



Polysorbate 20

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

Product Code: TC287M

Product Description :

CAS No.: 9005-64-5 Synonym : Tween[®] 20

Quality Control:

Appearance (USP)

Lemon to amber coloured liquid

Appearance (EP, BP)

Oily, yellow or brownish-yellow, clear or slightly opalescent liquid

Appearance (IP)

A clear or slightly opalescent, oily, yellowish or brownish yellow liquid

Solubility (USP)

Soluble in water, in alcohol, in ethyl acetate; in methanol and in dioxane; insoluble in mineral oil

Solubility (EP, BP)

Soluble in water, in anhydrous ethanol, in ethyl acetate and in methanol. Practically insoluble in fatty oils and in liquid paraffin.

Solubility (IP)

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

pH (5% in water) : (IP)

5.0 - 7.0

Identification A : FTIR (USP, EP, BP, IP)

Matches with the standard pattern

Identification B : Hydroxyl value (EP, BP) 96.0 - 108.0

Identification B : (IP)

A blue colour is produced

Identification B: Composition of fatty acid, GC (USP)

Meets the requirements

Identification C : Saponification value (EP, BP) 40.0 - 50.0 Identification D : Composition of fatty acids, GC (EP, BP) Complies Identification Test E (EP, BP) The solution becomes blue Acid value (USP, EP, BP, IP) <= 2.0Hydroxyl value (USP, EP, BP, IP) 96 - 108 Peroxide value (USP, EP, BP) <= 10.0Iodine value (IP) <= 5.0Saponification value (USP, EP, BP, IP) 40.0 - 50.0 **Relative density (EP, BP)** about 1.10 **Reducing impurities : (IP)** NMT 2.0 mL of 0.01M ceric ammonium sulphate is required viscosity (EP, BP) ~400 mPa.s at 25°C Heavy metals (IP) <= 0.0010% System suitability, limit of ethylene oxide : Resolution (USP) >= 2.0Limit of ethylene oxide, GC-HS (USP, EP, BP) <= 0.0001% Limit of Dioxane, GC-HS (USP, EP, BP) $\leq 0.0010\%$ **Residue on ignition (USP)** <= 0.25%Total ash (EP, BP) <= 0.25% Sulphted ash (IP) <= 0.2% Water (USP, EP, BP, IP) <= 3.0%

System suitability 1, composition of fatty acids, GC: **Resolution (USP)** >= 1.5, between methyl stearate and methyl oleate System suitability 2, composition of fatty acids, GC: RSD (USP) $\leq 6.0\%$, peak area responses for the palmitate and stearate peaks System suitability 3, composition of fatty acids, GC: RSD (USP) <= 1.0%, peak area response ratio for the palmitate and stearate peaks System suitability 4, composition of fatty acids, GC: **Resolution (EP, BP)** >= 4.0, between the peaks due to methyl caprylate and methyl decanoate System suitability 5, composition of fatty acids, GC: Theoretical plates (EP, BP) >= 15,000 for the peak due to methyl decanoate Composition of fatty acids 1, GC : Caproic acid (USP, EP, BP) <= 1.0%Composition of fatty acids 2, GC : Caprylic acid (USP, EP, BP) $\leq 10.0\%$ Composition of fatty acids 3, GC : Capric acid (USP, EP, BP) <= 10.0% Composition of fatty acids 4, GC : lauric acid (USP, EP, BP) 40.0 - 60.0% Composition of fatty acids 5, GC : myristic acid (USP, EP, BP) 14.0 - 25.0% Composition of fatty acids 6, GC : palmitic acid (USP, EP, BP) 7.0 - 15.0% Composition of fatty acids 7, GC : stearic acid (USP) <= 11.0% Composition of fatty acids 8, GC : stearic acid (EP, BP) <= 7.0% Composition of fatty acids 9, GC : oleic acid (USP, EP, BP) <= 11.0% Composition of fatty acids 10, GC : linoleic acid (USP, EP, BP) <= 3.0%**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 :

Revision: 04/2024

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 diagnostic or therapeutic use but for laboratory, 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.