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 0.03%	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 $C_{16}H_{16}N_4O_8S$
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.

	Tested by	Checked by	Approved by
Name	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

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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.

	Tested by	Checked by	Approved by
Name	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

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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.

	Tested by	Checked by	Approved by
Name	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

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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.

	Tested by	Checked by	Approved by
Name	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