

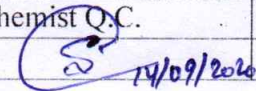
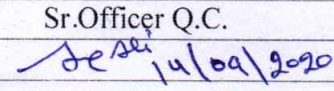
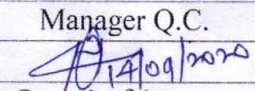
The Drugs & Cosmetic Act 1940 and the Rules there under

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

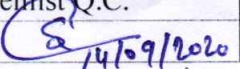
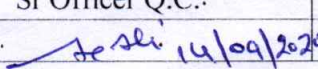
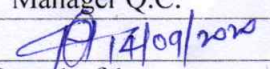
Name of Product : Cromidin 0.03%			Name of Product : Tacrolimus Ointment 0.03% w/w		
S.R..No. : 1292			Sampling Date : 28/08/2020		
Batch No. : H20163			Testing Date : 03/09/2020		
Batch Size : 62.00 Kg			Mfg . Date : 08/2020		
Sample Qty. : 20 Tube			Exp . Date : 07/2022		
Packing size : 1 x 5 gm			Release Date : 14/09/2020		
Finished Product AR No. HLL/FG-1292/20-21					
S.	PARAMETER	RESULT		SPECIFICATION	
1.	Description	White thick mass filled in printed lami tube.		White thick mass filled in printed lami tube..	
2.	Identification	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.		The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.	
3.	Average filled weight	5.0084gm		Not less than 5.0 gm.	
4.	Uniformity of filled weight	With in limits		Not less than 5.0 gm. and any single container with in ± 9.0 % labeled weight.	
5.	Viscosity	90257 cps		85000 cps to 115000 cps	
6.	Related Substances	Not detected Not detected		Individual Impurities NMT 0.2% Total Impurities NMT 1.0%	
7.	Assay				
	Tacrolimus USP 0.03 %w/w	0.0303%w/w (101.00%)		90.0 % to 110.0 % of the labeled amount of C ₁₆ H ₁₆ N ₄ O ₈ S	
8.	Microbial Limit Test				
	Total Aerobic Microbial count	5 CFU/g		Not more than 100 CFU/g	
	Total yeast and Mould count	<1 CFU/g		Not more than 10 CFU/g	
	Pseudomonas aeruginosa	Absent/g		Should be absent/g	
	Staphylococcus aureus	Absent/g		Should be absent/g	
	Salmonella	Absent/g		Should be absent/g	
	Escherichia Coli	Absent/g		Should be absent/g	

Remarks: Finished product sample complies / ~~does not complies~~ as per Specification No. HLL/QCD/FP/STS/0182A-03.

Name	Tested by	Checked by	Approved by
	Sachin Kumar	Javed Ali	Naveen Kumar Chauhan
Designation	Chemist Q.C.	Sr. Officer Q.C.	Manager Q.C.
Sign & Date	 14/09/2020	 14/09/2020	 14/09/2020

 Hiral Labs Ltd.		HIRAL LABS LTD KHASARA NO , 265, VILLAGE : SI SONA , PARGANA BHAGWANPUR , TEHSIL – ROORKEE, DIST : - HARIDWAR , (U.K) INDIA Mfg. Lic No. 56/UA/2006 & 55/UA/SC/P – 2006	
The Drugs & Cosmetic Act 1940 and the Rules there under			
QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
Name of Product : Cromidin 0.03%		Name of Product : Tacrolimus Ointment 0.03% w/w	
S.R.No. : 1293		Sampling Date : 29/08/2020	
Batch No. : H20164		Testing Date : 03/09/2020	
Batch Size : 61.00 Kg		Mfg. Date : 08/2020	
Sample Qty. : 20 Tube		Exp. Date : 07/2022	
Packing size : 1 x 15 gm		Release Date : 14/09/2020	
Finished Product AR No. HLL/FG-1293/20-21			
S.	PARAMETER	RESULT	SPECIFICATION
1.	Description	White thick mass filled in printed lami tube.	White thick mass filled in printed lami tube.
2.	Identification	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.
3.	Average filled weight	15.0618gm	Not less than 15.0 gm.
4.	Uniformity of filled weight	With in limits	Not less than 15.0 gm. and any single container with in ± 9.0 % labeled weight.
5.	Viscosity	92316 cps	85000 cps to 115000 cps
6.	Related Substances	Not detected Not detected	Individual Impurities NMT 0.2% Total Impurities NMT 1.0%
7.	Assay		
	Tacrolimus USP 0.03 %w/w	0.0304%w/w (101.33%)	90.0 % to 110.0 % of the labeled amount of $C_{16}H_{16}N_4O_8S$
8.	Microbial Limit Test		
	Total Aerobic Microbial count	10 CFU/g	Not more than 100 CFU/g
	Total yeast and Mould count	<1 CFU/g	Not more than 10 CFU/g
	Pseudomonas aeruginosa	Absent/g	Should be absent/g
	Staphylococcus aureus	Absent/g	Should be absent/g
	Salmonella	Absent/g	Should be absent/g
	Escherichia Coli	Absent/g	Should be absent/g

Remarks: Finished product sample complies / ~~does not complies~~ as per Specification No. HLL/QCD/FP/STS/0182-03.

