

OPES HEALTHCARE PVT. LTD.					
ACCELERATED STABILITY REPORT					
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6001
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018
Batch Size	:	100.0 Liters	Sample Size	:	130 Bottles
Storage Condition	:	40°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/07/2017

Test & Limit	Observations				
	Initial	1 month	2 months	3 months	6 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.08	5.10	5.13	5.15	5.19
Assay					
Composition:					
Prednisolone Acetate USP...1% w/v (Between 90.0% to 115.0% of the label claim)	99.9%	99.4%	98.8%	98.2%	97.6%
Benzalkonium Chloride BP.....0.006% w/v (Between 50.0% to 110.0% of the label claim)	98.7%	98.0%	97.1%	96.2%	95.3%
Related substance					
Hydrocortisone Acetate (Impurity A) (Not more than 1.0%)	0.65%	0.68%	0.70%	0.72%	0.75%
Prednisolone (Impurity B) (Not more than 2.0%)	0.76%	0.79%	0.82%	0.85%	0.89%
Any other unspecified impurity (Not more than 0.5%)	0.28%	0.30%	0.33%	0.35%	0.38%
Total impurities (Not more than 3.0%)	1.69%	1.77%	1.85%	1.92%	2.02%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	---	---	---	Complies

Conclusion: The product is found stable up to 06 months when stored at 40°C ± 2°C & 75% ± 5% RH.

Date : 10/07/2017	 Mr. Nilesh Patel (Q.C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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OPES HEALTHCARE PVT. LTD.					
ACCELERATED STABILITY REPORT					
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6002
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018
Batch Size	:	100.0 Liters	Sample Size	:	130 Bottles
Storage Condition	:	40°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/07/2017

Test & Limit	Observations				
	Initial	1 month	2 months	3 months	6 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.15	5.17	5.20	5.22	5.25
Assay					
Composition:					
Prednisolone Acetate USP...1% w/v (Between 90.0% to 115.0% of the label claim)	99.1%	98.4%	97.7%	97.1%	96.5%
Benzalkonium Chloride BP.....0.006% w/v (Between 50.0% to 110.0% of the label claim)	97.9%	97.0%	96.1%	95.3%	94.0%
Related substance					
Hydrocortisone Acetate (Impurity A) (Not more than 1.0%)	0.68%	0.70%	0.73%	0.75%	0.78%
Prednisolone (Impurity B) (Not more than 2.0%)	0.74%	0.78%	0.81%	0.84%	0.88%
Any other unspecified impurity (Not more than 0.5%)	0.25%	0.28%	0.30%	0.33%	0.35%
Total impurities (Not more than 3.0%)	1.67%	1.76%	1.84%	1.92%	2.01%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	---	---	---	Complies

Conclusion: The product is found stable up to 06 months when stored at 40°C ± 2°C & 75% ± 5% RH.

Date : 10/07/2017		 Mr. Nilesh Patel (Q.C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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OPES HEALTHCARE PVT. LTD.					
ACCELERATED STABILITY REPORT					
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6003
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018
Batch Size	:	100.0 Liters	Sample Size	:	130 Bottles
Storage Condition	:	40°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/07/2017

Test & Limit	Observations				
	Initial	1 month	2 months	3 months	6 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.12	5.15	5.18	5.20	5.24
Assay					
Composition:					
Prednisolone Acetate USP... 1% w/v (Between 90.0% to 115.0% of the label claim)	98.5%	97.9%	97.2%	96.5%	95.8%
Benzalkonium Chloride BP.....0.006% w/v (Between 50.0% to 110.0% of the label claim)	97.3%	96.1%	95.3%	94.5%	93.7%
Related substance					
Hydrocortisone Acetate (Impurity A) (Not more than 1.0%)	0.66%	0.69%	0.72%	0.75%	0.78%
Prednisolone (Impurity B) (Not more than 2.0%)	0.77%	0.80%	0.82%	0.85%	0.89%
Any other unspecified impurity (Not more than 0.5%)	0.26%	0.29%	0.32%	0.34%	0.37%
Total impurities (Not more than 3.0%)	1.69%	1.78%	1.86%	1.94%	2.04%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	---	---	---	Complies

Conclusion: The product is found stable up to 06 months when stored at 40°C ± 2°C & 75% ± 5% RH.

