Patel*  
28/01/19

Analysed By: Sunil Patel.

1 / 1

Checked By:

*28/01/19*

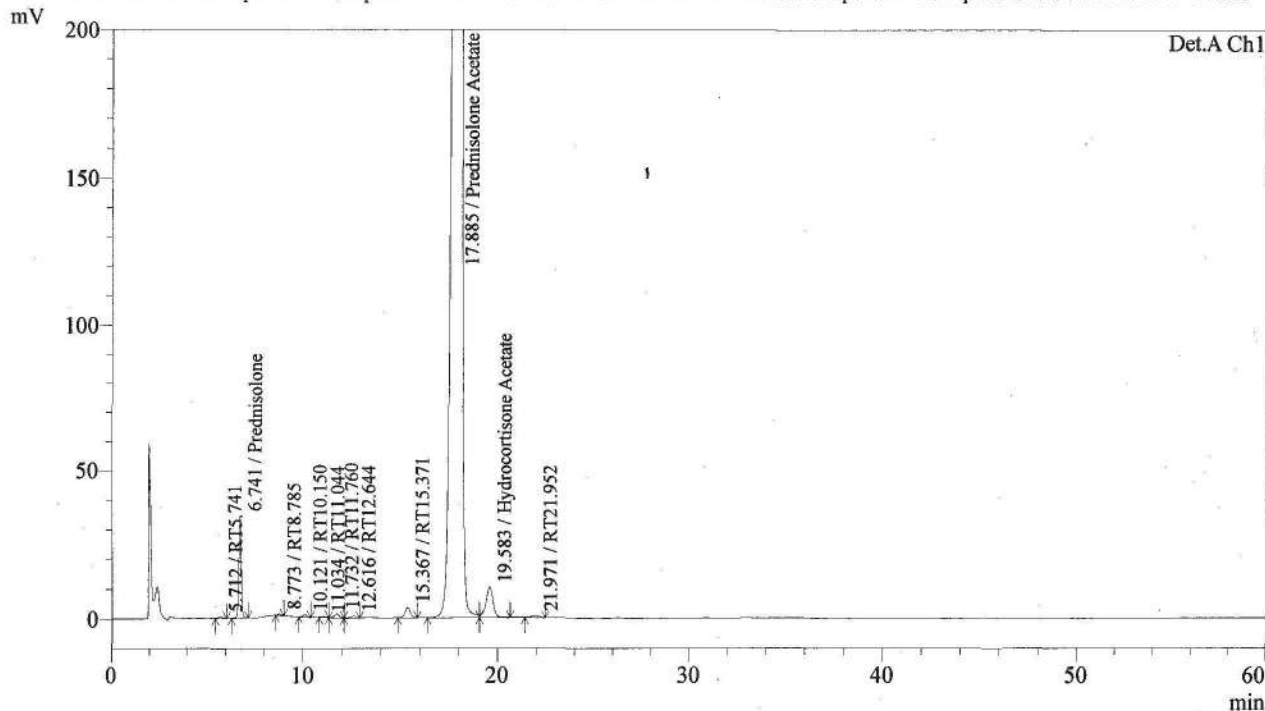


### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-07.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v  
 Sample ID : # JW8001\_Sam.Sol.  
 Description : RS\_After 14 Days  
 Vial : 7  
 Injection Volume : 10  
 Data Filename : 270119-07.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 18:31:52

### Chromatogram

Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v D:\...\Prednisolone Acetate Ophthalmic Suspension\270119\270119-07.lcd



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-07.lcd

Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical	Platcive Retention	Resolution
1	RT5.741	5.712	8179	534	0.02	3344	0.319	0.00
2	Prednisolone	6.741	292764	34211	0.86	13317	0.377	3.27
3	RT8.785	8.773	5260	505	0.02	14957	0.491	7.81
4	RT10.150	10.121	9849	700	0.03	10879	0.566	3.99
5	RT11.044	11.034	5195	267	0.02	6206	0.617	1.92
6	RT11.760	11.732	22008	1411	0.06	14371	0.656	1.47
7	RT12.644	12.616	10437	595	0.03	11905	0.705	2.07
8	RT15.371	15.367	62697	3408	0.18	15923	0.859	5.79
9	Prednisolone Acetate	17.885	33377775	1546153	97.99	16037	1.000	4.79
10	Hydrocortisone A	19.583	251254	10170	0.74	15616	1.095	2.85
11	RT21.952	21.971	15529	593	0.05	15815	1.228	3.60
Total			34060948	1598547	100.00			

*Sunil Patel*  
28/01/19

Analysed By: Sunil Patel.

1 / 1

Checked By:

*Sunil Patel*  
28/01/19



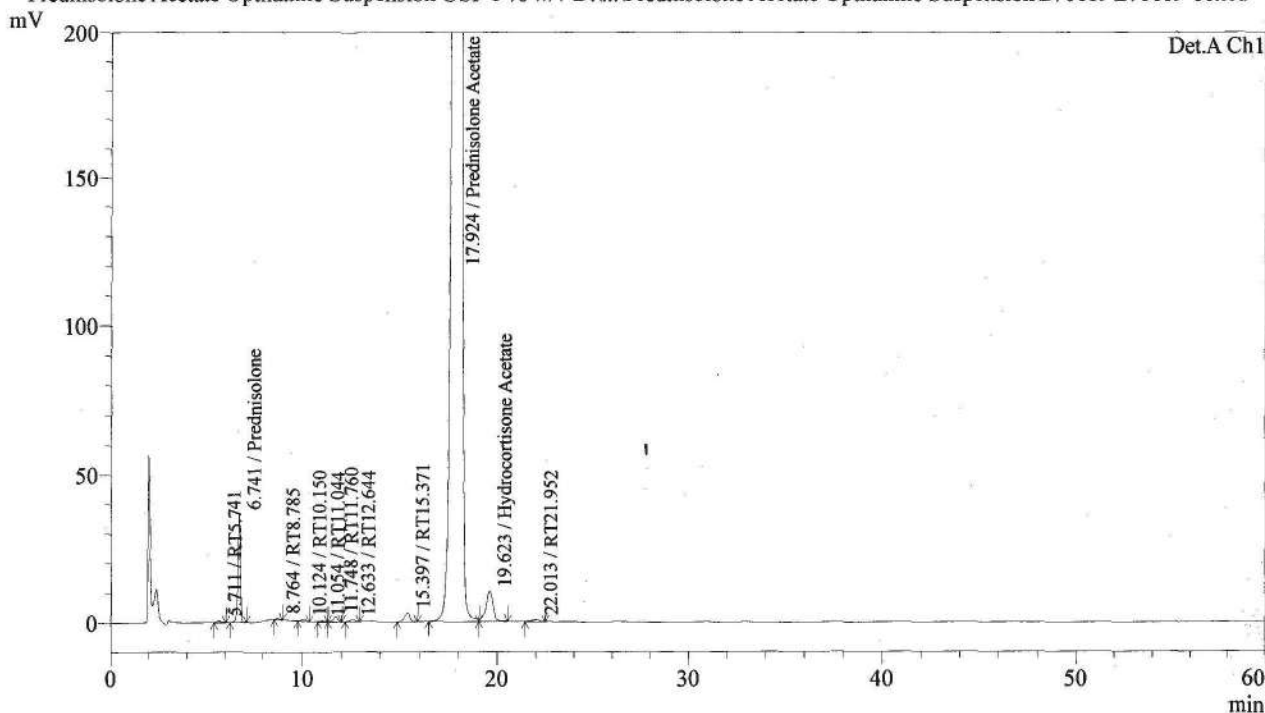
### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-08.lcd

Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v  
 Sample ID : # JW8001\_Sam.Sol.  
 Description : RS\_After 21 Days  
 Vial : 8  
 Injection Volume : 10  
 Data Filename : 270119-08.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 19:32:32

### Chromatogram

Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v D:\...\Prednisolone Acetate Ophthalmic Suspension\270119\270119-08.lcd



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-08.lcd

Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical Plat	ive Retention	Resolution
1	RT5.741	5.711	8490	549	0.02	3402	0.319	0.00
2	Prednisolone	6.741	313617	36693	0.92	13322	0.376	3.29
3	RT8.785	8.764	5017	523	0.01	17513	0.489	8.12
4	RT10.150	10.124	10150	715	0.03	10626	0.565	4.14
5	RT11.044	11.054	6085	293	0.02	5265	0.617	1.86
6	RT11.760	11.748	26501	1703	0.08	14281	0.655	1.38
7	RT12.644	12.633	10682	608	0.03	11789	0.705	2.06
8	RT15.371	15.397	55437	2997	0.16	15786	0.859	5.78
9	Prednisolone Ace	17.924	33466423	1550011	97.95	16094	1.000	4.79
10	Hydrocortisone A	19.623	250166	10174	0.73	15763	1.095	2.85
11	RT21.952	22.013	15242	587	0.04	16151	1.228	3.63
Total			34167811	1604854	100.00			

# OPES HEALTHCARE PVT. LTD.

## Analytical Development Laboratory

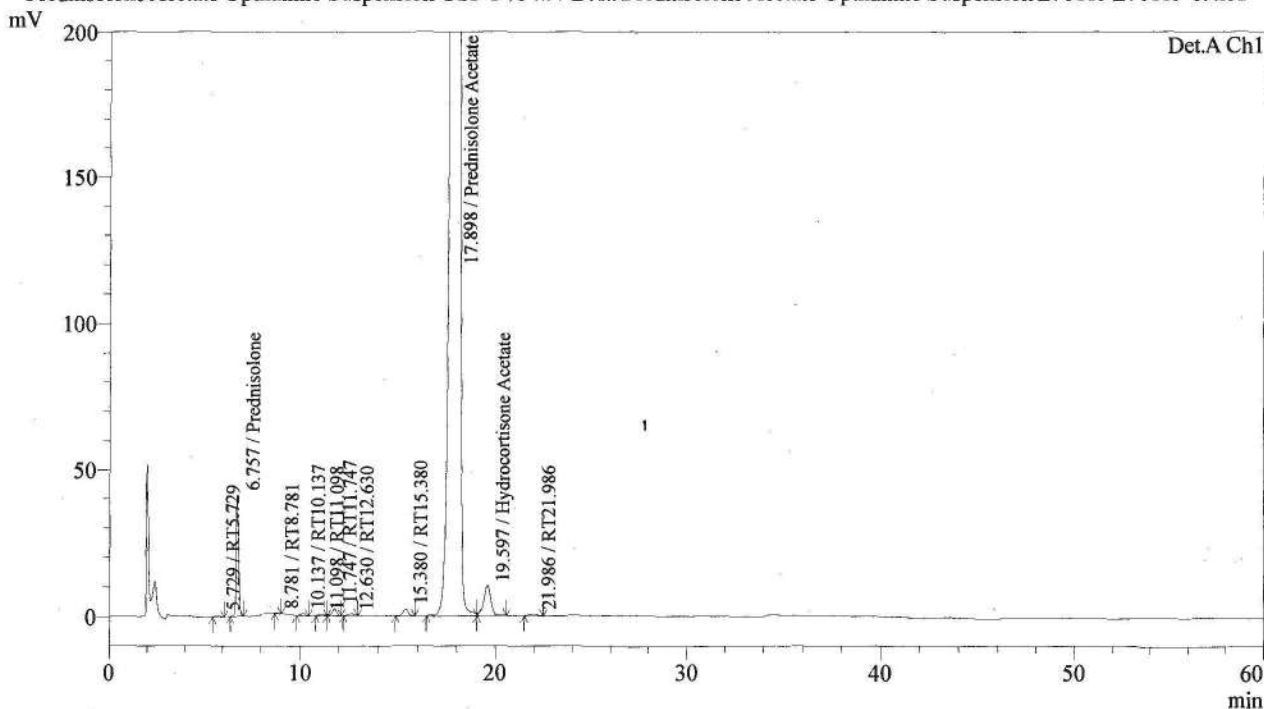
### Sample Information

Sample Information D:\...\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-09.lcd

Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v  
 Sample ID : # JW8001\_Sam.Sol.  
 Description : RS\_After 28 Days  
 Vial : 9  
 Injection Volume : 10  
 Data Filename : 270119-09.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension\_RS.lcm  
 Batch Filename : 270119.lcb  
 Date Acquired : 27/01/19 20:33:10

### Chromatogram

Prednisolone Acetate Ophthalmic Suspension USP 1 % w/v D:\...\Prednisolone Acetate Ophthalmic Suspension\270119\270119-09.lcd



1 Det.A Ch1 / 254nm

PeakTable D:\LPL2\_AL\_HPL\_008\Data\2019\January\Prednisolone Acetate Ophthalmic Suspension\270119\270119-09.lcd  
 Detector A Ch1 254nm

Peak#	Name	Ret. Time	Area	Height	Area %	theoretical	Platative Retention	Resolution
1	RT5.729	5.729	8809	578	0.03	3535	0.320	0.00
2	Prednisolone	6.757	353828	41201	1.04	13339	0.378	3.32
3	RT8.781	8.781	2082	256	0.01	22990	0.491	8.69
4	RT10.137	10.137	9832	709	0.03	11492	0.566	4.45
5	RT11.098	11.098	7109	316	0.02	4743	0.620	1.88
6	RT11.747	11.747	34559	2284	0.10	14774	0.656	1.26
7	RT12.630	12.630	9541	581	0.03	13097	0.706	2.13
8	RT15.380	15.380	41844	2275	0.12	15934	0.859	5.92
9	Prednisolone Acetate	17.898	33429865	1547823	97.85	16009	1.000	4.78
10	Hydrocortisone A	19.597	251241	10176	0.74	15638	1.095	2.85
11	RT21.986	21.986	14549	581	0.04	16802	1.228	3.66
Total			34163260	1606780	100.00			

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**OPES HEALTHCARE PVT. LTD.**  
**ANALYTICAL DEVELOPMENT LABORATORY**

Product Name:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v
Batch No:	# JW8001
Assay	Benzalkonium Chloride

Potency(%)	51.40
Claim (gm)	0.006
Per (ml)	100

Factor	1
	1

Standard			
SR NO	Area of C12	Area of C14	Total Area
1	95001	27864	122865
2	96001	27464	123465
3	96444	27762	124206
4	95751	27272	123023
5	95477	28295	123772
AVG	95735	27731	123466
SD	542.9	393.3	547.4
RSD	0.57	1.42	0.44

Sample			
SR NO	Area of C12	Area of C14	Total Area
Initial	113033	32899	145932
Initial	112861	33712	146573
After 7 Day	112819	33448	146267
After 7Day	112871	32910	145781
After 14 Day	111411	31351	142762
After 14 Day	111980	31242	143222
After 21 Day	115794	27121	142915
After 21 Day	115538	27042	142580
After 28 Day	109467	30024	139491
After 28 Day	109507	30528	140035

STD	20.26	→	100	→	10	→	100	→	1
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SAMPLE	5	→	25	→	1	→	1	→	1
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Sr. No.	Sample Detail	Sample (ml)	Sample Mean Area	Assay %
1	Initial	5.0	146253	102.8
2	After 7 Days	5.0	146024	102.6
3	After 14 Days	5.0	142992	100.5
4	After 21 Days	5.0	142748	100.3
5	After 28 Days	5.0	139763	98.2

Analysed by:

*[Signature]*  
30/10/19

Checked by:

*[Signature]*  
30/10/19

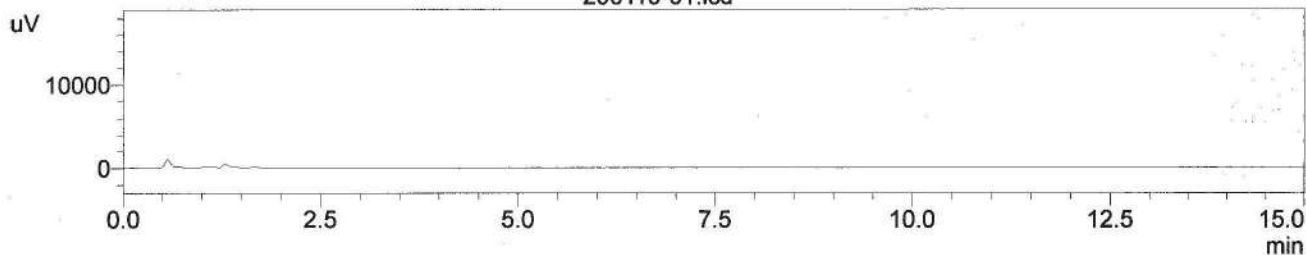


## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-01.lcd  
Acquired by : Sunil Patel.  
Sample Name : Blank  
Sample ID : Mobile Phase  
Vial# : 1  
Description : Assay  
Injection Volume : 20 uL  
Data Filename : 290119-01.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
Batch Filename : 290119.lcb  
Date Acquired : 29/01/19 14:39:10

## Chromatogram

Summary(Compound)  
290119-01.lcd



Analysed By : Sunil Patel.

Checked By :

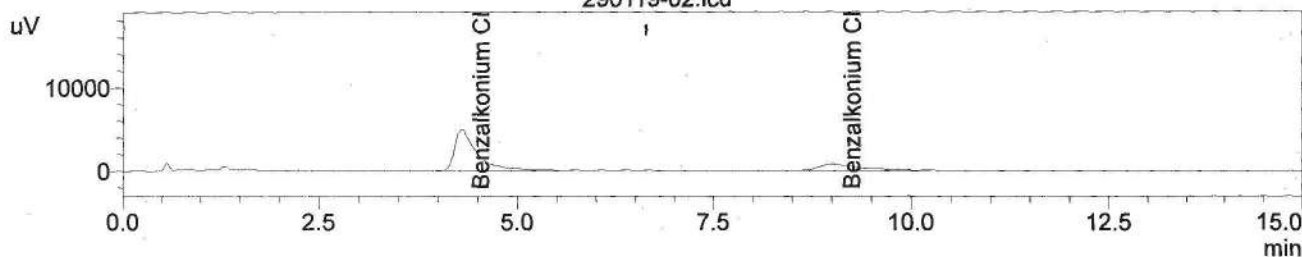
30/01/19

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Analytical Development Laboratory

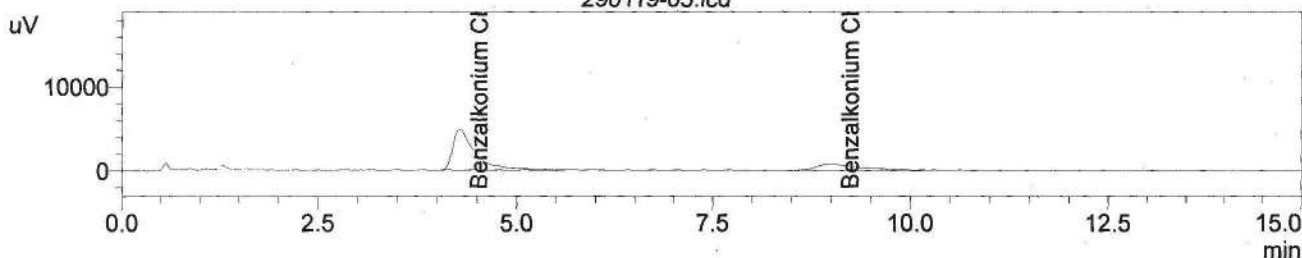
## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-02.lcd  
Acquired by : Sunil Patel.  
Sample Name : Benzalkonium Chloride  
Sample ID : Standard Solution  
Vial# : 2  
Description : Assay  
Injection Volume : 20 uL  
Data Filename : 290119-02.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
Batch Filename : 290119.lcb  
Date Acquired : 29/01/19 14:54:48

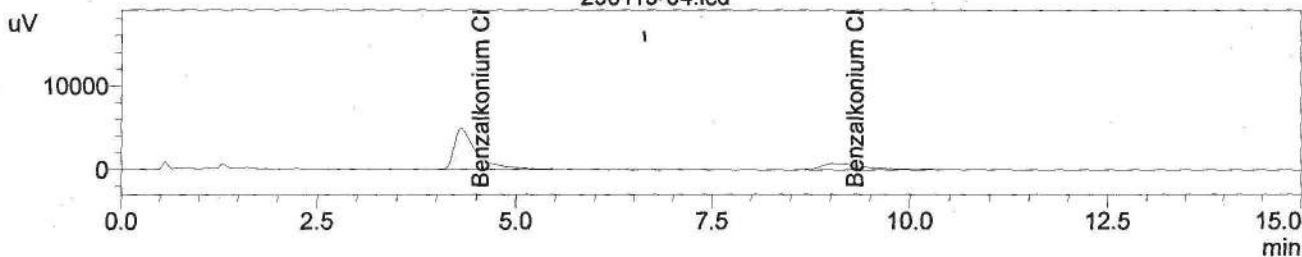
## Chromatogram

Summary(Compound)  
290119-02.lcd

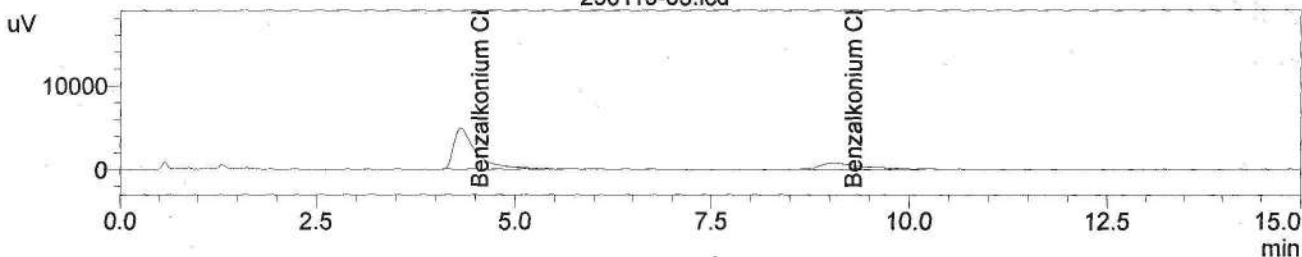
290119-03.lcd



290119-04.lcd



290119-05.lcd

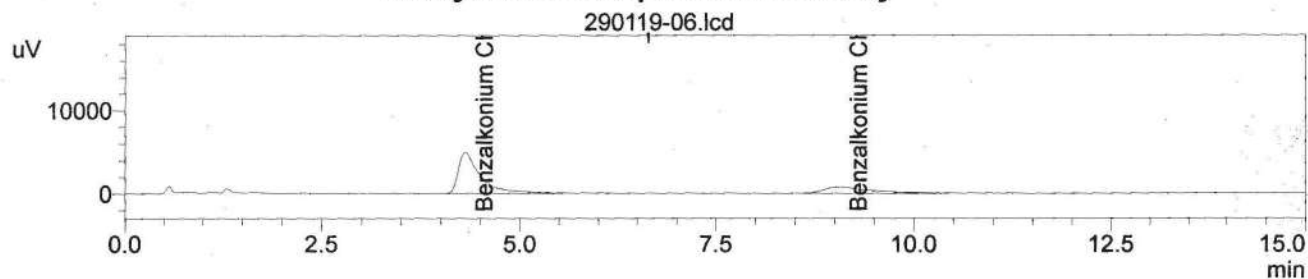


Analysed By : Sunil Patel.

