



Description

**Solveco Steril D70**  
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**Solveco Steril D70 is a sterile-filtered Eur.Ph Isopropanol denatured ethanol of 70% by volume, diluted with "Water For Injection, Eur.Ph".**

The product is aseptically produced according to cGMP under laminary air flow (LAF, GMP B grade). The product fulfils the European Pharmacopeia and the Swedish Medical Products Standard 97 with respect to ethanol content and density as well as sterility and particle levels. Each batch comes with a GMP-certificate and a certificate of analysis. The traceability includes the raw materials used in production. Each component of the product has been tested and validated according to cGMP. Solveco Steril 70 is suitable as disinfectant in clean-rooms GMP A-C and ISO 5-7. The product can be combined with a sterile trigger spray or extrusion cap in order to optimize the disinfection result.

**Product data for Solveco Steril D70**

Test	Method	Limits
Appearance	Eu.Pharmacopeia	Clear, colourless
Relative Density, Identification	Eu.Pharmacopeia	0,8850 - 0,8900
Sterility	Eu.Pharmacopeia	Pass
Particulate matter	Eu.Pharmacopeia	$\leq 25$ particles/ml $\geq 10$ $\mu$ m $\leq 3$ particles/ml $\geq 25$ $\mu$ m
Density @20°C	ASTM D 4052	0,8834 - 0,8884
Relative Density	ASTM D 4052	0,8850 - 0,8900
Ethanol Strength	GC	54,0 - 58,0 % w/w
IPA Strength	GC	6,0 - 6,4 % w/w
Methanol	Eu.Pharmacopeia	$\leq 200$ ppm V/V
Acetaldehyd + Acetal	Eu.Pharmacopeia	$\leq 10$ ppm V/V
Benzene	Eu.Pharmacopeia	$\leq 2$ ppm V/V
Tot. of other impurities	Eu.Pharmacopeia	$\leq 300$ ppm V/V
Residue on Evaporation	Eu.Pharmacopeia	$\leq 25$ ppm m/V

**Packaging**

Inner packaging	Amount / Box	Box / Pallet
1000ml HDPE; code: 1050	12	40

**Storage (see safety data sheets for further information about storage and handling)**

Storage (long term)	Storage (short term)	Sustainability
Temp: Room temp (18 - 30°C)	Temp: -15 - >30°C	2 years from date of production
		Sealed bottles
		3 months for opened bottles

Solveco AB is certified according to ISO 13485. **Quality management system:** Development, manufacture and distribution of chemical products for the pharmaceutical, food engineering, medical device and related activities.



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