Date : 10/07/2017	 Mr. Nilesh Patel (Q.C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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OPES HEALTHCARE PVT. LTD.							
REAL TIME STABILITY REPORT							
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6001		
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016		
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018		
Batch Size	:	100.0 Liters	Sample Size	:	211 Bottles		
Storage Condition	:	30°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016		
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/01/2019		

Test & Limit	Observations						
	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.08	5.11	5.13	5.16	5.20	5.24	5.28
Assay							
Composition:							
Prednisolone Acetate USP... 1% w/v (Between 90.0% to 115.0% of the label claim)	99.9%	99.2%	98.6%	98.1%	97.5%	96.9%	96.1%
Benzalkonium Chloride BP..... 0.006% w/v (Between 50.0% to 110.0% of the label claim)	98.7%	97.9%	97.0%	96.1%	95.3%	94.5%	93.2%
Related substance							
Hydrocortisone Acetate (Impurity A) (Not more than 1.0%)	0.65%	0.67%	0.69%	0.72%	0.75%	0.78%	0.82%
Prednisolone (Impurity B) (Not more than 2.0%)	0.76%	0.78%	0.80%	0.83%	0.86%	0.89%	0.94%
Any other unspecified impurity (Not more than 0.5%)	0.28%	0.31%	0.34%	0.37%	0.39%	0.42%	0.45%
Total impurities (Not more than 3.0%)	1.69%	1.76%	1.83%	1.92%	2.00%	2.09%	2.21%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	----	----	----	----	----	Complies

Conclusion: The product is found stable up to 24 months when stored at 30°C ± 2°C & 75% ± 5% RH.

Date : 10/01/2019	 Mr. Niles Patel (Q. C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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OPES HEALTHCARE PVT. LTD.							
REAL TIME STABILITY REPORT							
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6002		
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016		
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018		
Batch Size	:	100.0 Liters	Sample Size	:	211 Bottles		
Storage Condition	:	30°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016		
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/01/2019		

Test & Limit	Observations						
	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.15	5.18	5.20	5.23	5.26	5.30	5.34
Assay Composition: Prednisolone Acetate USP ... 1% w/v (Between 90.0% to 115.0% of the label claim) Benzalkonium Chloride BP 0.006% w/v (Between 50.0% to 110.0% of the label claim)	99.1%	98.6%	98.0%	97.4%	96.7%	96.1%	95.2%
Related substance Hydrocortisone Acetate (Impurity A) (Not more than 1.0%) Prednisolone (Impurity B) (Not more than 2.0%) Any other unspecified impurity (Not more than 0.5%) Total impurities (Not more than 3.0%)	0.68%	0.70%	0.73%	0.75%	0.78%	0.80%	0.83%
	0.74%	0.77%	0.72%	0.75%	0.78%	0.81%	0.84%
	0.25%	0.28%	0.30%	0.33%	0.35%	0.38%	0.41%
	1.67%	1.75%	1.75%	1.83%	1.91%	1.99%	2.08%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	----	----	----	----	----	Complies

Conclusion: The product is found stable up to 24 months when stored at 30°C ± 2°C & 75% ± 5% RH.

Date : 10/01/2019	 Mr. Nilesh Patel (Q. C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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OPES HEALTHCARE PVT. LTD.							
REAL TIME STABILITY REPORT							
Product Name	:	Prednisolone Acetate Ophthalmic Suspension USP 1% w/v	Batch No.	:	VO6003		
Composition	:	Prednisolone Acetate USP.....1% w/v Benzalkonium Chloride BP.....0.006% w/v (As Preservative) Sterile Aqueous Vehicle.....q.s.	Mfg. Date	:	11/2016		
Packing	:	5 ml plastic dropper bottle	Exp. Date	:	10/2018		
Batch Size	:	100.0 Liters	Sample Size	:	211 Bottles		
Storage Condition	:	30°C ± 2°C & 75% ± 5% RH	Dt. Started	:	26/12/2016		
Tested as per	:	USP & In-house specification	Dt. Completed	:	10/01/2019		

Test & Limit	Observations						
	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Description (White color suspension filled in bottle.)	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.	White color suspension filled in bottle.
pH (Between 5.0 and 6.0)	5.12	5.15	5.17	5.20	5.23	5.26	5.29
Assay							
Composition:							
Prednisolone Acetate USP... 1% w/v (Between 90.0% to 115.0% of the label claim)	98.5%	97.8%	97.3%	96.8%	96.2%	95.6%	94.8%
Benzalkonium Chloride BP..... 0.006% w/v (Between 50.0% to 110.0% of the label claim)	97.3%	96.5%	95.4%	94.2%	93.6%	92.8%	92.0%
Related substance							
Hydrocortisone Acetate (Impurity A) (Not more than 1.0%)	0.66%	0.69%	0.72%	0.75%	0.78%	0.80%	0.82%
Prednisolone (Impurity B) (Not more than 2.0%)	0.77%	0.80%	0.82%	0.85%	0.88%	0.91%	0.95%
Any other unspecified impurity (Not more than 0.5%)	0.26%	0.29%	0.32%	0.35%	0.39%	0.42%	0.45%
Total impurities (Not more than 3.0%)	1.69%	1.78%	1.86%	1.95%	2.05%	2.13%	2.22%
Sterility (Growth or turbidity should not be present in the original clear media.)	Complies	----	----	----	----	----	Complies

Conclusion: The product is found stable up to 24 months when stored at 30°C ± 2°C & 75% ± 5% RH.

Date : 10/01/2019		 Mr. Nilesh Patel (Q. C. Manager)	 Mr. Mahesh Kadiya (Q. A. Manager)
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