Checked By :

30/01/19

**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-02.lcd	Standard Solution	4.292	95001	4947	2.43	1533	0.000
290119-03.lcd	Standard Solution	4.281	96001	4937	2.49	1503	0.000
290119-04.lcd	Standard Solution	4.308	96444	4928	2.45	1486	0.000
290119-05.lcd	Standard Solution	4.309	95751	4899	2.46	1479	0.000
290119-06.lcd	Standard Solution	4.307	95477	4891	2.45	1464	0.000
Average		4.299	95735	4920	2.46	1493	0.000
%RSD		0.289	0.567	0.494	0.892	1.768	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-02.lcd	Standard Solution	9.011	27864	762	1.85	1648	7.116
290119-03.lcd	Standard Solution	8.998	27464	756	1.81	1640	7.090
290119-04.lcd	Standard Solution	9.069	27762	754	1.82	1688	7.161
290119-05.lcd	Standard Solution	9.056	27272	751	1.73	1708	7.168
290119-06.lcd	Standard Solution	9.059	28295	749	1.91	1530	6.903
Average		9.039	27731	754	1.82	1643	7.088
%RSD		0.352	1.418	0.667	3.587	4.201	1.525

Analysed By : Sunil Patel.

Checked By :

*[Signature]*  
 30/01/19

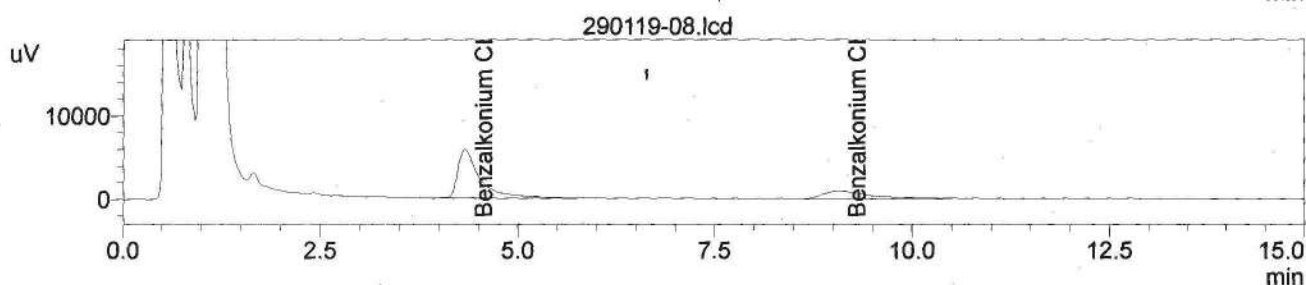
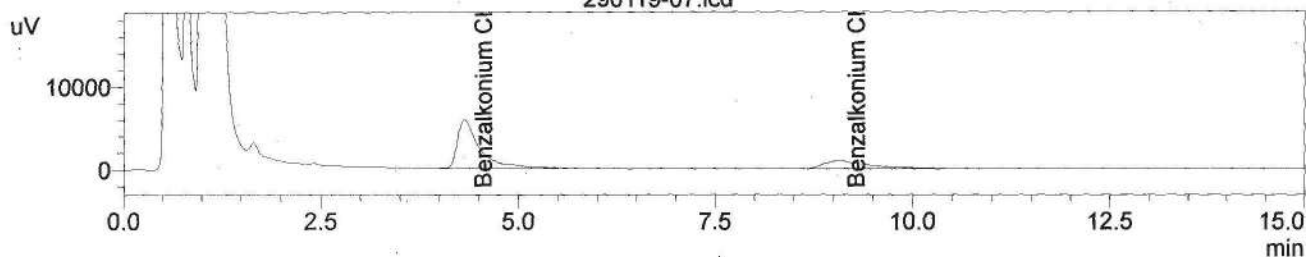


## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-07.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 3  
 Description : Assay\_Initial  
 Injection Volume : 20 uL  
 Data Filename : 290119-07.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
 Batch Filename : 290119.lcb  
 Date Acquired : 29/01/19 16:13:03

## Chromatogram

Summary(Compound)  
 290119-07.lcd



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-07.lcd	# JW8001	4.308	113033	5839	2.59	1558	0.000
290119-08.lcd	# JW8001	4.322	112861	5824	2.59	1556	0.000
Average		4.315	112947	5832	2.59	1557	0.000
%RSD		0.229	0.108	0.182	0.000	0.091	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-07.lcd	# JW8001	9.044	32899	896	1.95	1475	6.872
290119-08.lcd	# JW8001	9.061	33712	897	1.94	1607	7.060
Average		9.053	33306	897	1.94	1541	6.966
%RSD		0.133	1.726	0.079	0.364	6.057	1.908

Analysed By : Sunil Patel.

Checked By :

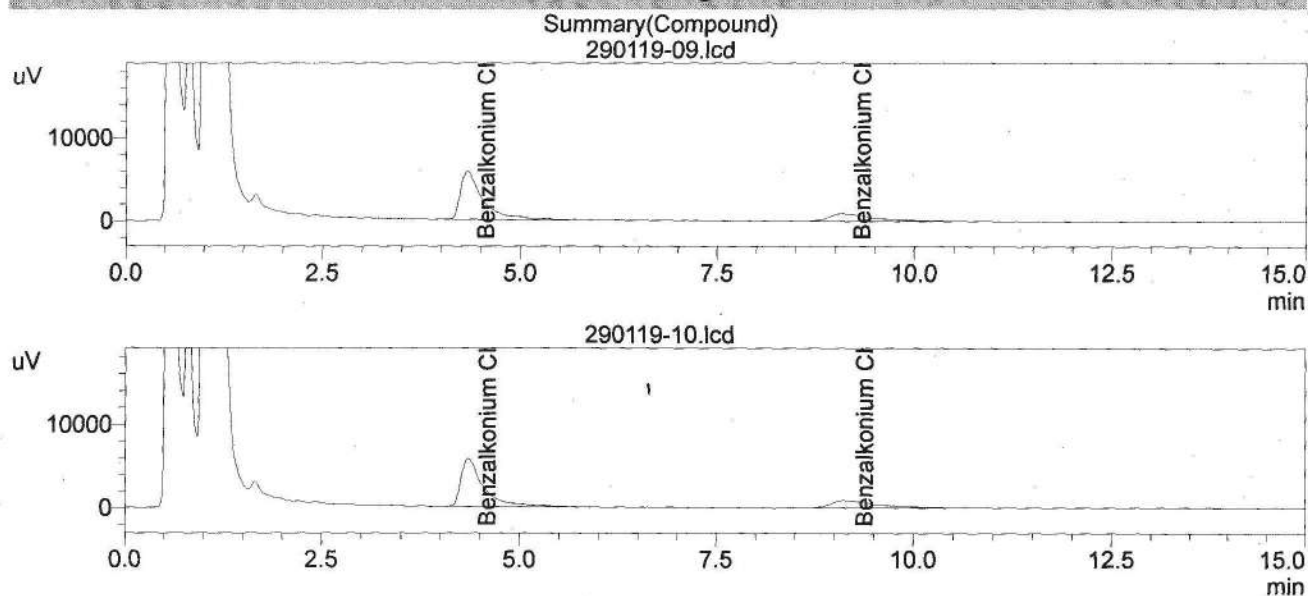
30/01/19

**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**

**Sample Information**

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-09.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 4  
 Description : Assay\_After 07 Days  
 Injection Volume : 20 uL  
 Data Filename : 290119-09.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
 Batch Filename : 290119.lcb  
 Date Acquired : 29/01/19 16:44:21

**Chromatogram**



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-09.lcd	# JW8001	4.323	112819	5799	2.57	1554	0.000
290119-10.lcd	# JW8001	4.350	112871	5770	2.55	1544	0.000
Average		4.337	112845	5785	2.56	1549	0.000
%RSD		0.440	0.033	0.355	0.552	0.456	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-09.lcd	# JW8001	9.098	33448	889	2.04	1424	6.806
290119-10.lcd	# JW8001	9.142	32910	889	1.87	1652	7.140
Average		9.120	33179	889	1.96	1538	6.973
%RSD		0.341	1.147	0.000	6.149	10.482	3.387

Analysed By : Sunil Patel.

Checked By :

*[Signature]*  
30/01/19



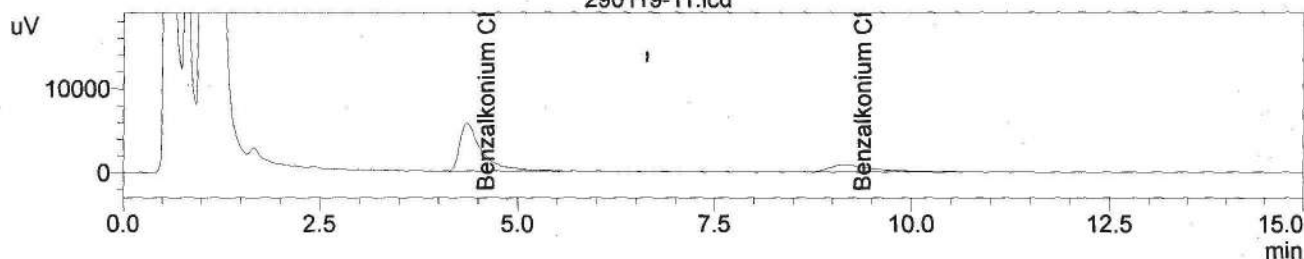
**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**

**Sample Information**

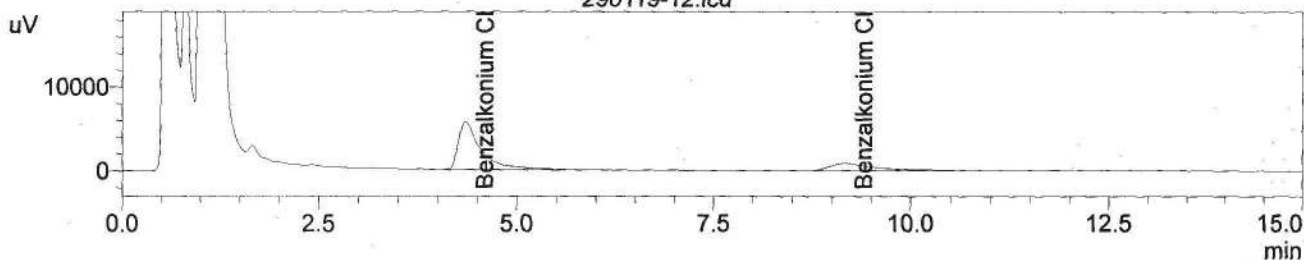
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 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 5  
 Description : Assay\_After 14 Days  
 Injection Volume : 20 uL  
 Data Filename : 290119-11.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
 Batch Filename : 290119.lcb  
 Date Acquired : 29/01/19 17:15:41

**Chromatogram**

Summary(Compound)  
 290119-11.lcd



290119-12.lcd



<< Detector A >>

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-11.lcd	# JW8001	4.354	111411	5704	2.51	1539	0.000
290119-12.lcd	# JW8001	4.352	111980	5681	2.51	1512	0.000
Average		4.353	111696	5693	2.51	1526	0.000
%RSD		0.032	0.360	0.286	0.000	1.252	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-11.lcd	# JW8001	9.138	31351	834	1.99	1486	6.873
290119-12.lcd	# JW8001	9.166	31242	832	1.92	1560	6.997
Average		9.152	31297	833	1.96	1523	6.935
%RSD		0.216	0.246	0.170	2.532	3.436	1.264

Analysed By : Sunil Patel.

