

ANALYSIS CERTIFICATE

CODE: 142436

BATCH: 0002180479

PRODUCT: Polyethylene Glycol 400 (BP, Ph. Eur.) pure, pharma grade

ISSUE DATE: 24/05/2022

RETEST DATE: 05/2028

SPECIFICATIONS	GUARANTEE VALUE	ACTUAL VALUE
Identity according to Pharmacopoeias:	passes test	passes test
pH of 5% solution	4,5-7,5	6,2
Viscosity dynamic at 20°C	105-130 mPa.s	105 mPa.s
Viscosity kinematic at 20°C	94-116 cSt	94 cSt
Average molecular weight	380-420	394
Maximum limit of impurities		
Appearance of solution	passes test	passes test
Acidity and alkalinity	passes test	passes test
Insoluble matter in in H ₂ O	passes test	passes test
Reducing substances	passes test	passes test
Residue on ignition (as SO ₄)	0,1 %	0,1 %
Hydroxyl value	264-300	284
Residual solvents (Ph.Eur.)	passes test	passes test
1,4-Dioxan (G.C.)	0,001%	<0,001%
Ethylene Glycol and Diethylene Glycol (G.C.)	0,25%	<0,25%
Formaldehyde (CH ₂ O)	0,0015%	<0,0015%
Ethylene Oxide (G.C.)	0,0001%	<0,0001%
Water (H ₂ O)	2 %	0,1 %
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	5 ppm	<5 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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