Datasheet

FeF Benzalkonium Chloride Solution 50% Ph.Eur., USP/NF

Item No. 7800004 (1 kg)
Item No. 7800005 (5 kg)
Item No. 7800006 (25 kg)

Application

FeF Benzalkonium Chloride (BKC) Solution 50% Ph.Eur., USP/NF is a viscous, aqueous solution of quaternary ammonium compounds. FeF BKC 50% 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% Ph.Eur., USP/NF is widely 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: 60 - 70%w/w, C14: 30 - 40%w/w, C16: Max. 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

QA No. 00864 Version 9

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Datasheet

Description

Composition:	FeF BKC 50% Ph.Eur., USP/NF consists of Benzyl (dodecyl) dimethyl ammonium chloride (approx. 65%) and Benzyl (tetradecyl) dimethyl ammonium chloride (approx. 35%). FeF BKC 50% 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:	60-70% w/w C_{12}, 30-40% w/w C_{14} and max. 5% w/w C_{16}.

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.
Documentation:	Certificate of Suitability (CEP)
TSE:	FeF BKC 50% Ph.Eur., USP/NF does not contain materials of animal origin.
Solubility:	FeF BKC 50% Ph.Eur., USP/NF is miscible with water or lower alcohols, such as methanol, ethanol and propanol in all ratios. FeF BKC 50% Ph.Eur., USP/NF is neither miscible with benzene nor ether.
Compatibility:	Mixing FeF BKC 50% 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% Ph.Eur., USP/NF 1 kg is packaged in rectangular HDPE containers with tamper proof HDPE Caps. FeF BKC 50% Ph.Eur., USP/NF 5 kg and 25 kg is packaged in rectangular HDPE containers with tamper proof HDPE screw Caps.
Shelf life:	5 years.
Storage:	Store at temperatures above 15°C. Store protected from excessive heat. FeF BKC 50% 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

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QA No. 00864 Version 9