

# D-(+)-Galactose anhydrous

Meets USP-NF testing specifications

**Product Code: TC127U**

## Product Description :

Molecular weight : 180.16

Molecular formula:  $C_6H_{12}O_6$

CAS No.: 59-23-4

## Quality Control:

### Appearance

A white crystalline or finely granulated powder

### Solubility

Soluble in water, very slightly soluble in alcohol

### Identification A : FTIR

Matches with the standard pattern

### Identification B

The retention time of the major peak of the Sample solution corresponds to the galactose peak of the Standard solution, as obtained in the Assay

### Identification C

An orange or red precipitate is formed.

### Appearance of solution

20% solution in water with heating at 50°C is not more intensely coloured than the control solution

### Acidity

$\leq 1.5$  mL of 0.01N sodium hydroxide is required

### Barium

Any opalescence in the Sample solution is not more intense than that in the Standard solution

### Lead

$\leq 0.00005\%$

### Water (K.F.)

$\leq 1.00\%$

### Residue on ignition

$\leq 0.10\%$

### Specific optical rotation

+78.00° to +81.50° ( $c = 10\%$  in water + 0.2 mL of ammonia solution, at 20°C)

### Microbial contamination, TAMC

$\leq 1000$  cfu/gm

### Microbial contamination, TYMC

$\leq 100$  cfu/gm

### Pathogens (Salmonella)

Not detected

### Pathogens (E. coli)

Not detected

### Pathogens (S. aureus)

Not detected

### Pathogens (P. aeruginosa)

Not detected

### System suitability 1, related substances and assay,

#### HPLC : Resolution

$\geq 3.0$  between the lactose and galacturonic acid peaks

### System suitability 2, related substances and assay,

#### HPLC : Resolution

$\geq 1.5$  between the galacturonic acid and dextrose peaks

### System suitability 3, related substances and assay,

#### HPLC : Resolution

$\geq 2.00$  between the dextrose and galactose peaks

### System suitability 4, related substances and assay,

#### HPLC : Resolution

$\geq 3.0$  between the galactose and arabinose peaks

### System suitability 5, Assay, HPLC : RSD

$\leq 1.00\%$

### Related substances, HPLC : Lactose and 1,6-galactosylgalactose

$\leq 0.60\%$

### Related substances, HPLC : Galacturonic acid

$\leq 0.60\%$

### Related substances, HPLC : Dextrose

$\leq 0.60\%$

**Related substances, HPLC : Tagatose**

<= 0.60%

**Related substances, HPLC : Dulcitol**

<= 0.60%

**Related substances, HPLC : Arabinose**

<= 0.60%

**Related substances, HPLC : any unspecified impurity**

<= 0.20%

**Related substances, HPLC : total impurity**

<= 1.00%

**Assay (HPLC, anhydrous basis)**

98.00 -102.00

**Storage and Shelf Life:**

Store below 30°C away from bright light.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision : 02/2024

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic , research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.