

ANALYSIS CERTIFICATE

CODE: 651085

BATCH: 0001587794

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

ISSUE DATE: 17/10/2018

RETEST DATE: 10/2024

SPECIFICATIONS	GUARANTEE VALUE	ACTUAL VALUE
Assay (G.C.) (v/v)	96,0-96,6 %	96,4 %
Identity according to Pharmacopoeias:	passes test	Passes test
Density 20/20	0,8051-0,8124	0,8060
Maximum limit of impurities		
Appearance	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 %	0,0005 %
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 %
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

Panreac Química S.L.U.
C/Garraf, 2
Polígono Pla de la Bruguera
E-08211 Castellar del Vallès
(Barcelona) España
Tel. (+34) 937 489 400
Fax (+34) 937 489 401
e-mail: info.es@itwreagents.com
www.itwreagents.com



Quality Assurance Director
Director de Garantía Calidad
P. Verge

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