Drug International Limited(Unit-2)

Department of Quality Assurance

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Test Report

Test Report No. : S19110003 **Date** : 26-Nov-2019

Date of Sample Received : 26-Nov-2019

Sample ID : S19110003

Name & Contact information of Sample Sender : Warehouse Department

Description of the Sample :

Name of Sample : Lactulose Solution

Batch No : 27NCA580

Received Quantity : 230

Manufacturer / Source : Fresenius Kabi iPSUM S.r.l - Vicchio (Italy)

Manufacturing Date : 02-Mar-2019

Expiry Date : 02-Mar-2022

Sample Description : All samples are in good condition. No dent drum is containing any material.

Detailed Description of Test/Analyses :

Test Items	Acceptance Criteria	Declared Claim	Test Result	Unit	Test Date	Reference Method	Uncertainity
Aerobic Microbial Count (TAMC)	Not more than 100 CFU/g		test in progress	cgu/g	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Appearance	clear, viscous liquid, colorless or pale brownfish		clear viscous liquid	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Solubility	Miscible with water. It may be a supersaturated solution or may contain crystals that disappear on heating		Miscible with water. It may be a	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Identification	A) Examine the chromatograms obtained in the assay B) A red precipitate is formed (Identification test of bp) C) A red colour develops (Identification test D of bp) D) The infrared absorption sepctrum of the sample should be concordant with the infrared absorption spectrum of the working standard		Conforms	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Optical Rotation	10% v/v solution is laevorotary		(-) 4.16	%	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Appearance of Solution	The Solution is clear and not more intensely colored than reference solution BY5		conforms	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Refractive Index	Not less than 1.451 (at 200C)		1.462	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
pH	3.0 to 7.0		4.7	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Assay (Lactulose % w/w)	Not less than 70.0% w/w		53.4%	%w/w	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Assay (Lactulose % w/v)	Not less than 50.7% w/v		71.4%	%w/v	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Related substances	Impurity B: Not more than 15.0% Impurities A, C: Not more than 10.0% Impurity E: Not more than 4.0% Impurity D: Not more than 1.0%		not detected	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	
lead	Not more than 0.5 ppm		less than 0.5 ppm	ppm	26-Nov-2019	British pharmacopoeia 2018, Volume III	
Boron	Not more than 5 ppm		less than 5 ppm	ppm	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Sulfites	Not more than 30 ppm		less than 30 ppm	ppm	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Methanol	Not more than 30 ppm		Less than 30 ppm	ppm	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Density	Not more than 1.38 gm/ml		1.34 gm/ml	gm/ml	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Sulfated ash	Not more than 0.2%		less than 0.2%	ppm	26-Nov-2019	British pharmacopoeia 2018, Volume I	
Escherichia coli	absence/g		absent	n/a	26-Nov-2019	British pharmacopoeia 2018, Volume I	

Remarks (If any) : All the test results meet the specification

Decision Rule : **Tested sample confirms to the specification**

MD. FIROJ MAHMUD
Engineering Incharge
Verified by

MD. ABUL KALAM AZAD
Head of QA
Approved by