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Pharmaceutical Division

PHARMACEUTICAL PRODUCT REGISTRATION – CHILIE

STABILITY DATA

ACCELERATED STABILITY STUDY REPORT FOR HYPROMELLOSE

Name of the product : Hypromellose eye drops BP 0.7% w/v- 10ml

Batch No : 2C050 Temp : $40 \pm 2^{\circ}\text{C}$ Primary pack : LDPE

Mfg.date : Mar'02 RH : 75 ± 5 % Secondary pack : Carton box

Exp.date : Feb'04 Shelf life: 2 years Formula : Same as in DMF

Manufg.method : MP-33 Source : Dow coming – USA.

S.N o	Tests	Specification	Initial	2 months	4 months	5 months	6 months
1.	Description	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution
2.	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3.	Uniformity of volume(ml)	NLT 10.0ml	10.1ml	10.1ml	10.0ml	10.1ml	10.0ml
4.	Identification a. with heating b. with acetic acid and tannic acid	The solution should be clear on cooling The yellowish white flocculent precipitate should be produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia
5.	pH	8.2 – 8.6	8.26	8.30	8.34	8.38	8.44
6.	Refractive index at 30°C	1.335 – 1.338	1.3356	1.3356	1.3356	1.3356	1.3356
7.	Specific gravity at 25°C	1.005 – 1.012	1.010	1.010	1.010	1.010	1.010
8.	Viscosity at 25°C (cps)	40 – 70	52	50	49	48	48
9.	Assay Hydroxy propyl methyl cellulose	0.45% - 0.75%	0.615	0.601	0.587	0.575	0.561
10.	Chloride	4000 – 4900ppm	4885	4780	4652	4515	4410
11.	Benzalkonium chloride	0.009% - 0.0120%	0.0117	0.0116	0.0110	0.0108	0.0104
12.	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth

Test conducted by: A. J. [Signature]

Quality control chemist

Date: 05/09/02

Reviewed by: S. J. Hart

Quality control chemist

Date: 05/09/02

Approved by: A. J. Karpman

Quality Assurance Manager

Date: 05/09/02

REAL TIME STABILITY STUDY REPORT FOR HYPMELLOSE

Name of the product : Hypromellose 0.7% eye drops BP - 10ml

Temp : 30 ± 2° C

RH : 60 ± 5%

Shelf life : 2 years

Primary pack : 1 DPE

Secondary pack : Cartonbox

Batch No : 2C050

Mfg date : Mar'02

Exp date : Feb'04

		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	
1	Description	Clear, slight viscous solution	Mar'02 Clear, slight viscous solution	June'02 Clear, slight viscous solution	Sep'02 Clear, slight viscous solution	Dec'02 Clear, slight viscous solution	Mar'03 Clear, slight viscous solution	Sep'03 Clear, slight viscous solution	Mar'04 Clear, slight viscous solution	Apr'04 Clear, slight viscous solution	May'04 Clear, slight viscous solution	June'04 Clear, slight viscous solution	
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 10.0ml	10	10	10	10	10	10	10	10	10	10	
4	Identification												
	a. with heating	The solution should be clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	
	b. With acetic acid and tannic acid	The yellowish white flocculent precipitate should be produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced this dissolves in 6M Ammonia	
5	pH	8.2 - 8.6	8.27	8.3	8.31	8.33	8.33	8.37	8.41	8.52	8.55	8.57	
	Refractive index at 6.30°C	1.335 - 1.338	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	
7	Specific gravity at 25°C	1.005 - 1.012	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	1.007	
8	Chloride	4000 - 4900ppm	4868	4835	4816	4800	4768	4734	4657	4587	4439	4398	
9	Viscosity Assay	40 - 70cps	52	52	50	49	49	49	48	48	46	46	
	Hydroxypropyl methyl cellulose												
10		0.45% - 0.75%	0.700		0.690	0.685	0.685	0.683	0.681	0.680	0.681	0.68	
	Benzalkonium chloride	0.0090% - 0.0120%	0.010	0.010	0.0098	0.0098	0.0097	0.0096	0.0096	0.0095	0.0093	0.0091	
12	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]*
Quality control chemist

Date : 23/6/04

Reviewed by : *[Signature]*
Quality control chemist

Date : 23/6/04

Approved by : *[Signature]*
Quality Assurance Manager

Date : 23/6/04

ACCELERATED STABILITY REPORT FOR HYPROMELLOSE EYE DROPS

Name of the product : Hypromellose eye drops BP 0.7% w/v- 10ml

Batch No : 2A018 Temp : $40 \pm 2^\circ \text{C}$ Primary pack : LDPE
Mfg.date : Jan'02 RH : $75 \pm 5\%$ Secondary pack : Carton box
Exp.date : Dec'03 Shelf life: 2 years Formula : Same as in DMF
Manufg.method : MP-33 Source : Dow corning – USA.

