

S KANT HEALTHCARE LIMITED.

1802 - 1805, GIDC, Phase III, Vapi - 396 195 (Gujarat), India. Tel : (+91-260) 2422516/7-8, Fax : (91-260) 2430527.

**QUALITY CONTROL DEPARTMENT****CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT****PRODUCT NAME: NYSTATIN OINTMENT USP 100000 IU/G****GENERIC NAME: NYSTATIN OINTMENT USP 100000 IU**

Batch No.	: NA20003	A.R.No	: SKF0854/20
Mfg. Date	: JUL-2020	Exp. Date	: JUN-2022
Qty. Sampled	: 14 x 15 g	Batch Size	: 300.00 KG
Sampled Date	: 17.07.2020	Report Date	: 13.08.2020

Sr. No.	TEST	OBSERVATION	ACCEPTANCE CRITERIA
1.	DESCRIPTION	Pale Yellow Coloured homogenous Ointment	Pale Yellow Coloured homogenous Ointment.
2.	WATER (METHOD-I)	0.2584 %	Not more than 0.5 %
3.	MINIMUM FILL	Min: 15.01 g Max: 15.02 g	Not less than 15.0 g
4.	ASSAY CONTENT OF Nystatin USP 100000 I.U./g	111277 IU/g 111.3 %	Release Limit: Between 97000 IU/g and 130000 IU/g (Between 97.0 and 130.0 % of L.A.) Shelf life Limit: Between 90000 IU/g and 130000 IU/g (Between 90.0 and 130.0 % of L.A.)
5.	MICROBIAL LIMIT TEST A) TOTAL BACTERIAL COUNT B) TOTAL FUNGAL COUNT C) ESCHERICHIA COLI D) SALMONELLA E) PSEUDOMONAS AERUGINOSA F) STAPHYLOCOCCUS AUREUS	Less than 10 cfu/g Less than 10 cfu/g Absent / g Absent / 10 g Absent / g Absent / g	Not more than 100 cfu / g Not more than 10 cfu / g Should be Absent / g Should be Absent / 10 g Should be Absent / g Should be Absent / g
6.	IDENTIFICATION BY HPLC	Complies	The retention time of Nystatin peak in the chromatogram of sample preparation should corresponds to that in the chromatogram of the standard preparation.
7.	VISCOSITY	1020000 to 1190000 cps	Between 600000 to 1300000 cps

Remarks: In the opinion of the undersigned the sample complies/~~does not comply~~ as per USP & specification no: SPC/FP/N08/03, SPC/FP/N08-A/00, and SPC/FP/N08-B/00. Pack Code No.N1018C01.

Prepared by:	Checked by:	Approved by :
Date:	Date:	Date:
Name: Vivek Panday	Name: Jayesh Patel	Name: Mahesh Patel
Designation: Officer	Designation: QC/QA Officer	Designation: Asst. Manager

Reg. Head office: 3-A, Shivsagar Estate, Dr. A.B. Road, Worli, Mumbai - 400 018, India. Tel : (+91-22) 66227575, Fax: (+ 91-22) 66227500.
 FORMAT No. : SK/QC/022 - 03/01