Checked By :

30/01/19

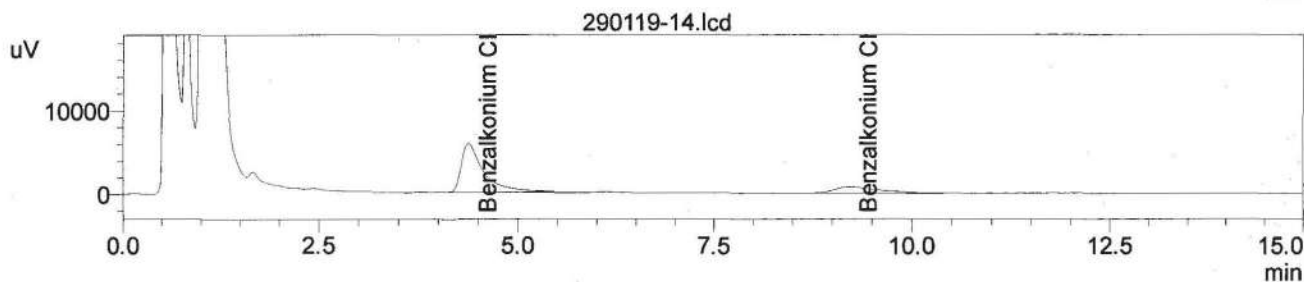
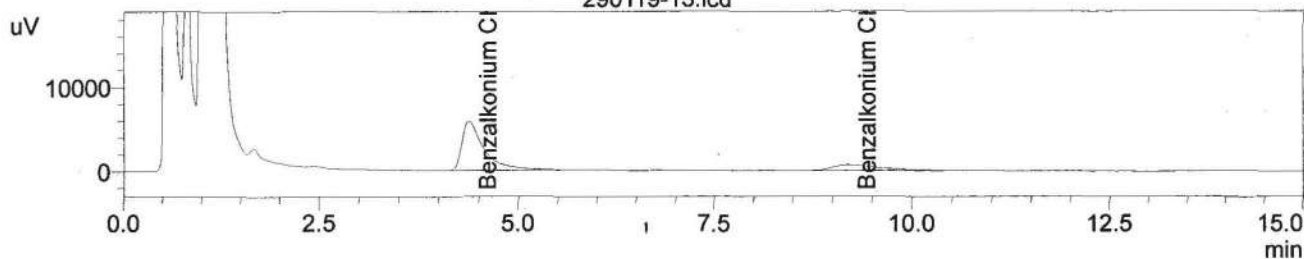


## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-13.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 6  
 Description : Assay\_After 21 Days  
 Injection Volume : 20 uL  
 Data Filename : 290119-13.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
 Batch Filename : 290119.lcb  
 Date Acquired : 29/01/19 17:46:59

## Chromatogram

Summary(Compound)  
290119-13.lcd



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-13.lcd	# JW8001	4.375	115794	5847	2.46	1496	0.000
290119-14.lcd	# JW8001	4.378	115538	5820	2.44	1485	0.000
Average		4.377	115666	5834	2.45	1491	0.000
%RSD		0.048	0.157	0.327	0.577	0.522	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-13.lcd	# JW8001	9.194	27121	729	1.83	1535	6.929
290119-14.lcd	# JW8001	9.213	27042	729	1.79	1505	6.886
Average		9.204	27082	729	1.81	1520	6.908
%RSD		0.146	0.206	0.000	1.563	1.396	0.440

*Sunil Patel*  
30/01/19

Analysed By : Sunil Patel.

Checked By :

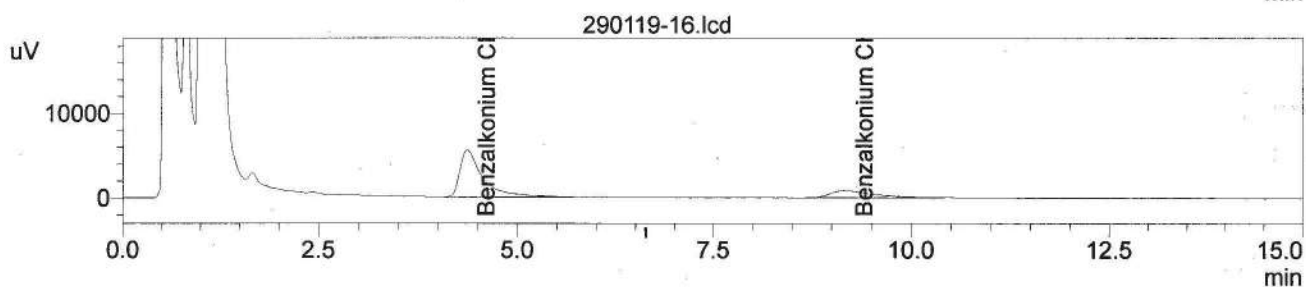
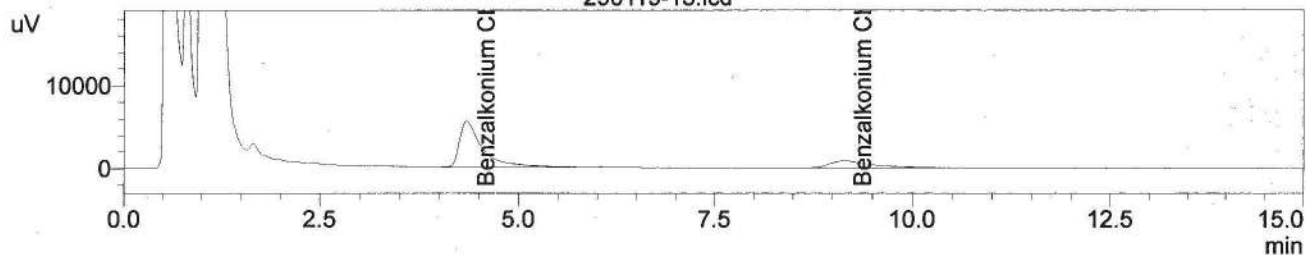
*Sunil Patel*  
30/01/19

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-15.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 7  
 Description : Assay\_After 28 Days  
 Injection Volume : 20 uL  
 Data Filename : 290119-15.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
 Batch Filename : 290119.lcb  
 Date Acquired : 29/01/19 18:18:17

## Chromatogram

Summary(Compound)  
290119-15.lcd



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-15.lcd	# JW8001	4.345	109467	5549	2.54	1515	0.000
290119-16.lcd	# JW8001	4.363	109507	5533	2.51	1508	0.000
Average		4.354	109487	5541	2.52	1512	0.000
%RSD		0.292	0.026	0.204	0.840	0.327	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-15.lcd	# JW8001	9.134	30024	823	1.82	1543	6.958
290119-16.lcd	# JW8001	9.164	30528	828	1.83	1561	6.973
Average		9.149	30276	826	1.83	1552	6.966
%RSD		0.232	1.177	0.428	0.387	0.820	0.152

Analysed By : Sunil Patel.

Checked By :

30/01/19

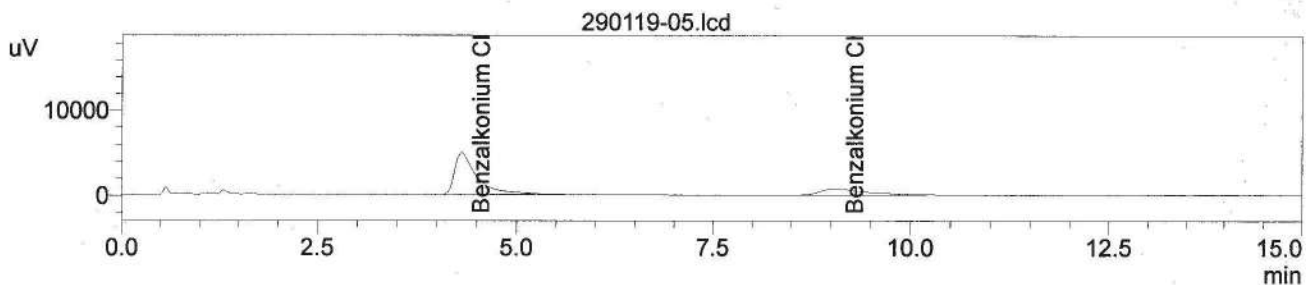
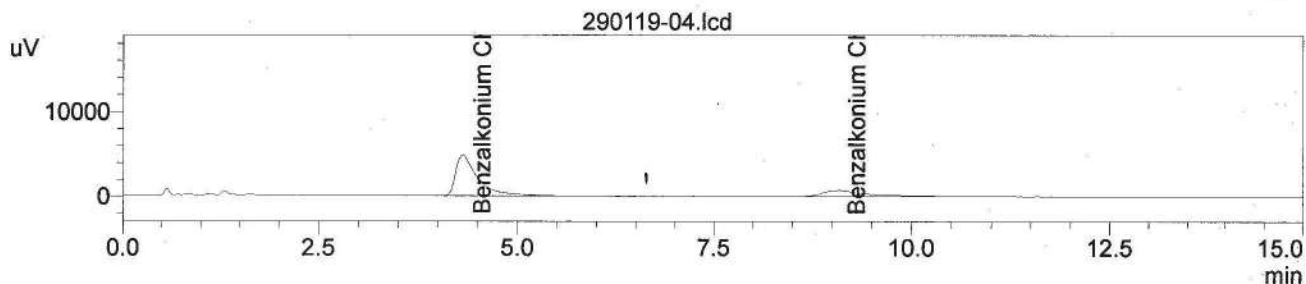
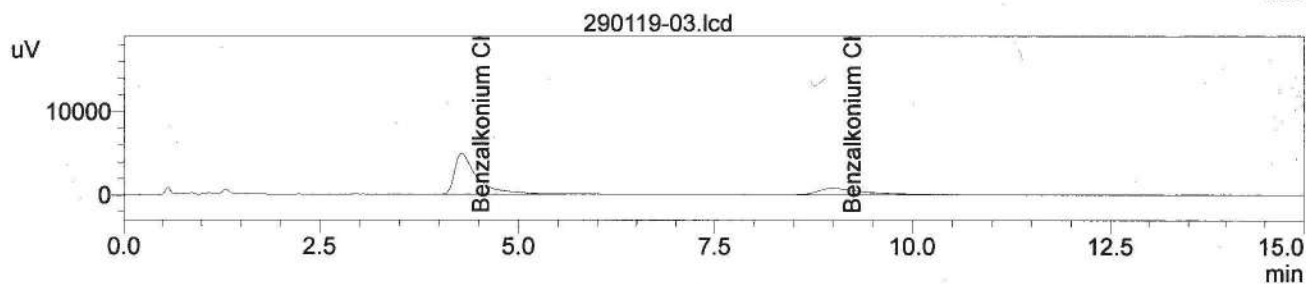
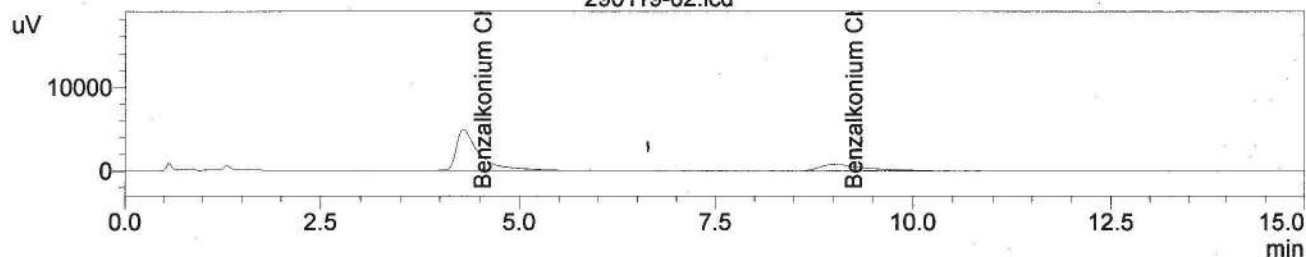


## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\290119\290119-02.lcd  
Acquired by : Sunil Patel.  
Sample Name : Benzalkonium Chloride  
Sample ID : Standard Solution  
Vial# : 2  
Description : Assay  
Injection Volume : 20 uL  
Data Filename : 290119-02.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay\_BKC.lcm  
Batch Filename : 290119.lcb  
Date Acquired : 29/01/19 14:54:48

## Chromatogram

Summary(Compound)  
290119-02.lcd



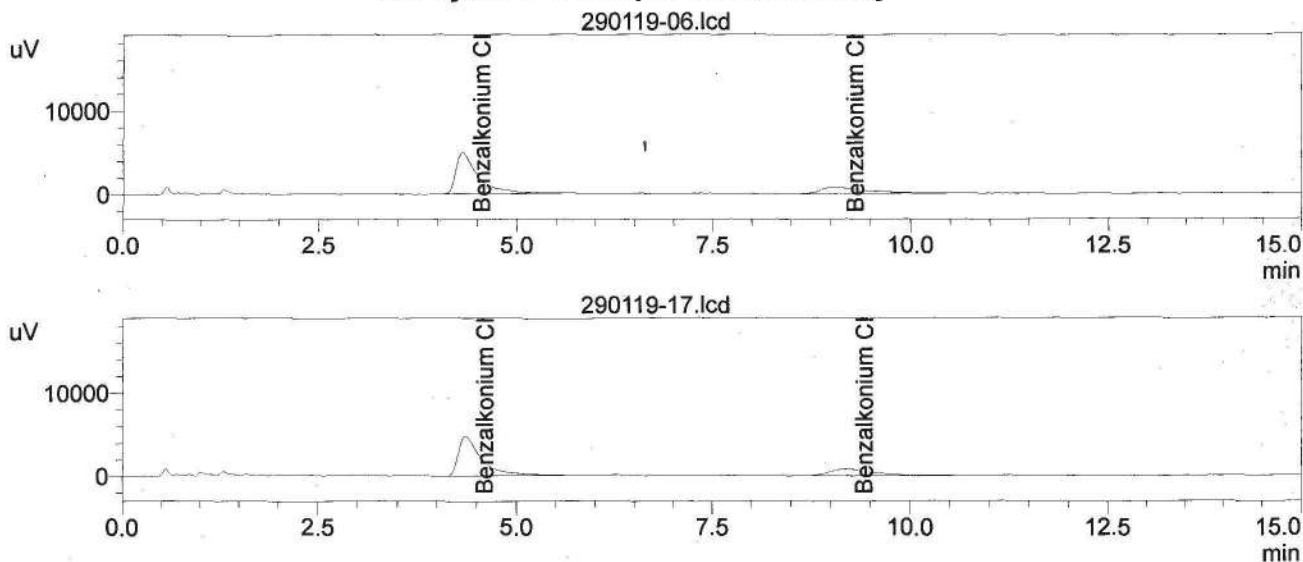
Analysed By : Sunil Patel.

Checked By :

30/01/19



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&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Benzalkonium Chloride C12

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-02.lcd	Standard Solution	4.292	95001	4947	2.43	1533	0.000
290119-03.lcd	Standard Solution	4.281	96001	4937	2.49	1503	0.000
290119-04.lcd	Standard Solution	4.308	98444	4928	2.45	1486	0.000
290119-05.lcd	Standard Solution	4.309	95751	4899	2.46	1479	0.000
290119-06.lcd	Standard Solution	4.307	95477	4891	2.45	1464	0.000
290119-17.lcd	BKT Standard Solution	4.357	96061	4758	2.43	1338	0.000
Average		4.309	95789	4893	2.45	1467	0.000
%RSD		0.604	0.526	1.426	0.909	4.603	0.000

ID#2 Compound Name: Benzalkonium Chloride C14

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
290119-02.lcd	Standard Solution	9.011	27864	762	1.85	1648	7.116
290119-03.lcd	Standard Solution	8.998	27464	756	1.81	1640	7.090
290119-04.lcd	Standard Solution	9.069	27762	754	1.82	1688	7.161
290119-05.lcd	Standard Solution	9.056	27272	751	1.73	1708	7.168
290119-06.lcd	Standard Solution	9.059	28295	749	1.91	1530	6.903
290119-17.lcd	BKT Standard Solution	9.183	28217	731	1.89	1440	6.683
Average		9.063	27812	751	1.84	1609	7.020
%RSD		0.722	1.452	1.407	3.511	6.418	2.726

Analysed By : Sunil Patel.

Checked By :

30/01/19



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Product Name:	Prednisolone Acetate Ophthalmic Suspension USP1 % w/v
Batch No:	# JW 8001
Assay	Prednisolone Acetate

Potency(%)	99.69
Claim (gm)	1
Per (ml)	100

STD Area	966935
----------	--------

Factor	1
	1

STD	50.47	→	100	→	10	→	50	→	1	→	1
-----	-------	---	-----	---	----	---	----	---	---	---	---

SAMPLE	Sam	→	100	→	1	→	1	→	1	→	1
--------	-----	---	-----	---	---	---	---	---	---	---	---

Sr. No.	Sample Detail	Sample (ml)	Sample Area	Assay %
1	Initial	1.0	977501	101.7
2	After 7 Days	1.0	973625	101.3
3	After 14 Days	1.0	973266	101.3
4	After 21 Days	1.0	962587	100.2
5	After 28 Days	1.0	965369	100.5

Analysed by:

*GAnt*  
29/01/19

Checked by:

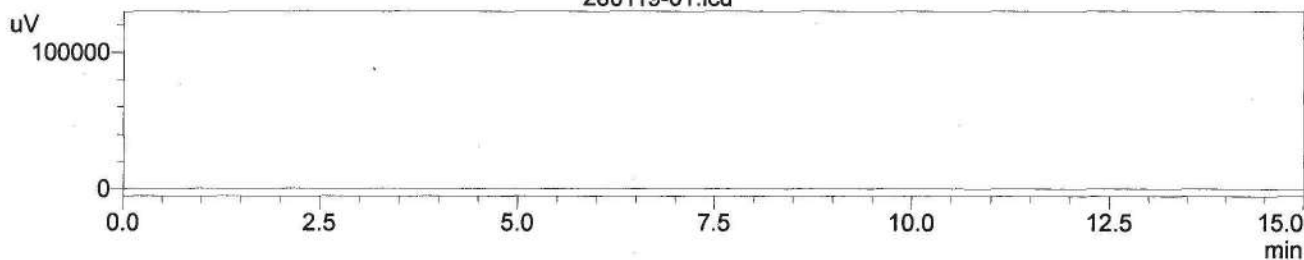
*lu*  
29/01/19

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-01.lcd  
Acquired by : Sunil Patel.  
Sample Name : Blank  
Sample ID : Diluent  
Vial# : 1  
Description : Assay  
Injection Volume : 10 uL  
Data Filename : 280119-01.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 15:52:48

## Chromatogram

Summary(Compound)  
280119-01.lcd



*Sunil Patel*  
29/01/19

Analysed By : Sunil Patel.

Checked By :

*Sunil Patel*  
29/01/19



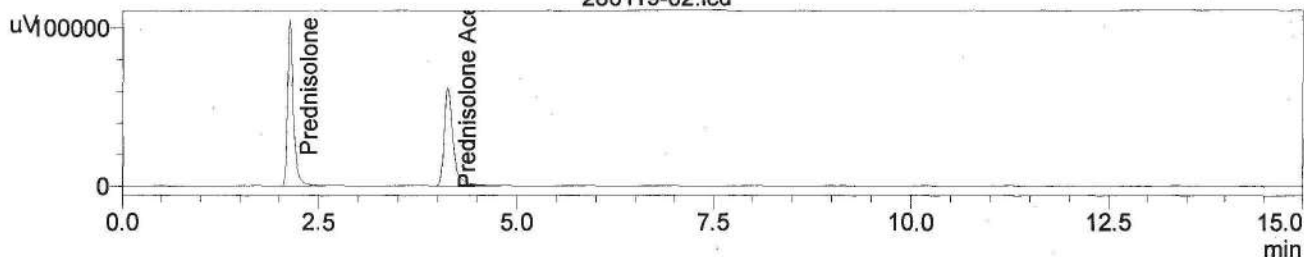
**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**

**Sample Information**

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-02.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone+Prednisolone Acetate  
 Sample ID : System Suaitability Solution  
 Vial# : 2  
 Description : Assay  
 Injection Volume : 10 uL  
 Data Filename : 280119-02.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
 Batch Filename : 280119.lcb  
 Date Acquired : 28/01/19 16:08:25

**Chromatogram**

Summary(Compound)  
 280119-02.lcd



<< Detector A >>

ID#1 Compound Name: Prednisolone

Title	Sample ID	Ret. Time	Area	Height	Failing Factor	theoretical Plate	Resolution
280119-02.lcd	ystem Suaitability Solutio	2.130	538569	104924	1.64	3546	0.000
Average		2.130	538569	104924	1.64	3546	0.000
%RSD		0.000	0.000	0.000	0.000	0.000	0.000

ID#2 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Failing Factor	theoretical Plate	Resolution
280119-02.lcd	ystem Suaitability Solutio	4.123	483569	61885	1.58	6810	11.623
Average		4.123	483569	61885	1.58	6810	11.623
%RSD		0.000	0.000	0.000	0.000	0.000	0.000

Analysed By : Sunil Patel.