S.No	Tests	Specification	Initial	2 months	4 months	5 months	6 months
1.	Description	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution
2.	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3.	Uniformity of volume(ml)	NLT 10.0ml	10.1ml	10.1ml	10.0ml	10.1ml	10.0ml
4.	Identification a. with heating b. with acetic acid and tannic acid	The solution should be clear on cooling The yellowish white flocculent precipitate should be produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia
5.	pH	8.2 – 8.6	8.28	8.32	8.345	8.389	8.47
6.	Refractive index at 30°C	1.335 – 1.338	1.3356	1.3356	1.3356	1.3356	1.3356
7.	Specific gravity at 25°C	1.005 – 1.012	1.010	1.010	1.010	1.010	1.010
8.	Viscosity at 25°C (cps)	40 – 70	55	53	52	50	49
9.	Assay Hydroxy propyl methyl cellulose	0.45% - 0.75%	0.700	0.690	0.683	0.652	0.615
10.	Chloride	4000 – 4900ppm	4800	4750	4652	4572	4470
11.	Benzalkonium chloride	0.009% - 0.0120%	0.0118	0.0116	0.0112	0.0108	0.0105
12.	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth

Test conducted by: *S. Paul*

Quality control chemist
Date : 03/07/02

Reviewed by: *S. Paul*

S. Paul IN BEHATARY
Quality control chemist
Date : 03/07/02

Approved by: *A. K. P.*

A. K. P.
Quality Assurance Manager
Date : 03/07/02

REAL TIME STABILITY STUDY REPORT FOR HYPROMELLOSE

Name of the product : Hypromellose eye drops 0.7% w/v - BP - 10ml

Batch No : 2A018
Mfg date : Jan'02
Exp.date : Dec'03

Temp : 30 ± 2° C
RH : 60 ± 5 %
Shelf life : 2 years

Primary pack : LDPE
Secondary pack : Cartonbox

		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	
1	Description	Clear, slight viscous solution	Jan'02 Clear, slight viscous solution	Apr'02 Clear, slight viscous solution	July'02 Clear, slight viscous solution	Oct'02 Clear, slight viscous solution	Jan'03 Clear, slight viscous solution	July'03 Clear, slight viscous solution	Jan'04 Clear, slight viscous solution	Feb'04 Clear, slight viscous solution	Mar'04 Clear, slight viscous solution	Apr'04 Clear, slight viscous solution	
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 10.0ml	10.1	10.1	10.1	10.1	10.1	10.1	10.1	10.1	10.1	10.1	
4	Identification												
a. with heating	The solution should be clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	
b. With acetic acid and tannic acid	The yellowish white flocculent precipitate should be produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	The yellowish white flocculent precipitate is produced in this dissolves in 6M Ammonia	
5	pH	8.2 - 8.6	8.25	8.31	8.34	8.36	8.39	8.39	8.41	8.52	8.56	8.57	
6	Refractive index at 30°C	1.335 - 1.338	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	
7	Specific gravity at 25°C	1.000 - 1.025	1.011	1.011	1.011	1.011	1.011	1.011	1.011	1.011	1.011	1.011	
8	Chloride	4000 - 4900ppm	4850	4828	4815	4800	4788	4761	4732	4652	4518	4500	
9	Viscosity	40 - 70cps	55	55	53	52	50	50	50	49	49	48	
10	Assay Hydroxypropyl methyl cellulose	0.45% - 0.75%	0.698	0.690	0.690	0.688	0.685	0.681	0.581	0.581	0.571	0.57	
11	Benzalkonium chloride	0.0090% - 0.0120%	0.011	0.0109	0.0099	0.0098	0.0098	0.0096	0.0096	0.0095	0.0093	0.0093	
12	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 : J. F. K. A. N. S.
Quality control chemist

Reviewed by : J. F. K. A. N. S.
Quality control chemist

Approved by : J. F. K. A. N. S.
Quality Assurance Manager

Date : 23/04/04

Date : 23/04/04

Date : 23/04/04

ACCELERATED STABILITY STUDY REPORT FOR HYPROMELLOSE

Name of the product : Hypromellose eye drops BP 0.7% w/v- 10ml

Batch No : 2F102 Temp : $40 \pm 2^{\circ}\text{C}$ Primary pack : LDPE
Mfg.date : June'02 RH : $75 \pm 5\%$ Secondary pack : Carton box
Exp.date : May'04 Shelf life: 2 years Formula : Same as in DMF

Manufg.method : MP-33

Source : Dow coming - USA.

