

MASTER COPY



Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Dextrose Monohydrate IP

Page No.: 1 of 4

Specification No.:
ACPL/FP/SP/052

Revision No.:
00

Effective Date
20/07/2021

Review Date
19/07/2024


Change Control No.

NA

Prepared By: 

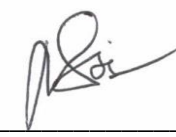
Date: 16/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 17/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 19/07/2021

Name : Naresh Solanki
(QA/QC In Charge / Designee)

UNCONTROLLED COPY

Format No. QC/017/F/01-00

Certified By (Sign/Date) :  20/07/2021

MASTER COPY



Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Dextrose Monohydrate IP

Page No.: 2 of 4

Specification No.:
ACPL/FP/SP/052

Revision No.:
00

Effective Date
20/07/2021

Review Date
19/07/2024

Change Control No.

NA

1.0 SAMPLING LEVEL :

As mentioned in the “Sampling procedure” SOP.

2.0 SAMPLING METHOD TO BE FOLLOWED:

100 % sampling to be done from each container.

3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED :

100 gm

4.0 EXPIRY :

Five years from the Date of Manufacturing.

5.0 CAS No: 77938-63-7

6.0 MOLECULAR FORMULA: C₆H₁₂O₆. H₂O

7.0 MOLECULAR WEIGHT: 198.20 gm/mol.

8.0 CATEGORY: Nutrient; fluid replenisher.

9.0 STORAGE: Store protected from moisture.

10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100 gm.

UNCONTROLLED COPY

Format No. QC/017/F/01-00

Certified By (Sign/Date) :

20/07/2021

MASTER COPY

Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control**Standard Test Specifications****Title: Dextrose Monohydrate IP****Page No.:** 3 of 4**Specification No.:**
ACPL/FP/SP/052**Revision No.:**
00**Effective Date**
20/07/2021**Review Date**
19/07/2024**Change Control No.**

NA

TEST PARAMETERS AND SPECIFICATIONS**REF: IP**

Sr.NO:	TEST PARAMETER	SPECIFICATION
1.	Description	White crystalline powder
2.	Identification A When heated, it melts, swells up and bums, and an odour of burnt sugar is perceptible.	To Pass test
	Identification B A copious red precipitate is formed	To Pass test
3.	Appearance and odour of solution	Not more intensely colored than reference solution BYS7 , and is odorless
4.	Acidity or alkalinity	The solution is colorless and not more than 0.15 ml of a 0.1 M sodium hydroxide is required to change the colour of the solution to pink
5.	Specific optical rotation	To Pass test
6.	Arsenic	Max. 1 ppm
7.	Heavy metals	Max. 5 ppm
8.	Chlorides	Max. 125 ppm
9.	Sulphates	Max. 200 ppm
10.	Sulphite	To Pass test (The absorbance is not more than that of a standard)
11.	Barium	To Pass test
12.	Foreign sugars, soluble starch and dextrans.	To Pass test(The appearance of the solution does not change on cooling)

UNCONTROLLED COPY**Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  20/07/2021

MASTER COPY

Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control**Standard Test Specifications****Title: Dextrose Monohydrate IP****Page No.:** 4 of 4**Specification No.:**
ACPL/FP/SP/052**Revision No.:**
00**Effective Date**
20/07/2021**Review Date**
19/07/2024**Change Control No.**

NA

13.	Sulphated ash	Max. 0.1 %
14.	Water	7.0 % to 9.5 %
Dextrose intended for use in the manufacture of parenteral preparations complies with the following additional requirement.		
15.	Bacterial endotoxins	Not more than 0.5 Endotoxin Unit per ml

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	20/07/2021	First Issuance	N A

UNCONTROLLED COPY**Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  20/07/2021