Propylene Glycol, USP/FCC K Certificate of Analysis

August 7, 2014 Chemworld.com

Re: Certificate of Analysis

Propylene Glycol, USP/FCC Kosher

Excipient Use Only

PO No.: 4357

Lot No.: 14-128-03

Mfg Date: 05/08/14

Exp. Date: 05/08/16

Customer No.: n/a

BOL No.: n/a

Attn: Quality Control Manager

Test	Method	Specification	Result
Appearance	Organoleptic	Clear, colorless, viscous liquid	PASS
Specific Gravity @ 25°C	USP <841>	1.035 - 1.037	1.036
Assay	USP	99.5% minimum	99.9
Identification A (IR)	USP <197F>	Meets requirements	PASS
Identification B, C (Limit of DEG and EG)	USP	Meets requirements	PASS
Chloride	USP <221>	Not more than 0.007% (70 ppm)	0 ppm
Heavy Metals	USP <231>	5 ppm maximum	PASS
Residue on Ignition	USP	Not more than 0.007% (70 ppm)	70 ppm
Sulfate	USP <221>	Not more than 0.006% (60 ppm)	PASS
Residual Solvents	USP <467>	Meets requirements	PASS
Acidity	USP	0.20 ml 0.10N NaOH maximum	0.001
Water	USP <921> Method I	Not more than 0.2%	0.06
Lead	FCC	Not more than 1 mg/kg (1 ppm)	<1
Distillation Range	FCC	185 – 189°C	187 IBP / 189 DP

Lbs: <u>8535</u>

This product is excipient grade and not intended to be used as an active pharmaceutical ingredient or for specialist applications, such as parenteral, ocular, inhalation, open wound use, or applications that require sterile and/or pyrogen-free excipients.