Name	Tested by Sachin Kumar	Checked by Javed Ali	Approved by Naveen Kumar Chauhan
Designation	Chemist Q.C.	Sr Officer Q.C.	Manager Q.C.
Sign & Date	 14/09/2020	 14/09/2020	 14/09/2020



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(U.K) INDIA
Mfg. Lic No. 56/UA/2006 & 55/UA/SC/P – 2006

The Drugs & Cosmetic Act 1940 and the Rules there under

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Name of Product : Cromidin 0.1%

Name of Product : Tacrolimus Ointment 0.1% w/w

S.R.No. : 1294

Sampling Date : 01/09/2020

Batch No. : H20166

Testing Date : 03/09/2020

Batch Size : 92.00 Kg

Mfg. Date : 08/2020

Sample Qty. : 20 Tube

Exp. Date : 07/2022

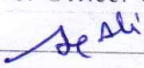
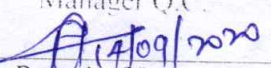
Packing size : 1 x 15 gm

Release Date : 14/09/2020

Finished Product AR No. HLL/FG-1294/20-21

S.	PARAMETER	RESULT	SPECIFICATION
1.	Description	White thick mass filled in printed lami tube.	White thick mass filled in printed lami tube.
2.	Identification	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.
3.	Average filled weight	15.0225gm	Not less than 15.0 gm.
4.	Uniformity of filled weight	With in limits	Not less than 15.0 gm. and any single container with in ± 9.0 % labeled weight.
5.	Viscosity	93253 cps	85000 cps.to 115000 cps
6.	Related Substances	Not detected Not detected	Individual Impurities NMT 0.2% Total Impurities NMT 1.0%
7.	Assay		
	Tacrolimus USP 0.10 %w/w	0.102%w/w (102.0%)	90.0 % to 110.0 % of the labeled amount of $C_{16}H_{16}N_4O_8S$
8.	Microbial Limit Test		
	Total Aerobic Microbial count	10 CFU/g	Not more than 100 CFU/g
	Total yeast and Mould count	<1 CFU/g	Not more than 10 CFU/g
	Pseudomonas aeruginosa	Absent/g	Should be absent/g
	Staphylococcus aureus	Absent/g	Should be absent/g
	Salmonella	Absent/g	Should be absent/g
	Escherichia Coli	Absent/g	Should be absent/g

Remarks: Finished product sample complies / ~~does not complies~~ as per Specification No. HLL/QCD/FP/STS/0269-03.

Name	Tested by	Checked by	Approved by
Designation	Sachin Kumar	Javed Ali	Naveen Kumar Chauhan
Sign & Date	Chemist Q.C.  14/09/2020	Sr Officer Q.C.  14/09/2020	Manager Q.C.  14/09/2020

 Hiral Labs Ltd.		HIRAL LABS LTD KHASARA NO , 265, VILLAGE : SISONA , PARGANA BHAGWANPUR , TEHSIL – ROORKEE, DIST : - HARIDWAR , (U.K) INDIA Mfg. Lic No. 56/UA/2006 & 55/UA/SC/P – 2006	
The Drugs & Cosmetic Act 1940 and the Rules there under			
QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
Name of Product : Cromidin 0.1%		Name of Product : Tacrolimus Ointment 0.1% w/w	
S.R.No. : 1295		Sampling Date : 30/08/2020	
Batch No. : H20165		Testing Date : 03/09/2020	
Batch Size : 62.00 Kg		Mfg. Date : 08/2020	
Sample Qty. : 20 Tube		Exp. Date : 07/2022	
Packing size : 1 x 5 gm		Release Date : 14/09/2020	
Finished Product AR No. HLL/FG-1295/20-21			
S.	PARAMETER	RESULT	SPECIFICATION
1.	Description	White thick mass filled in printed lami tube.	White thick mass filled in printed lami tube.
2.	Identification	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.	The retention time of the major peak of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.
3.	Average filled weight	5.0097gm	Not less than 5.0 gm.
4.	Uniformity of filled weight	With in limits	Not less than 5.0 gm. and any single container with in ± 9.0 % labeled weight.
5.	Viscosity	93287 cps	85000 cps to 115000 cps
6.	Related Substances	Not detected Not detected	Individual Impurities NMT 0.2% Total Impurities NMT 1.0%
7.	Assay		
	Tacrolimus USP 0.10 %w/w	0.103%w/w (103.0%)	90.0 % to 110.0 % of the labeled amount of $C_{16}H_{16}N_4O_8S$
8.	Microbial Limit Test		
	Total Aerobic Microbial count	20 CFU/g	Not more than 100 CFU/g
	Total yeast and Mould count	<1 CFU/g	Not more than 10 CFU/g
	Pseudomonas aeruginosa	Absent/g	Should be absent/g
	Staphylococcus aureus	Absent/g	Should be absent/g
	Salmonella	Absent/g	Should be absent/g
	Escherichia Coli	Absent/g	Should be absent/g

Remarks: Finished product sample complies / ~~does not complies~~ as per Specification No.

HLL/QCD/FP/STS/0269A-03.

Name	Tested by	Checked by	Approved by
	Sachin Kumar	Javed Ali	Naveen Kumar Chauhan
Designation	Chemist Q.C.	Sr Officer Q.C.	Manager Q.C.
Sign & Date	 14/09/2020	 14/09/2020	 14/09/2020