



Poloxamer 188

Meets USP 41-NF 36, EP 9.0, BP 2016 and IP 2018 testing specification

Product Code: TC222M

Product Description:

Molecular Formula: (C3H6O.C2H4O)x

CAS: 9003-11-6 Synonym: Pluronic® F-68

Quality Control:

Appearance (USP)

White, prilled or cast solid

Appearance (EP, BP, IP)

White or almost white, waxy powder, microbeads or flakes

Solubility (USP)

Freely soluble in water and in alcohol

Solubility (EP, BP)

Soluble in water and in ethanol (96%)

Solubility (IP)

Freely soluble in water and in ethanol (95%)

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

Matches with the standard pattern

Identification B : Average relative molecular mass

(**EP, BP, IP**) 7680 - 9510

Identification C: oxypropylene to oxyethylene

ratio, NMR (EP, BP, IP)

Complies

Appearance of solution (EP, BP)

10% solution in water is not more intensely coloured than

reference solution BY7

Appearance of solution (IP)

10% solution in water is not more intensely coloured than

reference solution BYS7

pH (10% in water at 25°C) : (EP, BP, IP)

5.00 - 7.50

pH (2.5% in water at 25°C): (USP)

5.00 - 7.50

Average molecular weight (USP, EP, BP, IP)

7680 - 9510

Weight percent oxyethylene, NMR: (USP)

79.90 - 83.70

Unsaturation, methanolic KOH titration (USP)

0.018 - 0.034 mEq/g

Oxypropylene: oxyethylene ratio, NMR (EP, BP, IP)

Complies

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

<= 1.00%

Total ash (EP, BP, IP)

<= 0.40%

Heavy metals (USP)

<= 0.0020%

Melting point (EP, BP)

~50°C

Melting point (IP, USP)

~52°C

Limit of ethylene oxide, propylene oxide and 1,4-dioxane,

System suitability, resolution, GC-HS: (USP)

min. 2.0 between ethylene oxide and propylene oxide

Limit of ethylene oxide, propylene oxide and 1,4-dioxane,

System suitability, RSD, GC-HS: (USP)

<= 15.00%

Limit of ethylene oxide, GC-HS: (EP, BP, USP, IP)

<=0.0001%

Limit of propylene oxide, GC-HS: (EP, BP, USP, IP)

<=0.0005%

Limit of dioxan, GC-HS: (EP, BP, IP)

<= 0.0010%

Limit of 1,4-dioxane, GC-HS: (USP)

<= 0.0005%

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: 03/2022

Disclaimer :

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