



WRS  
L33-1

**KAMRON LABORATORIES LIMITED.**  
**GUJARAT, INDIA**  
**WORKING STANDARD PREPARATION REPORT**  
**CERTIFICATE OF ANALYSIS OF WORKING STANDARD**

**DEPARTMENT: QUALITY CONTROL**

**Format No.: QC/F/018**

Name of Working Standard : Lactulose Concentrate

Working Standard No : WS/ CL/LLS/092/15

Date of Preparation of Working Standard: 23/01/2015

Mfg Date : 01/2015

Exp. Date: 12/2017

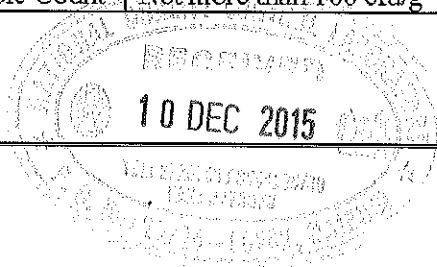
Batch No. : CL/LLS/092/15

Use Before: 1 year

Use within 6 months after opening

No. of vials prepared: 11

SR.NO.	TEST	SPECIFICATION	RESULT
1	Description	A colorless or pale brownish-yellow clear or not more than slightly opalescent viscous solution.	Complies
2	Solubility	Miscible with water.	Complies
3	Identification		
	Test A	The retention time of the major peak in the chromatogram of the assay test preparation corresponds to that in the chromatogram of the Standard preparation.	Complies
	Test B	A red precipitate of cuprous oxide should form.	A red precipitate of cuprous oxide is formed.
4	Refractive index	Not less than 1.451, at 20 °.	1.450
5	Residue on ignition	Not more than 0.1%	0.055 %
6	Related Substances		
	Galactose	NMT 16.0 %	Complies
	Lactose	NMT 12.0 %	Complies
	Epilactose	NMT 8.0 %	Complies
	Fructose	NMT 1.0 %	Complies
	Total unknown substances	NMT 10.0 %	Complies
7	Assay by HPLC	It contains not less than 66.5 % and not more than 73.5 % of lactulose (95.0 % to 105 % labeled amount of Lactulose.)	68.0 %
<b>ADDITIONAL TEST</b>			
	Microbial Purity Total Viable Aerobic Count	Not more than 100 cfu/g	55



1	Bacteria Yeast/ Mould Salmonella, Escherichia Coli	Should be Negative Should be Negative	Absent Absent
2	pH	2.5 to 6.5	4.40
3	Weight per ml	1.25 g/ml to 1.40 g/ml	1.34 g/ml

Remarks: The above working standard conforms to In House Specification.

<b>Analysed by: Q.C. Chemist</b>	<b>Checked by: Q.C. manager</b>
Ms. Komal Patel	Ms. Ankita Shah
<i>K. Patel</i>	<i>Anshah</i>

