1 Sivagangai Main Road
Veerapanjan, Madurai - 625 020, India
Tel : 91 452 309 6100 Fax: 91 452 244 6200

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STABILITY STUDY REPORT

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STABILITY TEST

I. Stability Study Protocol

Name of the product: AUROFORT- 5mL (Prednisolone acetate 1.0% w/v)

1.- Description of method used during the test

1.1 Quantitative Composition: *Each ml contains:*

Approved Generic Name (INN)	Quantity(mg)/mL	Specification
Prednisolone Acetate	10.0	USP
Hypromellose	2.5	BP
Sodium Chloride	5.0	BP
Sodium citrate	0.5	BP
EDTA	0.1	BP
Benzalkonium chloride	0.11	BP
Purified water	Quantity Sufficient	BP

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1.2 Study Method:

The same methodology of finished product.

1.2.1.Storage condition and Testing period

The study reports the accelerated degradation at 40 +/-2°C / 75% +/-5% RH, and the real degradation of the product at 30 +/-2°C / 60% +/-5% RH.

This stability test was executed each 0, 3, 4, 5, and 6 months for the accelerated degradation, and executed each 0, 3, 6, 9, 12, 18, 24, 25, 26, and 27 months for the real degradation from the initial experiment.

STORAGE CONDITION	**SAMPLING INTERVALS**
Real Time storage: 30+/-2°C/60%+/-5% RH	0, 3, 6 , 9, 12, 18, 24, 25, 26 and 27 months
Accelerated storage: 40+/-2°C/75%+/-5% RH	0, 3, 4, 5, 6 months

1.2.2.Testing time

Batch details are given below:

No.	Batch No.	Mfg. Date	Date of starting study	Batch size
1	AFT-08-001	Mar. 2008	10 Mar.2008	20 lts
2	AFT-08-002	Apr. 2008	05 Apr.2008	20 lts
3	AFT-08-003	May. 2008	11 May 2008	20 lts

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1.2.3. Specification and method

The acquired stability data of AUROFORT- 5mL (Prednisolone acetate ophthalmic suspension USP 1%w/v) (Batch No: AF-08-001, AF-08-002, and AF-08-003 of the same are enclosed at the end of the section. Stability studies of AURFORT- 5mL (Prednisolone acetate ophthalmic suspension USP 1%w/v) include following tests and the samples are analyzed as per the shelf life specification finished product specifications, as depicted in the table below:

No	Tests	Specification Limits
1	**Description**	Colorless sterile suspension
2	**Label checking**	Clear & Legible
3	**Uniformity of volume (ml)**	NLT 5.0ml
4	**Identification TLC method**	The Rf value of principal spot obtained from the samole should be same as the of standard
5	**pH**	5.0 - 6.0
6	**Specific gravity at 25°C**	1.000 - 1.025
7	**Assay of (%) Prednisolone acetate**	0.90 — 1.10%
8	**Assay of preservative Benzalkonium chloride**	0.0090 — 0.0120%
9	**Sterility**	Should be sterile

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2.- Package:

No	Packaging Material
1	Primary pack: White bottles: Low Density PolyEthylene White cap: High density PolyEthylene Nozzles: Polypropylene
2	Secondary pack: Carton box

3.- Stability summary and Conclusion:

Three batches of AUROFORT- 5mL (Prednisolone acetate ophthalmic suspension USP 1%w/v) manufactured were kept under stability study. These batches have completed 6 months accelerated study and 27 months real time study. The results obtained are well within the specified limits. The stability data already accomplished is complying with the existing shelf life specifications.

From the enclosed stability data, it is found that there are no significant physicochemical changes in the product in the both the stability studies. All parameters remain within the specification limits, with no evidence of degradation or loss of potency.

Based on Accelerated and Real time stability data, shelf life of 24 months can be assigned to AUROFORT- 5mL (Prednisolone acetate ophthalmic suspension USP 1%w/v).

Any extension of expiration dating (shelf life) shall be communicated to the agency following appropriate regulatory procedures.