Checked By :

*[Signature]*  
 29/01/19

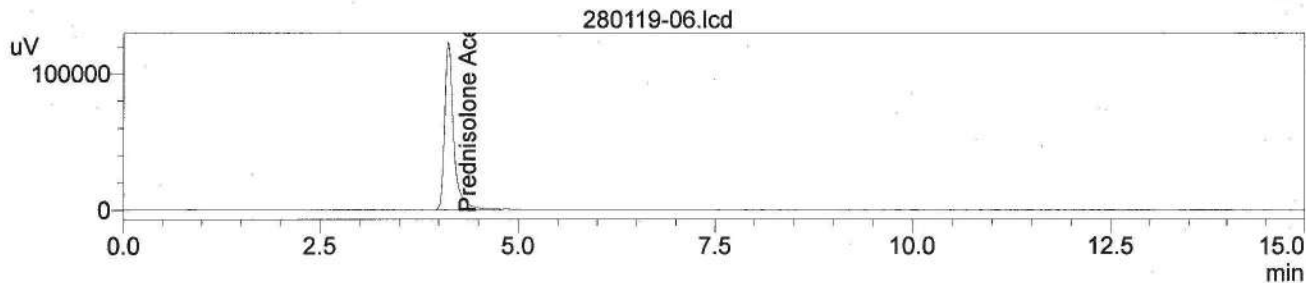
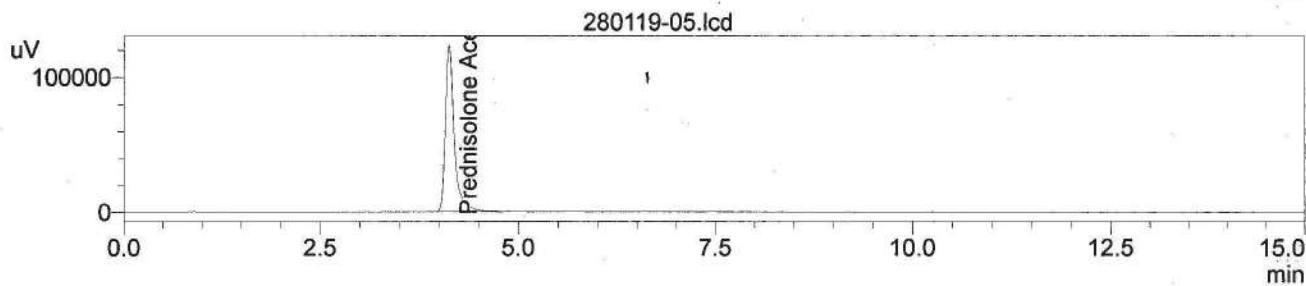
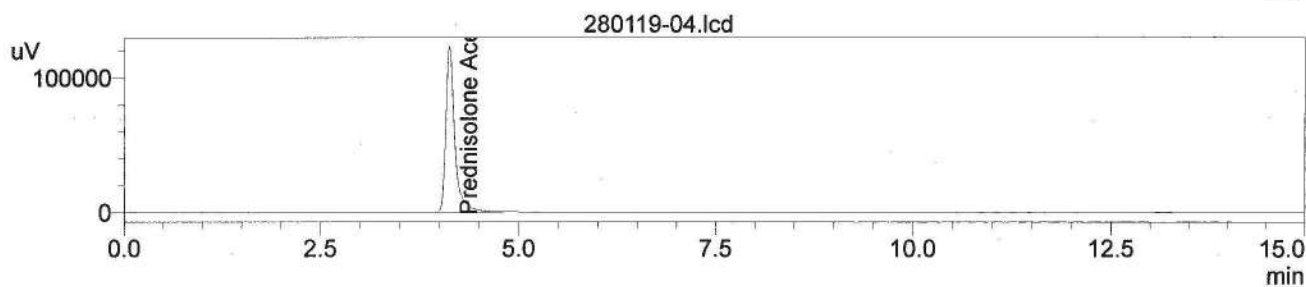
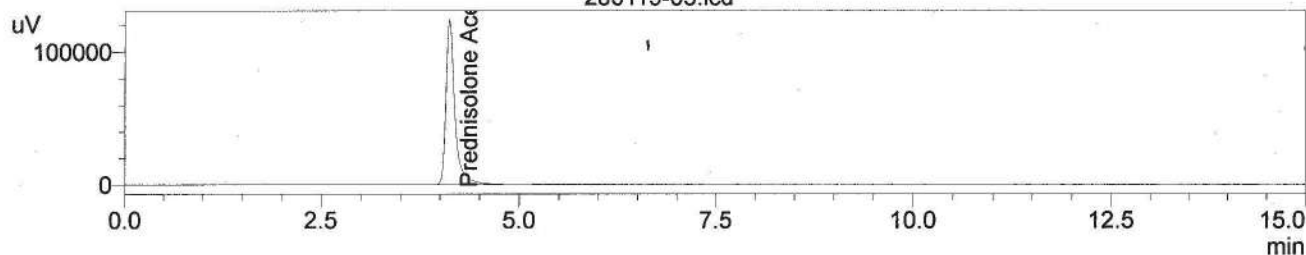
## Analytical Development Laboratory

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-03.lcd  
Acquired by : Sunil Patel.  
Sample Name : Prednisolone Acetate  
Sample ID : Standard Solution  
Vial# : 3  
Description : Assay  
Injection Volume : 10 uL  
Data Filename : 280119-03.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 16:24:03

## Chromatogram

Summary(Compound)  
280119-03.lcd

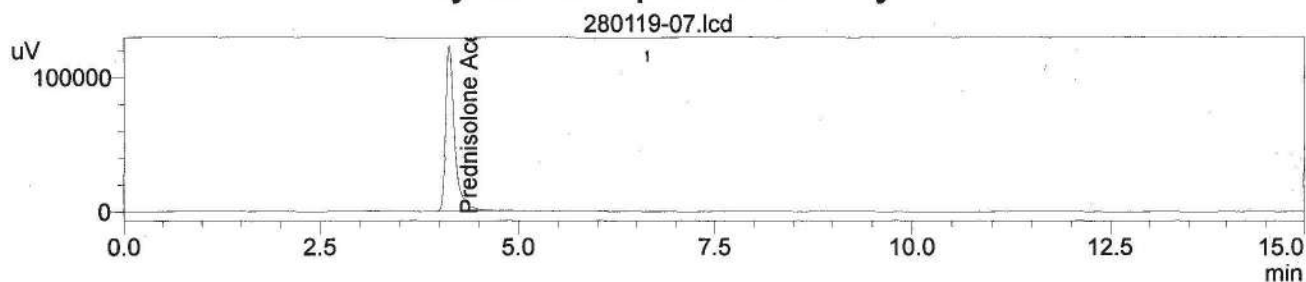


*Sunil Patel*  
28/01/19

Analysed By : Sunil Patel.

Checked By :

*Sunil Patel*  
29/01/19

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Analytical Development Laboratory

&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-03.lcd	Standard Solution	4.119	966581	123490	1.58	6736	0.000
280119-04.lcd	Standard Solution	4.123	966841	123101	1.58	6739	0.000
280119-05.lcd	Standard Solution	4.122	966824	123145	1.59	6729	0.000
280119-06.lcd	Standard Solution	4.119	967057	122999	1.58	6674	0.000
280119-07.lcd	Standard Solution	4.126	967370	122533	1.59	6663	0.000
Average		4.122	966935	123054	1.58	6708	0.000
%RSD		0.072	0.031	0.280	0.346	0.546	0.000

*Sunil Patel*  
29/11/19

Analysed By :Sunil Patel.

Checked By :

*[Signature]*  
29/11/19

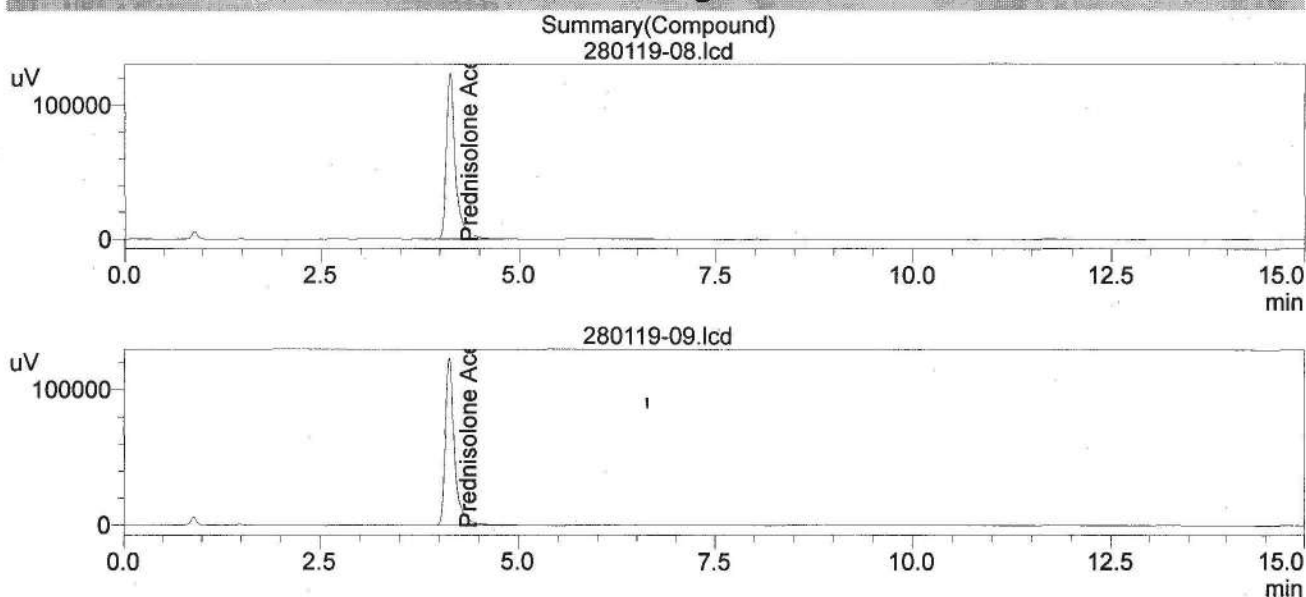


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## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-08.lcd  
Acquired by : Sunil Patel.  
Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
Sample ID : # JW8001  
Vial# : 4  
Description : Assay\_Initial  
Injection Volume : 10 uL  
Data Filename : 280119-08.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 17:42:14

## Chromatogram



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-08.lcd	# JW8001	4.128	977199	123672	1.62	6694	0.000
280119-09.lcd	# JW8001	4.126	977803	123468	1.61	6670	0.000
Average		4.127	977501	123570	1.62	6682	0.000
%RSD		0.034	0.044	0.117	0.438	0.254	0.000

Analysed By : Sunil Patel.

