Polysorbate 80

Meets USP 41-NF 36, BP 2016, EP 9.0, JP 17 and IP 2018 testing specifications

Product Code: TC543M

Product Description :

CAS : 9005-65-6
Synonym : Tween®80

Quality Control:

Appearance (USP)
Lemon to amber coloured, oily liquid

Appearance (EP, BP)
Oily, colourless or brownish-yellow, clear or slightly opalescent liquid

Appearance (JP)
Colorless or brownish yellow, clear or slightly opalescent, oily liquid.

Appearance (IP)
A clear or almost clear, oily, yellowish or brownish yellow liquid

Solubility (USP)
Very soluble in water, soluble in alcohol and in ethyl acetate; insoluble in mineral oil

Solubility (IP)
Miscible with water, with ethanol, with ethyl acetate and with methanol; practically insoluble in fixed oils and in liquid paraffin

Solubility (EP, BP)
Dispersible in water, in anhydrous ethanol, in ethyl acetate and in methanol, practically insoluble in fatty oils and in liquid paraffin.

Solubility (JP)
Miscible with water, with methanol, with ethanol (99.5%) and with ethyl acetate. Practically insoluble in fatty oils and in liquid paraffin

Identification, GC : (JP)
Meets the requirements of the composition of fatty acids

Relative density (EP, BP)
about 1.10

Identification A : composition of fatty, GC : (USP)
Complies

Identification A : FTIR (EP, BP, IP)
Matches with the standard pattern

Identification B : FTIR (USP)
Matches with the standard pattern

Identification B : Hydroxyl value (EP, BP)
65 - 80

Identification B (IP)
A blue color is produced

Identification C : Saponification value (EP, BP)
45 - 55

Identification C (IP)
Bromine is decolourised

Identification D : Composition of fatty acid, GC (EP, BP)
Complies

Identification E (EP, BP)
The solution becomes blue

System suitability 1, composition of fatty acids, GC : Resolution (USP, JP)
NLT 1.8 between the peaks methyl oleate and methyl stearate

System suitability 2, composition of fatty acids, GC : Theoretical plates (USP, JP)
>= 30,000 for the peak of methyl stearate

Composition of fatty acid, GC : Myristic acid (USP, EP, BP, JP)
<= 5.00%

Composition of fatty acid, GC : Palmitic acid (USP, EP, BP, JP)
<= 16.00%

Composition of fatty acid, GC : Oleic acid (USP, EP, BP, JP)
>= 58.00%

Composition of fatty acid, GC : Stearic acid (USP, EP, BP, JP)
<= 6.00%

Composition of fatty acid, GC : Palmitoleic acid (USP, EP, BP, JP)
<= 8.00%

Composition of fatty acid, GC : Linoleic acid (USP, EP, BP, JP)
<= 18.00%

Composition of fatty acid, GC : Linolenic acid (USP, EP, BP, JP)
<= 4.00%

Peroxide value (USP, EP, BP, JP)
<= 10.00

Hydroxyl value (USP, EP, BP, JP, IP)
65 - 80

Saponification value (USP, EP, BP, JP, IP)
45 - 55

Acid value (USP, EP, BP, JP, IP)
<=2.00

Iodine value (IP)
18.00 - 24.00

System suitability, Ethylene oxide and dioxane, GC-HS: Resolution (USP, EP, BP, JP)
NLT 2.0 between the peaks due to acetaldehyde and ethylene oxide

Ethylene oxide, GC-HS : (USP, EP, BP, JP)
<= 0.0001%

Dioxane, GC-HS : (USP, EP, BP, JP)
<= 0.0010%

Heavy metals (USP, BP, IP)
<= 0.0010%

Heavy metals (JP)
<= 0.0020%

Water : (USP, EP, BP, JP, IP)
<= 3.00%

Residue on ignition (USP, JP)
<= 0.25%

Total ash (EP, BP)
<= 0.25%

Sulphated ash (IP)
<= 0.20%

Specific gravity (USP)
1.06 - 1.09

Specific gravity, at 20°C : (JP)
about 1.10

Viscosity (EP, BP, JP)
~400 mPa.s at 25 °C

Viscosity (USP)
300 - 500 cSt

Reducing impurities (IP)
NMT 5.0 mL of 0.01M ceric ammonium sulphate is required

Storage and Shelf Life:

Store below 30°C away from bright light.

Self life is 48 months.

Use before expiry date given on the product lable.

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