

Cipla

Location: PATALGANGA

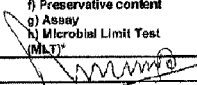
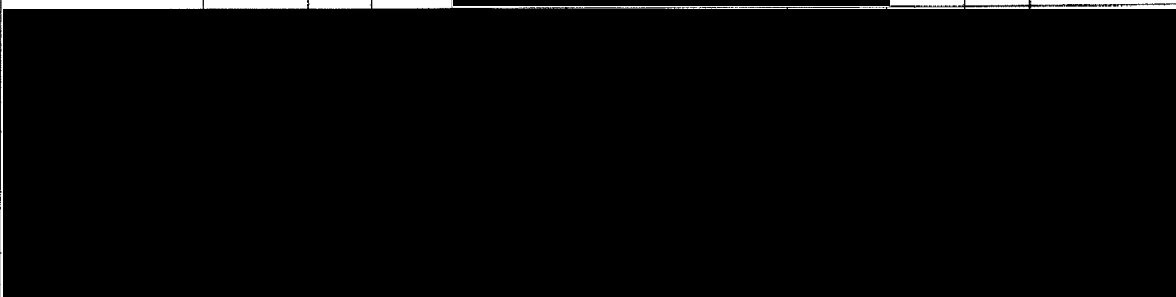
STABILITY TESTING FORM

(ACCELERATED TESTING)

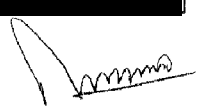
Label claim : Each spray delivers :

Azelastrone HCl BP 140 mcg

Fluticasone propionate BP 50 mcg

PROTOCOL									
Product : Duonase		Sample pack : PP transparent vials.		Tests to be performed:				Frequency of testing (Months)	
Batch No.: K51189		Quantity of sample: 10 Vials / Interval		a) Description b) Identification c) pH d) Wt per ml				Initial, 1, 2, 3 & 5	
Date of Manufacture : Dec. 2005.		Storage conditions : 40° ± 2° C / 75 % ± 5 % RH		e) Related substances f) Preservative content g) Assay h) Microbial Limit Test (MLT)*				Specification No.: SS FPS D1270 /01	
Page 1 of 2		Protocol approved by: 							
SUMMARY									
Period of keeping	A.R.No.	Tests to be performed						Tested By	Remarks
		Description	Identification	pH 5.00-7.00	Wt. per ml 0.95-1.05 g	Assay (% w/v)	Preservative content		
INITIAL	PG528355								
1 M	PG600322								
2 M	PG601733								
3 M	PG603079								
6 M	PG607717								

* To be done only at Initial, 24 M RT and 6 M ACC only


Head, Q.C. Dept.
QCP 15/F1

Cipla

STABILITY TESTING FORM

(ACCELERATED TESTING)

Location: PATALGANGA

Label claim : Each spray delivers :

Azelastin HCl BP 140 mcg

Fluticasone propionate BP 50 mcg

SUMMARY																		
Period of keeping	A.R.No.	Tests to be performed													Tested By	Remarks		
		For Azelastine content			Related substances												For Fluticasone content	
		1-methyl-4-(2-benzoylhydrazino)azepan NMT 0.20%	Single max. unknown impurity NMT 0.20%	Total impurities NMT 1.0%	Imp. A NMT 0.20%	IMP B NMT 0.20%	IMP C NMT 0.20%	IMP D NMT 0.30%	IMP E NMT 0.20%	IMP F NMT 0.20%	IMP G NMT 0.30%	IMP H NMT 0.20%	IMP I NMT 0.20%	Imp. with RRT about 1.23 NMT 0.20%			Single max. unknown imp. NMT 0.20%	Total Imp. NMT 1.50 %
INITIAL	PG528355																	
1 M	PG600322																	
2 M	PG601733																	
3 M	PG603079																	
6 M	PG607717																	

* To be done only at Initial , 24 M RT and 6 M ACC only

Head, Q.C. Dept.
QCP 15/F1

Cipla

Location: PATALGANGA

STABILITY TESTING FORM

(LONG TERM TESTING)

Label claim : Each spray delivers :

Azelastine HCl BP 140 mcg

Fluticasone propionate BP 50 mcg

Product : Duonase		Sample pack : PP transparent vials		Tests to be performed:				Frequency of testing (Months)			
Batch No.: K51189		Quantity of sample: 10 Vials / interval		a) Description b) Identification c) pH d) Wt per ml		e) Related substances f) Preservative content g) Assay h) Microbial Limit Test (MLT)*		Initial, 1, 2, 3, 6, 9, 12, 18, 24 & 36			
Date of Manufacture : Dec. 2005		Storage conditions : 30° ± 2° C / 65 % ± 5 % RH		Protocol approved by : <i>[Signature]</i>				Specification No.: SS FPS D1270 /01			
Page 1 of 2											
SUMMARY											
Period of keeping	A.R.No.	Tests to be performed								Tested By	Remark
		Description	Identification	pH 5.00-7.00	Wt. per ml 0.95-1.05 g	Assay (% w/v)	Preservative content	MLT*			
INITIAL	PG528355										
3 M	PG603111										
6 M	PG607769										
9 M	PG612400										
12 M	PG617104										
18 M											
24 M											
36 M											

* To be done only at Initial, 24 M RT and 6 M ACC only

[Signature]
Head, Q.C. Dept.
QCP 15/F1

Location: PATALGANGA

Label claim : Each spray delivers :

Azelastine HCl BP 140 mcg

Fluticasone propionate BP 50 mcg

PRODUCT INFORMATION				PROTOCOL			
Product : Duonase	Sample pack : PP transparent vials	Tests to be performed:		Frequency of testing (Months)			
Batch No.: K51189	Quantity of sample: 10 Vials / interval	a) Description b) Identification c) pH d) Wt per ml	e) Related substances f) Preservative content g) Assay h) Microbial Limit Test (MLT)*	Initial, 1, 2, 3, 6, 9, 12, 18, 24 & 36			
Date of Manufacture : Dec. 2005	Storage conditions : 30° ± 2° C / 65 % ± 5 % RH	Protocol approved by :		Specification No.: SS FPS D1270 /01			
Page 2 of 2							

SUMMARY																
Period of keeping	A.R.No.	Tests to be performed														
		Related substances														
		For Azelastine content					For Fluticasone content									
		1-methyl-4-(2-benzoylhydrazino)azepan NMT 0.20%	Single max. unknown impurity NMT 0.20%	Total Impurities NMT 1.0%	Imp. A NMT 0.20%	IMP B NMT 0.20%	IMP C NMT 0.20%	IMP D NMT 0.30%	IMP E NMT 0.20%	IMP F NMT 0.20%	IMP G NMT 0.30%	IMP H NMT 0.20%	IMP I NMT 0.20%	Imp. with RRT about 1.23 NMT 0.20%	Single max. unknown imp. NMT 0.20%	Total Imp. NMT 1.50 %
INITIAL	PG528355															
3 M	PG503111															
6 M	PG507796															
9 M	PG612400															
12 M	PG617104															
18 M																
24 M																
36 M																

* To be done only at Initial, 24 M RT and 6 M ACC only

Head, Q.C. Dept.

QCP 15/F1