Checked By : 29/01/19

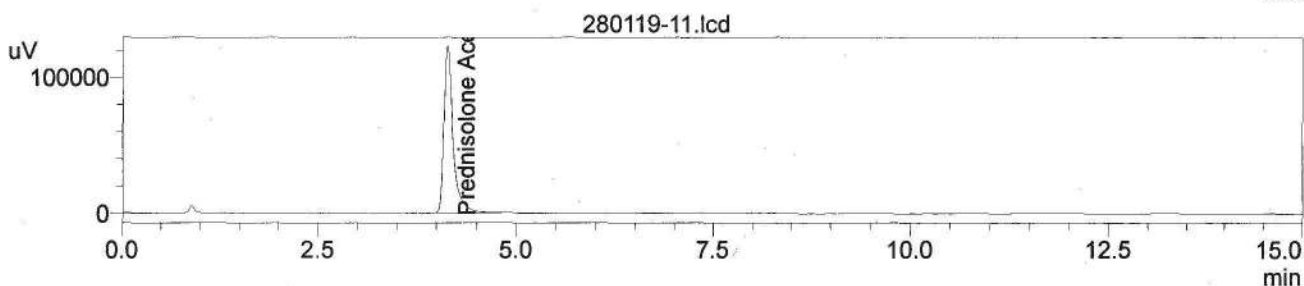
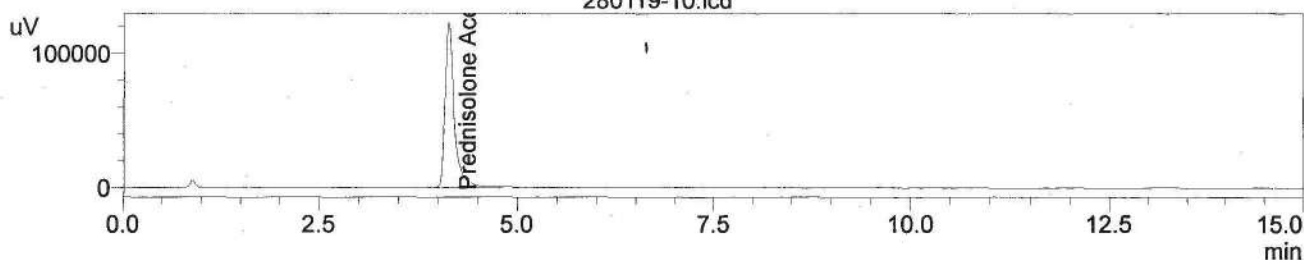
**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**

**Sample Information**

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-10.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 5  
 Description : Assay\_After 07 Days  
 Injection Volume : 10 uL  
 Data Filename : 280119-10.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
 Batch Filename : 280119.lcb  
 Date Acquired : 28/01/19 18:13:31

**Chromatogram**

Summary(Compound)  
 280119-10.lcd



<< Detector A >>

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-10.lcd	# JW8001	4.128	973201	123101	1.61	6648	0.000
280119-11.lcd	# JW8001	4.127	974049	122821	1.61	6617	0.000
Average		4.127	973625	122961	1.61	6633	0.000
%RSD		0.017	0.062	0.161	0.000	0.330	0.000

Analysed By : Sunil Patel.

Checked By :

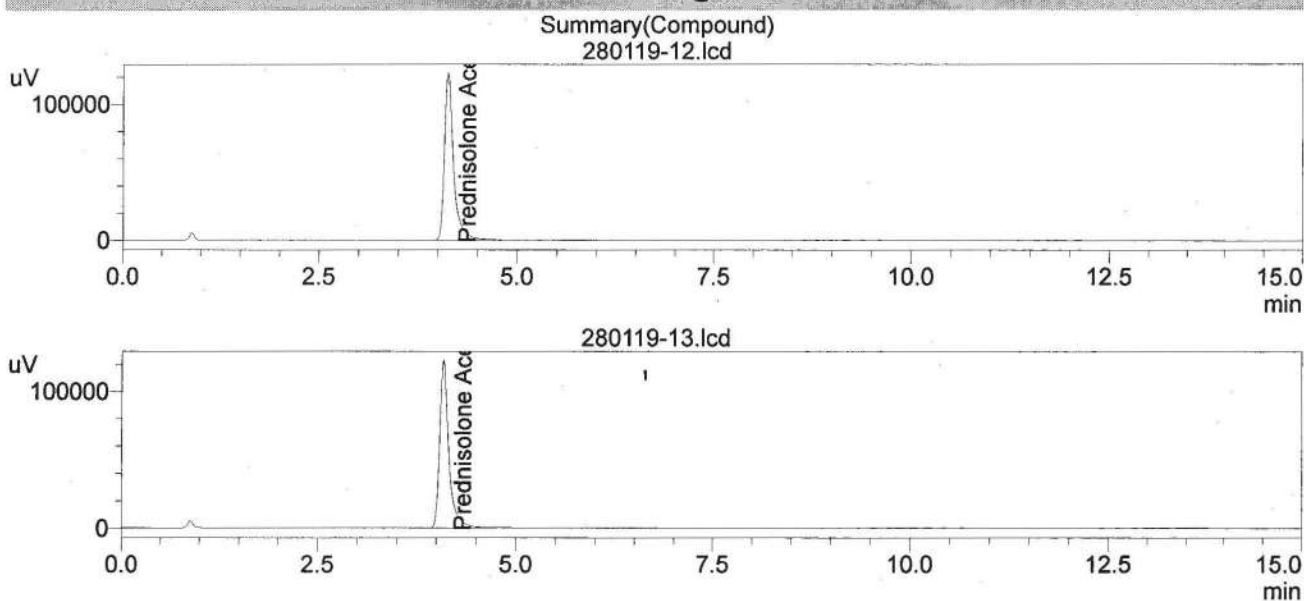
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29/01/19

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Analytical Development Laboratory

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-12.lcd  
Acquired by : Sunil Patel.  
Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
Sample ID : # JW8001  
Vial# : 6  
Description : Assay\_After 14 Days  
Injection Volume : 10 uL  
Data Filename : 280119-12.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 18:44:46

## Chromatogram



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-12.lcd	# JW8001	4.126	972792	122399	1.61	6597	0.000
280119-13.lcd	# JW8001	4.086	973739	122598	1.61	6456	0.000
Average		4.106	973266	122499	1.61	6527	0.000
%RSD		0.689	0.069	0.115	0.000	1.528	0.000

Analysed By : Sunil Patel.

Checked By :

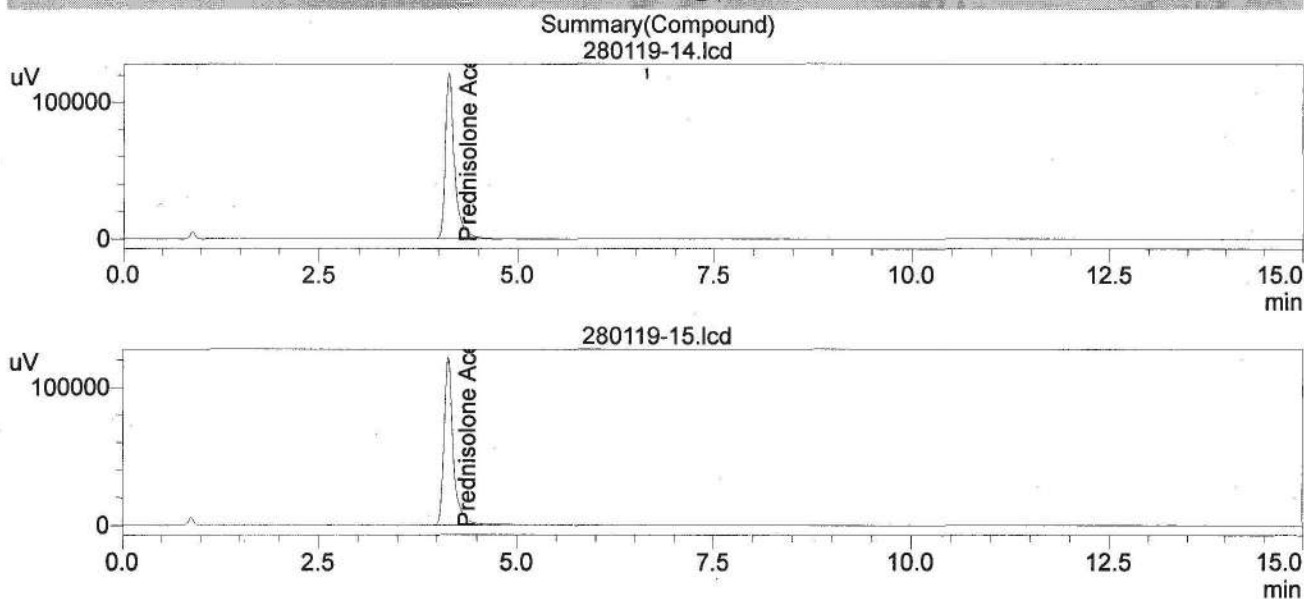
29/01/19



## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-14.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
 Sample ID : # JW8001  
 Vial# : 7  
 Description : Assay\_After 21 Days  
 Injection Volume : 10 uL  
 Data Filename : 280119-14.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
 Batch Filename : 280119.lcb  
 Date Acquired : 28/01/19 19:16:03

## Chromatogram



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-14.lcd	# JW8001	4.129	962285	121190	1.61	6614	0.000
280119-15.lcd	# JW8001	4.128	962889	121131	1.61	6575	0.000
Average		4.128	962587	121161	1.61	6595	0.000
%RSD		0.017	0.044	0.034	0.000	0.418	0.000

*Sunil Patel*  
29/01/19

Analysed By : Sunil Patel.

Checked By :

*Sunil Patel*  
29/01/19

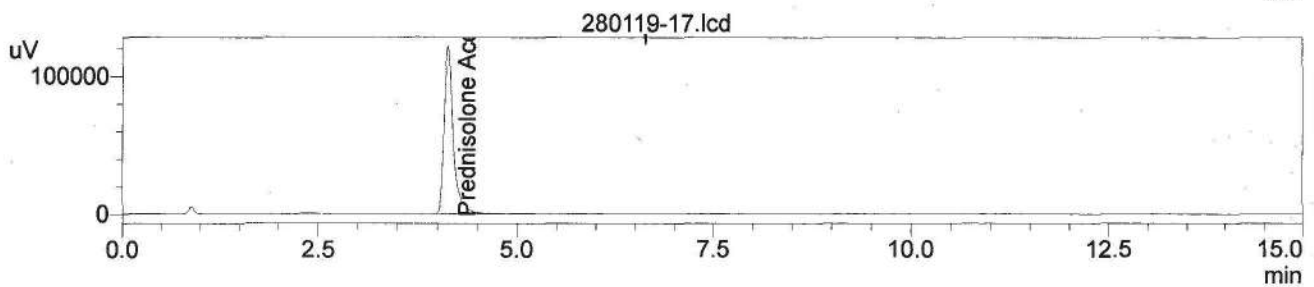
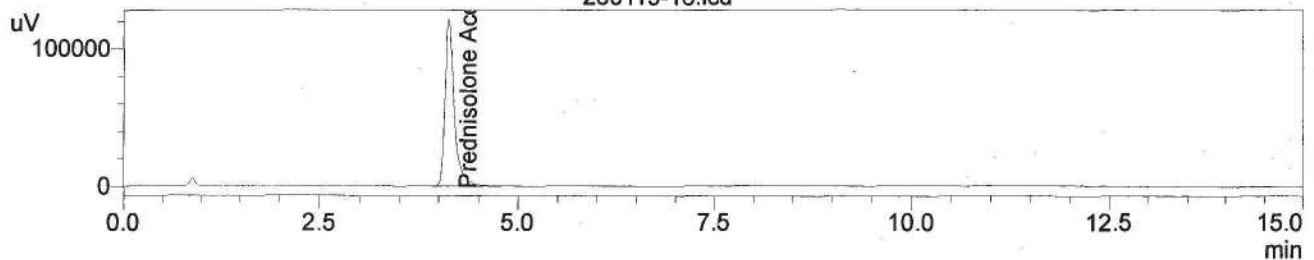
## Analytical Development Laboratory

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-16.lcd  
Acquired by : Sunil Patel.  
Sample Name : Prednisolone Acetate Ophthalmic Suspension USP 1% w/v  
Sample ID : # JW8001  
Vial# : 8  
Description : Assay\_After 28 Days  
Injection Volume : 10 uL  
Data Filename : 280119-16.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 19:47:20

## Chromatogram

Summary(Compound)  
280119-16.lcd



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-16.lcd	# JW8001	4.126	965580	120937	1.61	6517	0.000
280119-17.lcd	# JW8001	4.129	965157	121163	1.60	6510	0.000
Average		4.127	965369	121050	1.61	6514	0.000
%RSD		0.051	0.031	0.132	0.441	0.076	0.000

Analysed By : Sunil Patel.

