



FeF Benzalkonium Chloride Solution 50% (53/30/15/2) Ph.Eur., USP/NF

Application

Item No. 7800008 (1 kg)

FeF Benzalkonium Chloride Solution (BKC) 50% (53/30/15/2) Ph.Eur., USP/NF is a viscous, aqueous solution of quaternary ammonium compounds. FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF is a very efficient germicide which is active against most common micro-organisms, such as bacteria, fungi and algae. FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF can be used in pharmaceuticals as the active ingredient (API) due to its anti-microbial effect and as an excipient because of its preserving properties.

Specifications

Identification:	Complies to Ph.Eur., USP/NF
Appearance of solution:	Max. as reference suspension I Max. as reference solution Y6.
Acidity or alkalinity:	Max. 0.1 ml 0.1M HCl or NaOH
Ratio of alkyl components:	C12: 50.5-55.5% w/w, C14: 27.5-32.5% w/w C16: 15-20% w/w, C18: 2-5% w/w
Benzyl alcohol:	Max. 0.5% w/w
Benzaldehyde:	Max. 0.15% w/w
(Chloromethyl)benzene:	Max. 0.05% w/w
Any other detectable impurity:	Max. 0.10% w/w
Amines and amine salts:	Max. 0.5 ml/g
Sulphated ash:	Max. 0.1% w/w
Assay:	47.5 - 52.5% w/v
Total Aerobic Microbial Count:	Max. 1 CFU/g
Total comb. Yeast/Mould Count:	Max. 1 CFU/g
Staphylococcus aureus:	Absent in 1 g
Pseudomonas aeruginosa:	Absent in 1 g
Salmonella spp.:	Absent in 10 g
Escherichia coli:	Absent in 1 g
Bile-tol. gram-neg. bact.:	Absent in 1 g

Description

Composition:	FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF consists of Benzyl (dodecyl) dimethyl ammonium chloride (approx. 53%), Benzyl (tetradecyl) dimethyl ammonium chloride (approx. 30%), Benzyl (hexadecyl) dimethyl ammonium chloride (approx. 15%) and Benzyl dimethyl (octadecyl) ammonium chloride (approx. 2%). FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF contains approx. 50% active ingredients.
CAS No.:	8001-54-5
EINECS No.:	264-151-6
Names:	Benzalkonium Chloride (BKC). Alkyl dimethyl benzyl ammonium chloride.
Appearance of product:	Clear, colourless or slightly yellow, viscous liquid.
Chain length:	50.5-55.5%w/w C ₁₂ , 27.5-32.5%w/w C ₁₄ , 15-20%w/w C ₁₆ , 2-5%w/w C ₁₈ .

Technical information

Standards:	The quality system meets DS/EN ISO 9001. The environmental system meets DS/EN ISO 14001.
Grade:	Pharmaceutical grade.
Quality:	The product is manufactured in accordance with the cGMP Guide for Active Pharmaceutical Ingredients (API) ICH Q7.
TSE:	FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF does not contain materials of animal origin.
Solubility:	FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF is miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF is neither miscible with benzene nor ether.
Compatibility:	Mixing FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF with ordinary soaps and/or with anionic detergents may decrease the activity.
Density:	Approx. 0.98 g/ml.
Packaging:	FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF is packaged in rectangular HDPE plastic containers with tamper proof LDPE Caps.
Shelf life:	5 years.
Storage:	Store at temperatures above 15°C. Store protected from excessive heat. FeF BKC 50% (53/30/15/2) Ph.Eur., USP/NF may form a solid gel or a viscous precipitate at low temperatures.

Safety and handling

See the Material Safety Data Sheet on novonordiskpharmatech.com

Please note

The information contained herein is to our best knowledge true and accurate, but all recommendations or suggestions are made without guarantee since the conditions of use are beyond our control. Novo Nordisk Pharmatech A/S disclaims any liability incurred with the use of these data or suggestions.