

ANALYSIS CERTIFICATE

CODE: 141085

BATCH: 0001467155

PRODUCT: Ethanol 96% v/v (USP, BP, Ph.Eur.) pure, pharma grade

ISSUE DATE: 03/07/2018

RETEST DATE: 02/2020

SPECIFICATIONS	GUARANTEE VALUE	ACTUAL VALUE
Assay (G.C.) (v/v)	96,0-96,6 %	96,5%
Identity according to Pharmacopoeias:	passes test	Passes test
Density 20/20	0,8051-0,8124	0,8068
Maximum limit of impurities		
Appearance	passes test	Passes test
Acidity and alkalinity	passes test	Passes test
Alkalinity	0,001 meq/g	<0,001 meq/g
Insoluble matter in H ₂ O	passes test	Passes test
Non-volatile matter (w/v)	0,0025 %	0,0005 %
Reducing substances to KMnO ₄	passes test	Passes test
Clarity of solution	passes test	Passes test
Absorbance	passes test	Passes test
Fusel oil	passes test	Passes test
Residual solvents (Ph.Eur/USP)	passes test	Passes test
Acetone (G.C.)	0,005%	<0,005%
1-Pentanol, non-volatile subst. and carbonized subst. by H ₂ SO ₄	passes test	Passes test
2-Propanol (G.C.)	0,03%	<0,03%
Acetone, 2-Propanol and 2-Methyl-2-Propanol	passes test	Passes test
Aldehydes (as CH ₃ CHO)	0,001%	<0,001%
Benzene (U.V.)	0,0002%	<0,0002%
Butanone (G.C.)	0,02%	<0,02%
Volatile impurities (G.C.)		
Methanol	0,02%	<0,02%
Acetaldehyde and acetal	0,001 %	<0,001 %
Benzene	0,0002 %	<0,0002 %
Total other impurities	0,03 %	<0,03 %
Fe	0,00005 %	<0,00005 %
Elemental impurities (ICH Q3D):		
Class 1		
Cd	0,5 ppm	<0,5 ppm
Pb	0,5 ppm	<0,5 ppm
As	1,5 ppm	<1,5 ppm
Hg	1,5 ppm	<1,5 ppm
Class 2A		
Co	5 ppm	<5 ppm
V	10 ppm	<10 ppm
Ni	20 ppm	<20 ppm
Class 2B		
Tl	0,8 ppm	<0,8 ppm
Au	10 ppm	<10 ppm
Pd	10 ppm	<10 ppm
Ir	10 ppm	<10 ppm
Os	10 ppm	<10 ppm
Rh	10 ppm	<10 ppm
Ru	10 ppm	<10 ppm
Se	15 ppm	<15 ppm
Ag	15 ppm	<15 ppm
Pt	10 ppm	<10 ppm
Class 3		
Li	55 ppm	<55 ppm
Sb	120 ppm	<120 ppm
Ba	140 ppm	<140 ppm
Mo	25 ppm	<25 ppm
Cu	250 ppm	<250 ppm
Sn	600 ppm	<600 ppm
Cr	25 ppm	<25 ppm

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