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Technical Datasheet

Glycerol

Meets USP-NF, EP, BP, JP and IP testing specifications

Product Code: TC503M

Product Description :

Molecular weight : 92.09
Molecular formula: $C_3H_8O_3$
CAS No.: 56-81-5

Quality Control:

Appearance (USP)
Clear, colourless syrupy liquid; hygroscopic
Appearance (EP, BP)
Colourless or almost colourless, syrupy liquid; very hygroscopic
Appearance (JP)
A clear colourless and viscous liquid; hygroscopic
Appearance (IP)
A clear colourless or almost colourless, syrupy liquid; very hygroscopic
Solubility (USP)
Insoluble in chloroform, in ether and in fixed and volatile oils. Miscible with water and with alcohol.
Solubility (EP, BP)
Miscible with water and with ethanol (96%), slightly soluble in acetone, Practically insoluble in fatty oils in essential oil.
Solubility (JP)
Miscible with water and with ethanol (99.5%)
Solubility (IP)
Miscible with water and with ethanol (95%); slightly soluble in acetone; practically insoluble in ether and in fixed oils and volatile oils
Identification : FTIR (JP)
Matches with the standard pattern
Identification A : FTIR (USP, IP)
Matches with the standard pattern
Identification A : RI (EP, BP)
1.4700 - 1.4750
Identification B, System suitability : Resolution (GC) (USP)
>= 1.5 between diethylene glycol & glycerin
Identification B : Diethylene glycol & ethylene glycol : GC (USP)
<= 0.10% (each for diethylene glycol & ethylene glycol is found)
Identification B : FTIR (EP, BP)
Matches with the standard pattern
Identification B (IP)
A blue ring develops at the interface of the two liquids. Allow to stand for 10 min., the blue colour does not diffuse into the two layer
Identification C (USP)
The retention time of the glycerin peak of the sample solution corresponds to that obtained in the standard solution
Identification C : Relative density (EP, BP)
1.258 - 1.268
Identification C (IP)
Complies
Identification D : RI (IP)
1.4700 - 1.4750 (at 20°C)
Appearance of solution (EP, BP, IP)
20% Solution in water is colourless.
Acidity or alkalinity (EP, BP)
<= 0.2 mL of 0.1M NaOH is required to change the colour of the indicator to pink
Acidity or alkalinity (JP)
The solution in neutral
Acidity or alkalinity (IP)
<= 0.2 mL of 0.1M NaOH is required to produce a pink colour
Residue of ignition (USP, JP)
<= 0.01%
Ester (EP, BP)
>= 8.0 mL of 0.1M HCl is required to change the colour of the indicator
Colour (USP, JP)
Passes Test
Iron (IP)
<= 0.0004%
Chloride (IP)
<= 0.0025%
Chloride (USP, EP, BP, JP)
<= 0.001%
Calcium (JP)
The solution remains unchanged
Heavy metals (JP, IP)
<= 0.0005%
Arsenic (JP)
<= 0.0002%
Aldehyde (EP, BP)
<= 0.001%

Sulphate (USP, JP)
<= 0.002%
Sulphate (IP)
<= 0.003%
Ammonium (JP)
The gas evolved does not change moistened red litmus paper to blue
Acrolin, glucose or other reducing substances (JP)
The colour of the solution does not change and no turbidity is produced
System suitability : Resolution 1 : GC (JP)
>= 40 (between the peak of ethylene glycol and diethylene glycol)
System suitability : Resolution 2 : GC (JP)
>= 10 (between the peak of diethylene glycol and glycerin)
Ethylene glycol, diethylene glycol & related substances 1 (JP)
<= 0.1% (the amount of the peaks other than the glycerin, ethylene glycol and diethylene glycol)
Ethylene glycol, diethylene glycol & related substances 2 (JP)
<= 1.0% (the total amount of the peaks other than the glycerin)
Fatty acid & ester (JP)
<= 3.0 mL of 0.1 mol/L NaOH is consumed
Suger (EP, BP, IP)
The solution remains blue and no precipitate is formed.
Halogenated compound (EP, BP)
<= 0.0035%
Readily carbonizable substances (JP)
The solution has no more colour than matching fluid H
Aldehyde and reducing substances (IP)
The test is not valid unless the standard solution is pink
Ethylene glycol, diethylene glycol and related substances : GC (IP)
The area of any secondary peak in the chromatogram obotained with the test solution is less than the area of the peak corresponding to diethylene glycol in the chromatogram obtained with the reference solution
Ester (IP)
>= 8.0 mL of 0.1M hydrochloric acid is required to decolourise the solution
Sulphated ash (EP, BP, IP)
<= 0.01%
Related substance : System suitability : Resolution : GC (EP, BP)
>= 7.0 between the peaks due to impurity A and glycerol
Related substance : Impurity A : GC (EP, BP)
<= 0.1%
Related substance : Any other impurity : GC (EP, BP)
<= 0.1%
Related substance : Total impurity : GC (EP, BP)
<= 0.50%
Organic impurities 1: Related compound : System suitability : Resolution : GC (USP)
>= 7.0 between diethylene glycol and glycerin
Organic impurities 2: Related compound : Individual impurity (USP)
<= 0.1%
Organic impurities 3: Related compound : Total impurity : GC (USP)
<= 1.0%
Organic impurities : Limit of chlorinated compound (USP)
<= 0.003% of Cl
Organic impurities : Fatty acids and esters (USP)
<= 1.0 mL of 0.5N NaOH is consumed
Specific gravity (USP)
>= 1.249
Specific gravity (JP)
>= 1.258
Refractive index (JP)
>= 1.470
Refractive index (EP, BP)
1.4700 - 1.4750
Water (K.F.) (USP)
<= 5.0%
Water (K.F.) (EP, BP, JP, IP)
<= 2.0%
Assay (NaOH T, anhydrous basis) (USP)
99.00 - 101.00%
Assay (NaOH T, anhydrous basis) (EP, BP, JP, IP)
98.00 - 101.00%

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.