

D-(+)-Galactose anhydrous

Meets USP-NF, EP and BP Testing specifications

Product Code: TC127M

Product Description :

Molecular weight : 180.16

Molecular formula: $C_6H_{12}O_6$

CAS No.: 59-23-4

Quality Control:

Appearance (EP, BP)

White or almost white crystalline or finely granulated powder

Appearance (USP)

A white crystalline or finely granulated powder

Solubility (EP, BP)

Freely soluble or soluble in water, very slightly soluble in 96% ethanol

Solubility : (USP)

Soluble in water, very slightly soluble in alcohol

Identification A : FTIR (USP, EP, BP)

Matches with the standard pattern

Identification B : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a)

Identification B : (USP)

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 : (USP, EP, BP)

An orange or red precipitate is formed.

Appearance of solution : (USP)

The sample solution is not more intensely coloured than the control solution

Appearance of solution : (EP, BP)

20% solution at 50°C is not more intensely coloured than the reference solution B₈

Acidity and alkalinity : (USP, EP, BP)

≤ 1.5 mL of 0.01 M sodium hydroxide is required to change the colour of the indicator to pink.

Barium : (BP)

Any opalescence in the solution is not more intense than that in a mixture of 5 mL of solution S and 6 mL of distilled water R.

Barium : (USP)

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

Lead : (USP, BP)

$\leq 0.00005\%$

Water (K.F.) : (USP, EP, BP)

$\leq 1.00\%$

Sulphated ash : (EP, BP)

$\leq 0.10\%$

Residue on ignition : (USP)

$\leq 0.10\%$

Specific optical rotation : (USP)

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

Proteins : (EP, BP)

$\leq 0.1\text{mg/mL}$

Microbial contamination, TAMC : (EP, BP)

$\leq 100.00\text{ cfu/gm}$

Microbial contamination, TAMC : (USP)

$\leq 1000\text{ cfu/gm}$

Microbial contamination, TYMC : (USP)

$\leq 100\text{ cfu/gm}$

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 (EP, BP)

min. 2.0 between the peak due to impurity C and galactose

System suitability 2, related substances and assay, HPLC : Resolution (USP)

≥ 3.0 between the lactose and galacturonic acid peaks

System suitability 3, related substances and assay, HPLC : Resolution (USP)

≥ 1.5 between the galacturonic acid and dextrose peaks

System suitability 4, related substances and assay, HPLC : Resolution (USP)

≥ 2.00 between the dextrose and galactose peaks

System suitability 5, related substances and assay, HPLC : Resolution (USP)

≥ 3.0 between the galactose and arabinose peaks

System suitability 6, related substances, HPLC : RSD (USP)

$\leq 1.00\%$

Related substances, HPLC : Sum of impurities A & B (EP, BP)

$\leq 1.0\%$

Related substances, HPLC : Unspecified impurities, for each impurity (EP, BP)

$\leq 0.3\%$

Related substances, HPLC : Total impurities (EP, BP)

$\leq 2.0\%$

Related substances, HPLC : Lactose and 1,6-galactosylgalactose (USP)

$\leq 0.60\%$

Related substances, HPLC : Galacturonic acid (USP)

$\leq 0.60\%$

Related substances, HPLC : Dextrose (USP)

$\leq 0.60\%$

Related substances, HPLC : Tagatose (USP)

$\leq 0.60\%$

Related substances, HPLC : Dulcitol (USP)

$\leq 0.60\%$

Related substances, HPLC : Arabinose (USP)

$\leq 0.60\%$

Related substances, HPLC : any unspecified impurity (USP)

$\leq 0.20\%$

Related substances, HPLC : total impurity (USP)

$\leq 1.00\%$

Assay (HPLC, anhydrous basis) : (EP, BP)

97.0 - 102.0%

Assay (HPLC, anhydrous basis) : (USP)

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.

Disclaimer :

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