

ANALYSIS CERTIFICATE

CODE: 651086

BATCH: 0001261654

PRODUCT: Ethanol absolute (USP, BP, Ph.Eur.) pharma grade

ISSUE DATE: 27/11/2017

RETEST DATE: 11/2023

SPECIFICATIONS	GUARANTEE VALUE	ACTUAL VALUE
Minimum assay (G.C.) (v/v)	99,5%	99,9%
Identity according to Pharmacopoeias:	passes test	Passes test
Density 20/20	0,7907-0,7932	0,7910
Maximum limit of impurities		
Appearance of solution	passes test	Passes test
Acidity and alkalinity	passes test	Passes test
Insoluble matter in in H2O	passes test	Passes test
Non-volatile matter (w/v)	0,0025 %	0,0002 %
Reducing substances to KMnO4	passes test	Passes test
Colour of solution (USP)	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
1-Pentanol, non-volatile subst. and carbonized subst. by H2SO4	passes test	Passes test
Acetone, 2-Propanol and 2-Methyl-2-Propanol	passes test	Passes test
Benzene	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 %
Total other impurities	0,03 %	<0,03 %
Aldehydes (CH3CHO)	0,001%	<0,001%
Water (H2O)	0,5 %	0,01 %
Residual metals ICP: (according to EMEA/CHMP/SWP/4446/2000)		
Class 1A (Pt, Pd)	10 ppm	<10 ppm
Class 1B (Ir, Rh, Ru, Os)	10 ppm	<10 ppm
Class 1C (Mo, Ni, Cr, V)	25 ppm	<25 ppm
Class 2 (Cu, Mn)	250 ppm	<250 ppm
Class 3 (Fe, Zn)	1.300 ppm	<1.300 ppm

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