



Sanpras Healthcare
Pvt. Ltd.

CERTIFICATE OF ANALYSIS

Name of Product	:	LACTULOSE SOLUTION USP		
Batch No.	:	SH1892005	Batch Size	: 3000 Litres
Date of Mfg.	:	05/2020	Date of Exp.	: 04/2022
Date of Sampling	:	27/05/2020	Date of Analysis	: 27/05/2020
Sample Qty.	:	13 X 200 ML	A. R. No.	: FP-20-135
Date of Released	:	01/06/2020	USP R.S No.	: LOT:R04531

LC No.: I023040 Dt. 25/05/2020

Sr	Test	Specification	Results
1.	Description	Colourless or pale brownish yellow clear or not more than slightly opalescent viscous solution.	A clear almost colourless not more than slightly opalescent viscous solution.
2.	pH	2.5 to 6.5	4.12
3.	Weight per ml	1.30 to 1.40 gm/ml	1.3251 gm/ml
4.	Filled Volume	NLT 200.0 ml	201.2
5.	Leak Test	Test with 8 bottles, no bottle should show leakage.	Complies
6.	Identification A	The retention time for the main peak in the sample solution corresponds to the peak of the standard solution.	Complies
	Identification B	A red precipitate of cuprous oxide is formed.	Complies
7.	Uniformity of Dosage Units	NMT 15	0.50
8.	Assay: Each 100 ml Contains 1) Lactulose Concentrate USP eq. to Lactulose ----- 66.7 gm	90.0 % to 110.0 % of label claim	97.72 %
9.	Organic Impurities		
	a) Fructose	NMT 1 %	0.011 %
	b) Galactose	NMT 16 %	3.384 %
	c) Epilactose	NMT 8 %	1.036 %
	d) Lactose	NMT 12 %	1.823 %
	e) Tagatose	NMT 4 %	0.229 %
10.	Microbial Limit Test		
	Total Aerobic Microbial Count	NMT 100 cfu/ml	15 cfu/ml
	Total yeast & mould count	NMT 10 cfu/ml	<1 cfu/ml
	<i>Escherichia coli</i>	Should be absent per ml	Absent
	<i>Salmonella Spp.</i>	Should be absent per ml	Absent
	<i>Pseudomonas aeruginosa</i>	Should be absent per ml	Absent
	<i>Staphylococcus aureus</i>	Should be absent per ml	Absent

Remark: The above batch has been analysed against USP reference standard no. LOT: R04531. The above sample complies with USP/Inhouse specification.

ANALYSED BY	CHECKED BY	AUTHORISED BY
<i>S 01/06/2020</i> SANTOSH PAWASE Q.C. EXECUTIVE	<i>S 01/06/2020</i> SUNIL THORAT Q.A. EXECUTIVE	<i>@ 01/06/2020</i> MAHESH RANADE Q.C. EXECUTIVE

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