



1389, Trasad Road,
Dholka-387810,
Dist.: Ahmedabad (INDIA)

Annexure-V
Quality Control Department
ANALYTICAL REPORT – WORKING STANDARD
(Ref SOP No.: DQC309)

Name : Lactitol Monohydrate Working std. Lot No. : QC/WS/LACTI.-EP/01/14
Date of Analysis : 31/07/2014 Method Reference : BP/EP
Effective Date : 02/08/2014 Valid upto : 21/07/2016
Evaluated against : EP reference standard Batch No.: 2

TESTS	RESULTS	SPECIFICATIONS
1. Appearance	White crystalline powder.	White or almost white powder.
2. Identification	B: Positive	B: The infra-red absorption spectrum of the substance being examined in potassium bromide dispersion should be concordant with the spectrum obtained from similar preparation of Lactitol Monohydrate standard.
3. Water	4.9 % w/w	Between 4.5 % w/w to 5.5 % w/w
4. Assay	94.6 % w/w as is basis. 99.5 % w/w on anhy. basis.	It should contain not less than 96.5 % w/w and not more than 102.0 % w/w of $C_{12}H_{24}O_{11}$, calculated on the anhydrous basis.

The product complies / does not comply with the above specifications.

Remark: For unopened container: $+ 5^{\circ}C \pm 3^{\circ}C$

Prepared By: *Sj*
02/08/14

FORM NO.: FQA309-05/00

Checked By: *NW*
02/08/14

Approved By: *M*
02/08/14

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