

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 Exp . Date. Sample Qty.: 20 Tube 07/2022 Packing size: 1 x 5 gm Release Date 14/09/2020 Finished Product AR No. HLL/FG-1292/20-21 PARAMETER. S. RESULT **SPECIFICATION** Description 1. ·White thick mass filled in printed White thick mass filled in printed lami tube. lami tube... 2. The retention time of the major peak The retention time of the major peak of the Sample solution Corresponds of the Sample solution Corresponds Identification to that of the Standard solution as to that of the Standard solution as obtained in the assay. obtained in the assay. 3. Average filled weight 5.0084gm Not less than 5.0 gm. With in limits 4. Not less than 5.0 gm. and any single Uniformity of filled weight container with in ±9.0 % labeled weight. 90257 cps 5. Viscosity 85000 cps to 115000 cps Not detected 6 Related Substances Individual Impurities NMT 0.2% Not detected Total Impurities NMT 1.0% 7. Assay 90.0 % to 110.0 % of the labeled Tacrolimus USP 0.03 %w/w 0.0303%w/w (101.00%) amount of C16H16N4O8S 8. Microbial Limit Test Total Aerobic Microbial count 5 CFU/g Not more than 100 CFU/g

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

<1· CFU/g

Absent/g

Absent/g

Absent/g

Absent/g

Total yeast and Mould count

Pseudomonas aeruginosa

Staphylococcus aureus

Salmonella

Escherichia Coli

	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 ·	(5) 19/09/2020	de sei 4/09/ 2020	A14109 2020
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Not more than 10 CFU/g

Should be absent/g

Should be absent/g

Should be absent/g

Should be absent/g



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		QUALITY CON	TROL DEPARTMENT		
		CERTIFICA	TE OF, ANALYSIS		
Nan	ne of Product: Cromidin 0.039	% .	Name of Product	: Tacrolimus Ointment 0.03% w/w	
S.R	No. : 1293		Sampling Date :	29/08/2020	
Bate	ch No. : H20164		Testing Date :		
	ch Size : 61.00 Kg		Mfg . Date :		
	iple Qty.: 20 Tube		Exp. Date : 07/2022		
	king size : 1 x 15 gm		Release Date :	14/09/2020	
		G-1293/20-21		CDECUEIG A TION	
S.	PARAMETER	RESULT		SPECIFICATION	
1.	Description .	White thick mass lami tube.	s filled in printed	White thick mass filled in printed lami tube.	
2.		The retention tim	e of the major peak	The retention time of the major peak	
	Identification	of the Sample solution Corresponds to that of the Standard solution as obtained in the assay.		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 Şubstances	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					
0.	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	(8/11/09/2020	· 10/09/20	020 A 14/09/20x
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		e Drugs & Cosmetic Act			
		QUALITY CONT	ROL DEPARTMENT		
		CERTIFICAT	E OF ANALYSIS		
Na	me of Product : Cromidin 0.19	/0	Name of Product	: Tacrolimus Ointment 0.1% w/w	
-	RNo. : 1294 .		Sampling Date .	01/09/2020	
	tch No. : H20166		Sampling Date : 01/09/2020 Testing Date : 03/09/2020		
	tch Size : 92.00 Kg			08/2020	
	nple Qty.: 20 Tube		Exp. Date	: 07/2022	
Pac	cking size: 1 x 15 gm		Release Date	: 14/09/2020	
S.	ished Product AR No. HLL/F PARAMETER	G-1294/20-21			
1.	Description	RESULT .		SPECIFICATION	
	Description	White thick mass lami tube.		White thick mass filled in printed lami tube.	
2.	Identification The retention time of to fine Sample solution to that of the Standar obtained in the assay.		ution Corresponds ndard solution as	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.	
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			Total Impurities (WIT 1.070	
	Tacrolimus USP 0.10 %w/w	0.102%w/w (102	2.0%)	90.0 % to 110.0 % of the labeled amount of $C_{16}H_{16}N_4O_8S$	
3.	Microbial Limit Test			1 11/16/11/6/14085	
	Total Aérobic 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 Sachin Kumar	Checked by Javed Ali	Approved by Naveen Kumar Chauhan
Designation .	Chemist Q.C.	Sr Officer Q.C.	Manager O.C.
Sign & Date	(STUT. 9/20	de shi 14/09/2020	A14/09/2020
	14/-11	. 700 1310 17	Part (4/04) 1/2



Escherichia Coli

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The Drugs & Cosmetic Act 1940 and the Rules there under

		QUALITY CONT	ROL DEPARTMENT		
		CERTIFICAT	E OF ANALYSIS		
Nar	me of Product: Cromidin 0.1%	ó	Name of Product	: Tacrolimus Ointment 0.1% w/w	
S.R	No. : 1295		Sampling Date:	30/08/2020	
	ch No. : H20165		Testing Date :		
	ch Size : 62.00 Kg		Mfg . Date :		
	nple Qty.: 20 Tube		Exp. Date · : 07/2022		
	king size: 1 x 5 gm		Release Date :	14/09/2020	
		G-1295/20-21		apparer a man	
S.	PARAMETER	RESULT		SPECIFICATION	
1.	Description	White thick mass lami tube.	filled in printed	White thick mass filled in printed lami tube.	
2.			of the major peak	The retention time of the major peak	
	1.14:G4:	of the Sample solution Corresponds		of the Sample solution Corresponds	
	Identification	to that of the Standard solution as		to that of the Standard solution as	
		obtained in the ass	ay.	obtained in the assay.	
3.	Average filled weight	5.0097gm .		Not less than 5.0 gm.	
4.	•	With in limits		Not less than 5.0 gm. and any single	
	Uniformity of filled weight			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 (10	3.0%)	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	
	C I 'I' C I'			C1 111 1	

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

Absent/g

	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	. (Symbol 2020	se Alylog 2000	\$1A109/2020
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Should be absent/g