

# Ethanol 70% Sterile

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## STERILE FILTERED ETHANOL SOLUTION 70 VOL -%, DILUTED WITH "WATER FOR INJECTION, PH.EUR".

Ethanol 70% Sterile is a sterile filtered 70 vol-% ethanol solution, diluted with water for injection (WFI). The disinfectant meets the requirements for use in clean rooms GMP Grade A-C and ISO Grade 5-7.

Ethanol 70% Sterile is delivered with a batch-linked certificate of analysis; the traceability also includes the raw materials. The ethanol, WFI and methods of analysis are all according to Ph.Eur specifications. All packaging material are gamma sterilized prior to use.

The product is blended in a GMP Grade C environment with aseptic filling and enclosure in Grade A laminary air flow (LAF).

## SPECIFICATION

TEST	METHOD	LIMITS
UV-absorbing impurities	Ph.Eur	≤ 0,40 at 240 nm ≤ 0,30 at 250-260 nm ≤ 0,10 at 270-340 nm
Residue on Evaporation	Ph.Eur	≤ 0,025 mg/ml
Appearance	Ph.Eur	Clear, colourless
Relative density	Ph.Eur (ASTM D 4052)	0,8850 – 0,8900
Ethanol % V/V	Calculated from relative density	68,9 – 70,9 % V/V
Sterility test	Ph.Eur	Pass
Particulate matter ≥ 10 µm ≥ 25 µm	Ph.Eur	≤ 25 particles/ml ≤ 3 particles/ml
Methanol	Ph.Eur (GC)	≤ 200 ppm V/V
Benzene	Ph.Eur (GC)	≤ 2 ppm V/V
Acetaldehyd + Acetal	Ph.Eur (GC)	≤ 10 ppm V/V
Total of other impurities	Ph.Eur (GC)	≤ 300 ppm V/V

## PACKAGE SIZES

ART.CODE	SIZE	UNITS / BOX	BOX / PALLET
1047	1000 ml	12 x 1000 ml	40 boxes – 480 bottles
1122	500 ml	20 x 500 ml	40 boxes – 800 bottles