S.No	Tests	Specification	Initial	2 months	4 months	5 months	6 months
1.	Description	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution	Clear, colorless slight viscous solution
2.	Label checking	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible	Clear & legible
3.	Uniformity of volume(ml)	NLT 10.0ml	10.1ml	10.1ml	10.0ml	10.1ml	10.0ml
4.	Identification a. with heating b. with acetic acid and tannic acid	The solution should be clear on cooling The yellowish white flocculent precipitate should be produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia	The solution should be clear on cooling The yellowish white flocculent precipitate is produced which is dissolves in 6M ammonia
5.	pH	8.2 - 8.6	8.21	8.31	8.36	8.42	8.46
6.	Refractive index at 30°C	1.335 - 1.338	1.3356	1.3356	1.3356	1.3356	1.3356
7.	Specific gravity at 25°C	1.005 - 1.012	1.010	1.010	1.010	1.010	1.010
8.	Viscosity at 25°C (cps)	40 - 70	58	55	50	50	48
9.	Assay Hydroxy propyl methyl cellulose	0.45% - 0.75%	0.725	0.720	0.685	0.680	0.678
10.	Chloride	4000 - 4900ppm	4875	4870	4850	4840	4825
11.	Benzalkonium chloride	0.009% - 0.0120%	0.0118	0.0114	0.0112	0.0109	0.0107
12.	Sterility	Should be No growth	No growth	No growth	No growth	No growth	No growth

Test conducted by: *S. Paulin Benta Mary*
Quality control chemist
Date: 15/12/02

Reviewed by: *S. Paulin Benta Mary*
Quality control chemist
Date: 15/12/02

Approved by: *A. Karpa Giam*
Quality Assurance Manager
Date: 15/12/02

REAL TIME STABILITY STUDY REPORT FOR HYPROMELLOSE

Batch No : 2F102
Mfg.date : Jun'02
Exp.date : May'04

Name of the product : Hypromellose 0.7% eye drops BP - 10ml
Temp : $30 \pm 2^\circ\text{C}$
RH : $60 \pm 5\%$
Shelf life : 2 years

Primary pack : 1.DPE
Secondary pack : Cartonbox

Exp. date : May'04		OBSERVED RESULTS												27 months
S.No	Tests	Specification	Initial Jun'02	3 months Sep'02	6 months Dec'02	9 months Mar'03	12 months June'04	18 months Dec'03	24 months June'04	25 months July'04	26 months Aug'04	27 months Sep'04		
1	Description	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution	Clear, slight viscous solution		
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 10.0ml	10	10	10	10	10	10	10	10	10	10		
4	Identification													
	a. with heating	The solution should be clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling	The solution is clear on cooling		
	b. With acetic acid and tannic acid	The yellowish white flocculent precipitate should be produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M	The yellowish white flocculent precipitate is produced this dissolves in 6M		
5	pH	Ammonia 8.2 - 8.6	8.21	8.23	8.28	8.31	8.33	8.36	8.41	8.42	8.45	8.52		
6	Refractive index at 30°C	1.335 - 1.338	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366	1.3366		
7	Specific gravity at 25°C	1.000 - 1.025	1.012	1.012	1.012	1.012	1.012	1.012	1.012	1.012	1.012	1.012		
8	Chloride	4000 - 4900ppm	4875	4845	4816	4805	4788	4764	4687	4587	4479	4398		
9	Viscosity	40 - 70cps	58	56	52	49	48	46	44	44	42	42		
10	Assay													
10	Hydroxy propyl methyl cellulose	0.45% - 0.75%	0.725	0.714	0.704	0.695	0.688	0.685	0.682	0.680	0.680	0.67		
11	Benzalkonium chloride	0.0090% - 0.0120%	0.011	0.0108	0.0101	0.0099	0.0098	0.0098	0.0095	0.0095	0.0094	0.0092		
12	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]*
Quality control chemist
Date : 20/09/04

Reviewed by : *[Signature]*
Quality control chemist
Date : 20/09/04

Approved by : *[Signature]*
Quality Assurance Manager
Date : 20/09/04