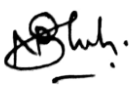



MASTER COPY

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

Quality Control**Standard Test Specifications****Title: Dextrose Anhydrous BP****Page No.:** 1 of 4**Specification No.:**
ACPL/FP/SP/051**Revision No.:**
00**Effective Date**
20/07/2021**Review Date**
19/07/2024**Change Control No.**

NA

Prepared By: Date: 16/07/2021Name : Pankaj Patel
(QC Officer / Designee)Reviewed By: Date: 17/07/2021Name : Nilesh Shah
(Unit Head / Designee)Approved By: Date: 19/07/2021Name : 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 Anhydrous BP

Page No.: 2 of 4

Specification No.:
ACPL/FP/SP/051

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: 50-99-7

6.0 MOLECULAR FORMULA: $C_6H_{12}O_6$

7.0 MOLECULAR WEIGHT: 180.20 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 Anhydrous BP

Page No.: 3 of 4

Specification No.:
ACPL/FP/SP/051

Revision No.:
00

Effective Date
20/07/2021

Review Date
19/07/2024

Change Control No.

NA

TEST PARAMETERS AND SPECIFICATIONS

REF: BP

Sr.NO:	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder.
2.	Solubility	Freely soluble in water, very slightly soluble in ethanol (96%)
3.	Identification A Specific optical rotation : + 52.5 to + 53.3 (anhydrous substance) Identification B Examine the chromatograms obtained in the assay. Results The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a). Identification C Thin-layer chromatography Identification D A red precipitate is formed. Identification E Water (see Tests).	To Pass test To Pass test To Pass test To Pass test To Pass test
4.	Appearance of solution	Appearance of solution The solution is clear and not more intensely colored than reference solution BY7.
5.	Conductivity	Max. 20 $\mu\text{S}\cdot\text{cm}^{-1}$.
6.	Related substances	Liquid chromatography (the area of the principal peak in the chromatogram obtained with reference solution (c) (0.05 %))

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 Anhydrous BP****Page No.:** 4 of 4**Specification No.:**
ACPL/FP/SP/051**Revision No.:**
00**Effective Date**
20/07/2021**Review Date**
19/07/2024**Change Control No.**

NA

7.	Dextrin	To Pass test (The substance dissolves completely)
8.	Soluble starch, sulfite	Max. 15 ppm
9.	Water	Max. 1 %
10.	Pyrogens	To Pass test
11.	Assay %(Dried Basis)	97.5 % to 102.0 %.

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