PRODUCT SALES SPECIFICATION

ACTIVE PHARMACEUTICAL INGREDIENT
ETHYL ALCOHOL
GRAIN ORIGIN 96.0 %

I. PRODUCT DESCRIPTION

Active pharmaceutical ingredient „Ethyl alcohol grain origin 96.0 %“ is produced from cereal raw materials through distillation and rectification, and has characters that meet the requirements laid down in the 1317 monograph of the European Pharmacopoeia.

II. PHYSICO-CHEMICAL AND MICROBIOLOGICAL PARAMETERS

	Parameter	Unit	Limits, set by Ph.Eur.
1.	Ethanol content	% V/V	95,1 to 96,9 at 20 °C
2.	Relative density	-	0,805 – 0,812
3.	Appearance	-	Colourless, clear, volatile, flammable liquid, hygroscopic
4.	Solubility	-	Miscible with water and with methylene chloride
5.	Identification	-	To meet the tests
6.	Appearance of solution	-	The solution is clear and colorless
7.	Acidity or alkalinity	ppm	maximum 30, expressed as acetic acid (CH3COOH))
8.	Residue on evaporation	ppm m/V	maximum 25
9.	Absorbance	-	
	at 240 nm		maximum 0,40
	between 250 and 260 nm		maximum 0,30
	between 270 and 340 nm		maximum 0,10
10.	Volatile impurities:	ppm V/V	
	-Methanol		maximum 200
	-Acetaldehyde and acetal (expressed as acetaldehyde)		maximum 10
	-Benzene		maximum 2
	-Total of other impurities		maximum 300
11.	Microbiological quality:	CFU/ml	
	TAMC		maximum 10^3
	TYMC		maximum 10^2

III. USES

The active pharmaceutical ingredient "Ethyl alcohol grain origin 96.0 %" is widely used in the pharmaceutical industry for the production of medicinal products for human use.

IV. HANDLING AND STORAGE

Recommended storage temperature: < 35 °C. For further information, regarding handling and storage, see Safety Data Sheet of the product.

Head office
4003 Plovdiv, Bulgaria 5 Dunav Blvd.
Tel: +359 32 306 783 Fax: +359 32 606 910
sales@essentica.eu office@essentica.eu

Essentica Ethanol Factory
4120 Katunitsa, Bulgaria 1 I. Stoyanov Str.
Tel: +359 3117 9902
www.essentica.eu