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4.- Place

4.1 Manufacturer Laboratory Place and Place where Stability Studies conducted:

Aurolab, 1 Sivagangai Main Road Veerapanjan, Madurai - 625 020, India. Tel : 91 452 309 6100 Fax: 91 452 244 6200

4.2 Manufacturer of API:

Details of Active Pharmaceutical Ingredient (API):

Name of the API: Prednisolone acetate USP

Name of the Manufacturer:

NEXUS PHARMACHEM PvT. Ltd.
Plot #2511, Phase III, GIDC Naroda, Ahmedabad-382330, India
Phone: 91 79 2280 8200
Fax: 91 79 2280 8300
E-mail: info@nexuspharma.com

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Excellence...in sight *ACCELERATED STABILITY STUDY REPORT FOR AUROFORT*

Pharmaceutical Division

AUROFORT (PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION 1%w/v)

Name of the product : Prednisolone Acetate ophthalmic suspension USP 1.0%w/v – 5ml

Batch No : AFT-08 -001 Temp : 40 ± 2^0 C Primary pack : LDPE Container

Mfg.Date : Mar'08 RH : 25 ± 5 % Secondary pack : Carton box

Exp.date : Feb'10 Shelf life: 2 years Formula : Same as in DMF

Manufg.method : ED-MP- 12 Source : Symbiotec- India

S.No	Tests	Specification	Initial Mar'08	3 months June'08	4 months July'08	5 months Aug'08	6 months Sep'08
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.1ml	5.0ml	5.0ml	5.1ml	5.0ml
4	Identification TLC method	The Rf value of principle spot obtained with test solution should corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution
5	pH	5.0 – 6.0	5.95	5.82	5.77	5.61	5.54
6	Specific gravity at 25°C	1.000 – 1.025	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone Acetate	0.90 – 1.10%	1.02%	1.011%	0.99%	0.98%	0.975%
	Benzalkonium chloride	0.0090 – 0.0120%	0.011%	0.0099%	0.0097%	0.0097%	0.0096%

Remarks: The product is stable upto 6months when stored at accelerated conditions

Test conducted by: P. Bhaskar
Quality control chemist
Date: 05/10/2008

Reviewed by: S. Pathy
Quality control chemist
Date: 05/10/2008

Approved by: J. Venkateswarlu
Quality Assurance Manager
Date: 05/10/2008

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Excellence...in sight *ACCELERATED STABILITY STUDY REPORT FOR AUROFORT*
Pharmaceutical Division

AUROFORT (PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION 1%w/v)

Name of the product : Prednisolone Acetate ophthalmic suspension USP 1.0%w/v – 5ml

Batch No : AFT-08 -002 Temp : 40 ± 2^0 C Primary pack : LDPE Container

Mfg.Date : Apr'08 RH : 25 ± 5 % Secondary pack : Carton box

Exp.date : Mar'10 Shelf life: 2 years Formula : Same as in DMF

Manufg.method : ED-MP- 12 Source : Symbiotec- Mumbai

S.No	Tests	Specification	Initial Apr'08	3 months July'08	4 months Aug'08	5 months Sep'08	6 months Oct'08
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.0ml	5.0ml	5.1ml	5.1ml	5.1ml
4	Identification TLC method	The Rf value of principle spot obtained with test solution should corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution
5	pH	5.0 – 6.0	5.92	5.83	5.72	5.56	5.50
6	Specific gravity at 25°C	1.000 – 1.025	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone Acetate	0.90 – 1.10%	1.00%	0.997%	0.99%	0.982%	0.978%
	Benzalkonium chloride	0.0090 – 0.0120%	0.011%	0.010%	0.0099%	0.0098%	0.0098%

Remarks: The product is stable upto 6months when stored at accelerated conditions.

