
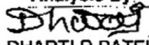
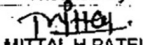
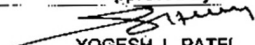


Figure S1. Impurity test results of the batch of lactulose used.

 <b>TUTON PHARMACEUTICALS</b> 85, G.I.D.C. ESTATE,,RELIANCE ROAD,NARODA,AHMEDABAD-382330 REG.OFF.: 85, G.I.D.C. ESTATE,,RELIANCE ROAD,NARODA,AHMEDABAD-382330 Phone : 40082244 TO 48 Fax : 40082248 Email : jaimish@tutonpharma.com; pankil@tutonpharma.com <b>A/C OF INTAS PHARMACEUTICALS LTD</b> <b>QUALITY CONTROL DEPARTMENT</b> THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F)) <b>CERTIFICATE OF ANALYSIS (FINISH STAGE)</b>			
<b>Product Name</b> : LOOZ <b>Generic Name</b> : LACTULOSE SOLUTION U.S.P. <b>Product Code</b> : 37LL03U		<b>Batch No.</b> : LY55161 <b>Batch Size</b> : 2000 LTR	
<b>Label Claim</b> Each 15 ml contain: Lactulose concentrate U.S.P. eq. to Lactulose..... 10 gm Aqueous flavoured..... q.s. Colour: Caramel		<b>Location</b> : NARODA <b>Make</b> : INTAS <b>Mfg. Lic No.</b> : G/1177-A <b>Specification No.</b> : 1617FPSL03U <b>Specification Dt.</b> : 15-07-2016  <b>Test As Per</b> : USP <b>Test Packing</b> : 1X202ML <b>Sample Size</b> : 202.000 ML <b>Mfg. Dt.</b> : JUL-2019 <b>Exp. Dt.</b> : JUN-2021 <b>T.R. Slip No.</b> : NIFFT19712 <b>T.R. Slip Dt.</b> : 22-07-2019 <b>Analysis Date</b> : 29-07-2019 <b>A.R. No.</b> : F719200178 <b>A.R. Dt.</b> : 29-07-2019 <b>Released Qty.</b> : 2000 LTR	
Sr	Test	Result	Specification
1	DESCRIPTION	Amber coloured viscous liquid with sweet flavour in amber coloured PVC bottles.	Amber coloured viscous liquid with sweet flavour in amber coloured PVC bottles.
2	IDENTIFICATION A	Complies.	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that of the standard preparation.
3	IDENTIFICATION B	Complies.	Red precipitate of cuprous oxide should be formed.
4	IMPURITY	Organic impurities:- Complies. Fructose : Not detected Galactose: 10.5128 % Epilactose: 3.7334 % lactose: 7.2858 % Tagatose : 0.6759 %	Organic impurities:- Fructose : NMT 1 % Galactose:NMT 16 % Epilactose: NMT 8 % lactose: NMT 12 % Tagatose : NMT 3 %
5	SPECIFIC TESTS	Microbial Enumeration tests :- Total Bacterial Counts: 30 cfu/gm of Lactulose.	Microbial Enumeration tests :- Total Bacterial Counts: NMT 100 cfu/gm of Lactulose.
6	TESTS FOR SPECIFIED MICROORGANISMS	Escherichia coli : Escherichia coli is absent. Salmonella species: Salmonella is absent.	Escherichia coli : Escherichia coli should be absent. Salmonella species: Salmonella should be absent.
7	PH	4.26 pH	2.5 to 6.5 pH
8	ASSAY OF LACTULOSE CONCENTRATE EQ. TO LACTULOSE	98.67 % of the Label Claim.	90.0 % to 110.0 % of the LA.
<b>Conclusion</b> : The above sample complies as per USP In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"			
Analysis By  DHARTI R PATEL Q.C. OFFICER		Checked By  MITTAL H PATEL Q.C. OFFICER	
		Approved By  YOGESH J. PATEL MANAGER - QA & QC	