Checked By :

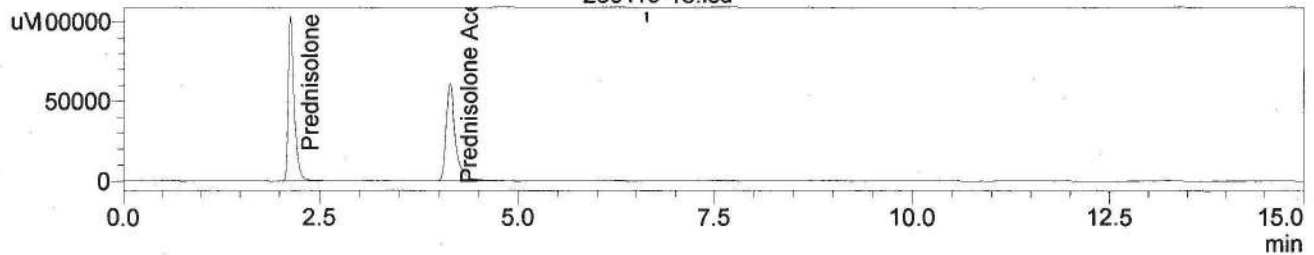
29/01/19

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-18.lcd  
 Acquired by : Sunil Patel.  
 Sample Name : Prednisolone+Prednisolone Acetate  
 Sample ID : BKTSYSTEM Suaitability Solution  
 Vial# : 2  
 Description : Assay  
 Injection Volume : 10 uL  
 Data Filename : 280119-18.lcd  
 Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
 Batch Filename : 280119.lcb  
 Date Acquired : 28/01/19 20:18:36

## Chromatogram

Summary(Compound)  
 280119-18.lcd



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-18.lcd	System Suaitability Solu	2.131	535024	102998	1.61	3368	0.000
Average		2.131	535024	102998	1.61	3368	0.000
%RSD		0.000	0.000	0.000	0.000	0.000	0.000

ID#2 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-18.lcd	System Suaitability Solu	4.129	485470	60710	1.59	6430	11.324
Average		4.129	485470	60710	1.59	6430	11.324
%RSD		0.000	0.000	0.000	0.000	0.000	0.000

Analysed By : Sunil Patel.

Checked By :

29/01/19



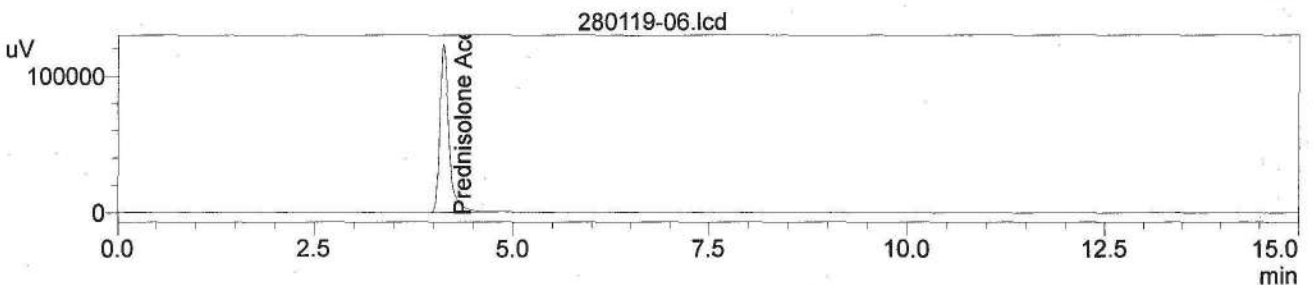
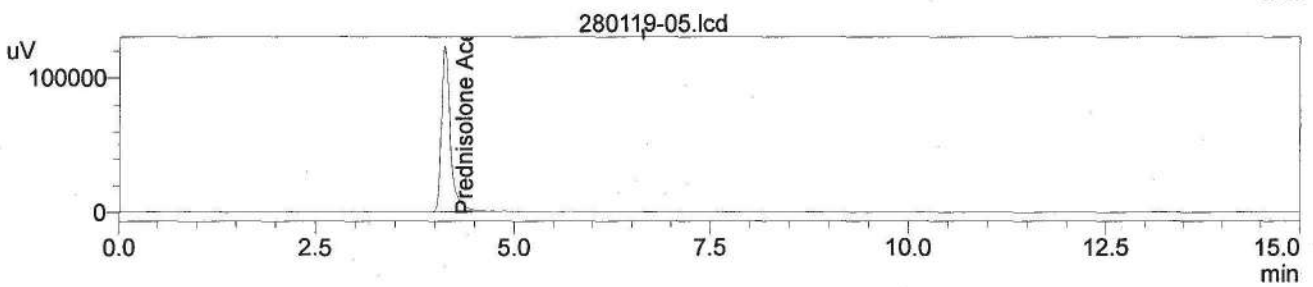
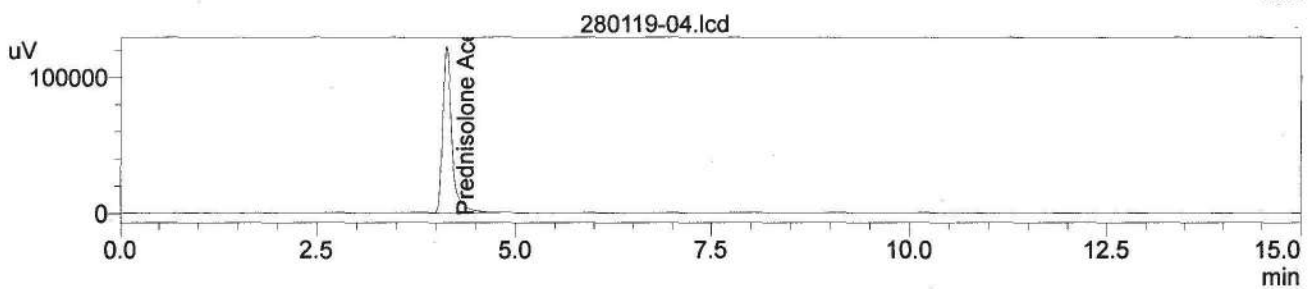
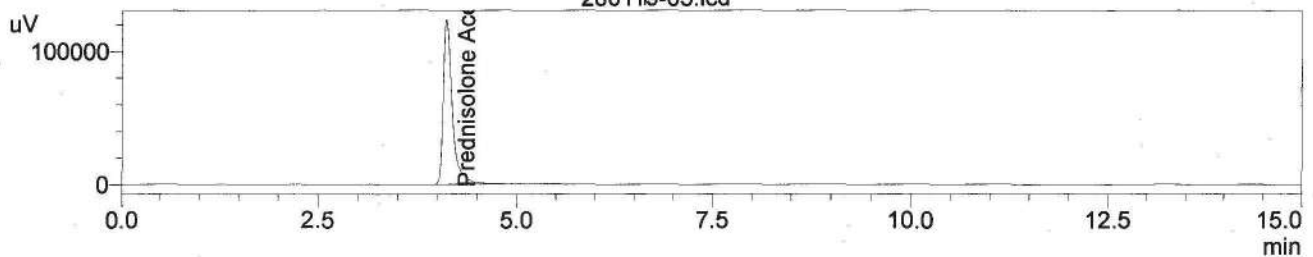
OPES HEALTHCARE PVT. LTD.  
Analytical Development Laboratory

## Sample Information

Sample Information D:\...January\Prednisolone Acetate Ophthalmic Suspension\280119\280119-03.lcd

Acquired by : Sunil Patel.  
Sample Name : Prednisolone Acetate  
Sample ID : Standard Solution  
Vial# : 3  
Description : Assay  
Injection Volume : 10 uL  
Data Filename : 280119-03.lcd  
Method Filename : Prednisolone Acetate Ophthalmic Suspension USP\_Assay.lcm  
Batch Filename : 280119.lcb  
Date Acquired : 28/01/19 16:24:03

## Chromatogram

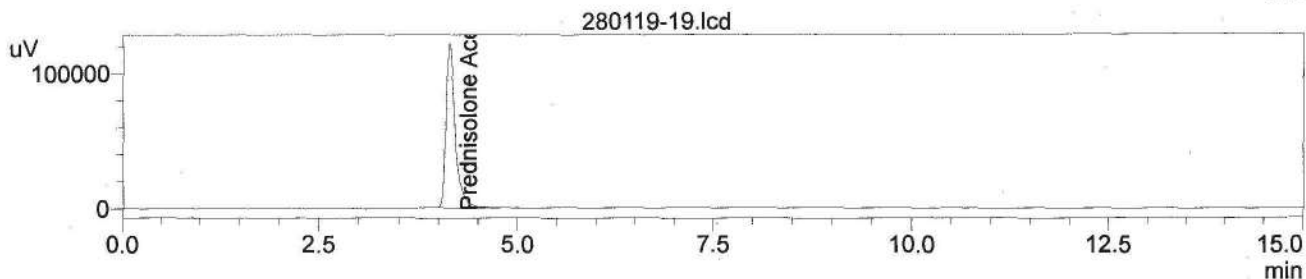
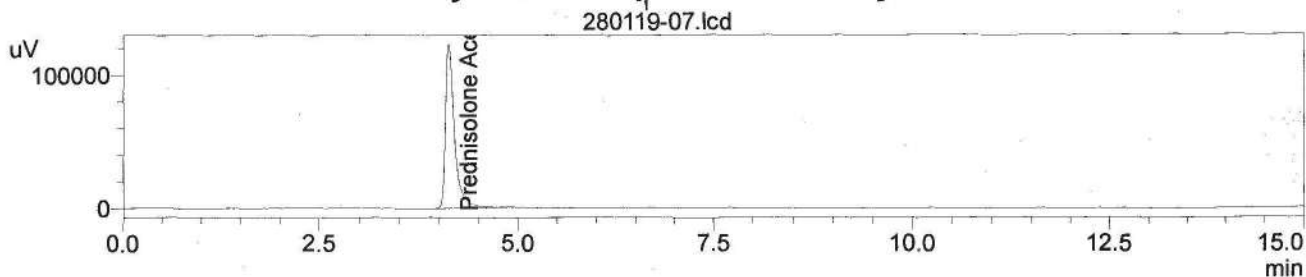
Summary(Compound)  
280119-03.lcd  
29/1/19

Analysed By : Sunil Patel.

Checked By :

  
29/01/19

**OPES HEALTHCARE PVT. LTD.**  
**Analytical Development Laboratory**



&lt;&lt; Detector A &gt;&gt;

ID#1 Compound Name: Prednisolone Acetate

Title	Sample ID	Ret. Time	Area	Height	Tailing Factor	Theoretical Plate	Resolution
280119-03.lcd	Standard Solution	4.119	966581	123490	1.58	6736	0.000
280119-04.lcd	Standard Solution	4.123	966841	123101	1.58	6739	0.000
280119-05.lcd	Standard Solution	4.122	966824	123145	1.59	6729	0.000
280119-06.lcd	Standard Solution	4.119	967057	122999	1.58	6674	0.000
280119-07.lcd	Standard Solution	4.126	967370	122533	1.59	6663	0.000
280119-19.lcd	BKTStandard Solution	4.130	972253	121671	1.57	6383	0.000
Average		4.123	967821	122823	1.58	6654	0.000
%RSD		0.103	0.226	0.524	0.476	2.055	0.000

Analysed By : Sunil Patel.

Checked By :

*[Signature]*  
29/01/19