Test conducted by: P. Bhanu
Quality control chemist
Date: 01/11/2008

Reviewed by: B. Pattnaik
Quality control chemist
Date: 01/11/2008

Approved by: J. Venkateswara
Quality Assurance Manager
Date: 01/11/2008

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Excellence...in sight *ACCELERATED STABILITY STUDY REPORT FOR AUROFORT*

Pharmaceutical Division

AUROFORT (PREDNISOLONE ACETATE OPHTHALMIC SUSPENSION 1%w/v)

Name of the product : Prednisolone Acetate ophthalmic suspension USP 1.0%w/v – 5ml

Batch No : AFT-08 -003 Temp : 40 ± 2° C Primary pack : LDPE Container

Mfg.Date : May'08 RH : 25 ± 5 % Secondary pack : Carton box

Exp.date : Apri'10 Shelf life: 2 years Formula : Same as in DMF

Manufg.method : ED- MP- 12 Source : Symbiotec-India

S.No	Tests	Specification	Initial May'08	3 months Aug'08	4 months Sep'08	5 months Oct'08	6 months Nov'08
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.0ml	5.0ml	5.0ml	5.0ml	5.0ml
4	Identification TLC method	The Rf value of principle spot obtained with test solution should corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution	The Rf value of principle spot obtained with test solution is corresponds to that of standard solution
5	pH	5.0 – 6.0	5.87	5.81	5.73	5.65	5.50
6	Specific gravity at 25°C	1.000 – 1.025	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone Acetate	0.90 – 1.10%	1.05%	1.03%	1.00%	0.99%	0.98%
	Benzalkonium chloride	0.0090 – 0.0120%	0.0112%	0.010%	0.0099%	0.0098%	0.0098%

Remarks: The product is stable upto 6months when stored at accelerated conditions

Test conducted by: P. Bhaskar
Quality control chemist
Date: 15/12/2008

Reviewed by: S. Padhy
Quality control chemist
Date: 15/12/2008

Approved by: J. Venkateswarlu
Quality Assurance Manager
Date: 15/12/2008

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REAL TIME STABILITY STUDY REPORT FOR AUROFORT

Batch No : AFT-08-001 Temp : 30 ± 2°C Primary pack : LowDensityPolyEthylene Container

Mfg.date : Mar' 08 RH : 35 ± 5 % Secondary pack : Carton box

Exp.date : Feb'10 Shelf life : 2 years

S.No	Tests	Specification	OBSERVED RESULTS									
			Initial Mar'08	3 months Jun'08	6 months Sep'08	9 months Dec'08	12 months Mar'09	18 months Sep'09	24 months Mar'10	25 months Apr'10	26 months May'10	27 months June'10
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.1	5.0	5.1	5.1	5.0	5.0	5.1	5.0	5.1	5.1
4	Identification By TLC Method	The Rf value of the principal spot obtained from the solution under test corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the	The Rf value of the principal spot obtained from the solution under test solution iscorrespond s to that obtained from the	The Rf value of the principal spot obtained from the solution under test solution iscorresponds to that obtained from the standard solution
5	pH	5.0 - 6.0	5.95	5.95	5.93	5.89	5.82	5.8	5.76	5.74	5.7	5.68
6	Specific gravity	1.000 - 1.025	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone acetate	0.90% - 1.10%	1.020	1.015	1.010	1.000	0.990	0.983	0.980	0.975	0.971	0.965
8	Assay of Benzalkonium chloride	0.0090% - 0.0120%	0.0110	0.0120	0.0100	0.0099	0.0098	0.0098	0.0097	0.0097	0.0096	0.0096
9	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth

Remarks: The product is stable for 27 months at temperature not exceeding 32° C. The declared shelf life is 24 months from the date of manufacturing.

