Macleods Pharmaceuticals Limited, Block-N2, Village: Theda, P.O.:Lodhimaira, Tehsil: Baddi, Dist.-Solan, Himachal Pradesh 174101, India.	MACLEODS

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Name of Product: LAMIVUDINE ORAL SOLUTION (10 mg/ mL)

Batch No.	BLH12305A	**Batch Size**	3333 Bottle
A.R. No.	BAFPS23000291	**Stage**	FINISHED (PACKING)
Product Code	WP003462	**Market**	PFSCM (ENG/FRENCH/SPANISH)
Mfg. Date	Jun-2023	**Exp. Date**	May-2025
Specification Id	CO/SPC/CQA/WP003462R-000	**STP No.**	CO/STP/CQA/WP003462-000
Date of Analysis	14-Jul-2023 13:00	**Date of Release**	17-Jul-2023 14:30

S. No.	TEST	SPECIFICATION	RESULT
1	**DESCRIPTION**	Clear, colorless to pale yellow, flavored liquid.	Clear, colorless, flavored liquid.
2	**IDENTIFICATION**		
2.1	**For Lamivudine By HPLC**	The retention time of the Lamivudine peak in the chromatogram of sample preparation should correspond to that of the Lamivudine peak in the chromatogram of standard preparation as obtained in the "Assay".	The retention time of the Lamivudine peak in the chromatogram of sample preparation correspond to that of the Lamivudine peak in the chromatogram of standard preparation as obtained in the "Assay".
2.2	**By UV**	The UV absorption spectra of sample and standard preparation should be concordant.	The UV absorption spectra of sample and standard preparation is concordant.
2.3	**For Preservatives (By HPLC) Propyl paraben and methyl paraben**	The retention time of the Propyl paraben and Methyl paraben peaks in the chromatogram of sample preparation should correspond to that of the Propyl paraben and Methyl paraben peaks in the chromatogram of standard preparation as obtained in the test for "Antimicrobial Preservative Content".	The retention time of the Propyl paraben and Methyl paraben peaks in the chromatogram of sample preparation correspond to that of the Propyl paraben and Methyl paraben peaks in the chromatogram of standard preparation as obtained in the test for "Antimicrobial Preservative Content".
3	**WEIGHT PER ML (g/mL)**	1.10 ± 0.1	1.08 g/mL
4	**DELIVERABLE VOLUME (Labeled volume : 240 mL)**	The average volume should not be less than 100% of the volume declared in the labeling and volume of no container should be less than 95% of the volume declared in the labeling.	Min volume:100 % Max volume:101 % Average volume:100 %

Remark(s): APPROVED (Sample conforms to above Specification)

Comment(s): Approved

Prepared By (Role/Employee ID)	MANOJ.KUMAR (Reviewer/H017985)	**Reviewed By (Role/Employee ID)**	SUCHINDRA.KUMAR (Manager QC/H002521)	**Approved By (Role/Employee ID)**	NITIN.SINGH (Manager QA/H017560)
Prepared On	15-Jul-2023 14:16	**Reviewed On**	15-Jul-2023 15:11	**Approved On**	17-Jul-2023 14:30

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5	**pH**	5.7 to 6.3	6.092
6	**RELATED SUBSTANCES (By HPLC, % w/w)**		
6.1	**Unknown - 1 impurity (with RRT of about 0.41)**	Not more than 0.7	BELOW LIMIT OF QUANTITATION
6.2	**Unknown - 2 impurity (with RRT of about 0.43)**	Not more than 0.3	BELOW LIMIT OF QUANTITATION
6.3	**Impurity J**	Not more than 3.5	Not Detected
6.4	**Any other impurity**	Not more than 0.20	BELOW LIMIT OF QUANTITATION
6.5	**Total impurities**	Not more than 6.5	BELOW LIMIT OF QUANTITATION
7	**RESIDUAL SOLVENTS**	Should comply with option 1 of USP residual solvents <467>.	Complies with option 1 of USP residual solvents <467>.
8	**ASSAY (By HPLC, For Lamivudine [$C_8H_{11}N_3O_3S$])**	mg per mL - Not less than 9.0 and not more than 10.5 % label claim - Not less than 90.0 and not more than 105.0	mg per mL:9.98 mg % label claim:99.8 %
9	**ANTIMICROBIAL PRESERVATIVE CONTENTS (By HPLC)**		
9.1	**Methyl paraben [$C_8H_8O_3$]**	mg per mL - Not less than 0.75 % added amount (1.5 mg/ mL) - Not less than 50.0	mg per mL:1.50 mg % added amount (1.5 mg/ mL):100.0 %
9.2	**Propyl paraben [$C_{10}H_{12}O_3$]**	mg per mL - Not less than 0.09 % added amount (0.18 mg/ mL) - Not less than 50.0	mg per mL:0.18 mg % added amount (0.18 mg/ mL):99.2 %
10	**MICROBIAL ENUMERATION TESTS AND TESTS FOR SPECIFIED MICROORGANISMS**		

Remark(s): APPROVED (Sample conforms to above Specification)

Comment(s): Approved

Prepared By (Role/Employee ID)	MANOJ.KUMAR (Reviewer/H017985)	**Reviewed By (Role/Employee ID)**	SUCHINDRA.KUMAR (Manager QC/H002521)	**Approved By (Role/Employee ID)**	NITIN.SINGH (Manager QA/H017560)
Prepared On	15-Jul-2023 14:16	**Reviewed On**	15-Jul-2023 15:11	**Approved On**	17-Jul-2023 14:30

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S. No.	TEST	SPECIFICATION	RESULT
10.1	**Microbial enumeration tests**		
10.1.1	**Total aerobic microbial count (cfu / mL)**	Not more than 100	<10 cfu/mL
10.1.2	**Total combined molds and yeast (cfu/ mL)**	Not more than 10	<10 cfu/mL
10.2	**Tests for specified microorganisms**		
10.2.1	**Staphylococcus aureus**	Should be absent	Absent
10.2.2	**Pseudomonas aeruginosa**	Should be absent	Absent
10.2.3	**Salmonella species**	Should be absent	Absent
10.2.4	**Escherichia coli**	Should be absent	Absent

Remark(s): APPROVED (Sample conforms to above Specification)

Comment(s): Approved

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