Analysed by : P. Ayraj
Quality control chemist
Date: 01/07/2010

Reviewed by : S. Pathy
Quality control chemist
Date: 01/07/2010

Approved by : J. Venkatesan
Quality Assurance Manager
Date: 01/07/2010

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REAL TIME STABILITY STUDY REPORT FOR AUROFORT

Batch No : AFT-08-003 | Temp : 30 ± 2° C | Primary pack : LowDensityPolyEthylene Container
Mfg.date : May' 08 | RH : 35 ± 5 % | Secondary pack : Carton box
Exp.date :Apr'10 | Shelf life : 2 years

			OBSERVED RESULTS									
S.No	**Tests**	**Specification**	**Initial**	**3 months**	**6 months**	**9 months**	**12 months**	**18 months**	**24 months**	**25 months**	**26 months**	**27 months**
			May'08	**Aug'08**	**Nov'08**	**Feb'09**	**May'09**	**Nov'09**	**May'10**	**June'10**	**July'10**	**Aug'10**
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.0	5.1	5.1	5.0	5.0	5.0	5.0	5.0	5.1	5.0
4	Identification By TLC Method	The Rf value of the principal spot obtained from the solution under test corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the	The Rf value of the principal spot obtained from the solution under test is solution corresponds to that obtained from the standard solution
5	pH	5.0 - 6.0	5.87	5.81	5.76	5.71	5.65	5.6	5.53	5.47	5.4	5.35
6	Specific gravity	1.000 - 1.025	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone acetate	0.90% - 1.10%	1.050	1.020	1.010	1.000	0.993	0.990	0.984	0.980	0.976	0.97
8	Assay of Benzalkonium chloride	0.0090% - 0.0120%	0.0112	0.0110	0.0100	0.0099	0.0099	0.0098	0.0098	0.0098	0.0097	0.0097
9	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth

Remarks: The product is stable for 27 months at temperature not exceeding 32° C. The declared shelf life is 24 months from the date of manufacturing.

Analysed by : P. [signature] | Reviewed by : S. [signature] | Approved by : J. [signature]
Quality control chemist | Quality control chemist | Quality Assurance Manager
Date: 20/08/2010 | Date: 20/08/2010 | Date: 20/08/2010

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Pharmaceutical Division

REAL TIME STABILITY STUDY REPORT FOR AUROFORT

Batch No : AFT-08-002 Temp : 30 ± 2^0 C Primary pack : LowDensityPolyEthylene Container

Mfg.date : Apr' 08 RH : 35 ± 5 % Secondary pack : Carton box

Exp.date : Mar'10 Shelf life : 2 years

			OBSERVED RESULTS									
S.No	**Tests**	**Specification**	**Initial**	**3 months**	**6 months**	**9 months**	**12 months**	**18 months**	**24 months**	**25 months**	**26 months**	**27 months**
			Apr'08	**July'08**	**OCt'08**	**Jan'09**	**Apr'09**	**Oct'09**	**Apr'10**	**May'10**	**June'10**	**July'10**
1	Description	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension	Colorless suspension
2	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3	Uniformity of volume (ml)	NLT 5.0ml	5.0	5.1	5.0	5.0	5.1	5.1	5.1	5.0	5.1	5.0
4	Identification	The Rf value of the principal spot obtained from the solution under test corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution	The Rf value of the principal spot obtained from the solution under test solution is corresponds to that obtained from the standard solution
5	pH	5.0 - 6.0	5.92	5.84	5.78	5.72	5.65	5.52	5.48	5.4	5.33	5.3
6	Specific gravity	1.000 - 1.025	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007
7	Assay Prednisolone acetate	0.90% - 1.10%	1.000	1.010	0.994	0.990	0.984	0.980	0.976	0.971	0.968	0.96
8	Assay of Benzalkonium chloride	0.0090% - 0.0120%	0.0110	0.0105	0.0100	0.0099	0.0099	0.0098	0.0098	0.0097	0.0097	0.0097
9	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth	No growth

Remarks: The product is stable for 27 months at temperature not exceeding 32° C. The declared shelf life is 24 months from the date of manufacturing.

Analysed by : [signature] Reviewed by : S. Pathy Approved by : J. Varadarajan

Quality control chemist Quality control chemist Quality Assurance Manager

Date: 01/08/2010 Date: 01/08/2010 Date: 01/08/2010