Renova

Specification Sheet
USP 35
Refined Glycerin 99, 7% Min

Glycerol Eur PH, USP, BP Vegetable origin (soy based), KOSHER and HALAL, produced in San Lorenzo, Argentina

USP 35

PARAMETERS	TEST METHODS	SPECIFICATION
ASSAY, % ***(*) See note at the end***	USP35 % M/M	99.0 – 101.0
COLOR APHA 10 MAX Units Pt/Co	AOCS Ea 9-65:1997	PASSED
IR, IDENTIFICATION TEST A	USP 35	PASSED
IDENTIFICATION TEST B	USP 35	PASSED
Limit DEG Max 0.10	USP 35 % M/M	PASSED
Limit EG Max 0.10	USP 35 % M/M	PASSED
IDENTIFICATION TEST C: GC	USP 35	PASSED
SPECIFIC GRAVITY 25 g / 25 g ***(**) se note at the end***	USP 35	1.249
RESIDUE ON IGNITION, % M/M	USP 35	0.01 MAX
WATER CONTENT , 5% M/M	USP 35	0.3 MAX
CHLORIDES , PPM	USP 35	10 MAX
SULPHATES , PPM	USP 35	20 MAX
HEAVY METALS (as Pb) , PPM	USP 35	5 MAX
LIMIT OF CHLORINATED COMPOUNDS , PPM	USP 35	30 MAX
FA & E, AS ML NaOH 0,5 N	USP 35	1.0 MAX
RELATED COMPOUNDS (INDIVIDUAL IMPURITY),% M/M	USP 35	0.1 MAX
RELATED COMPOUNDS (TOTAL IMPURITY), % M/M	USP 35	1.0 MAX
GLYCEROL CONTENT , %	USP 35 % M/M	99.7% MIN

EUR Ph

PARAMETERS	TEST METHODS	SPECIFICATION
Water %	EP	0,2
Chloride, ppm	EP	<10
Fatty Acids & Esters, ml 0.1N NaOH	EP	0,01
Aldehydes Test in glycerin by UV-VIS Spectroscopy	EP	PASS
Sugars in refined glycerin by visual comparison	EP	PASS
Sulphated Ash Wt%	EP	0,01
Halogenated compounds	EP	PASS

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REQUIRED BY CUSTOMERS (specifics under requirement)

PARAMETERS	TEST METHODS	SPECIFICATION
U.V Absorbance 240 nm	USP 35	0,854
Purity	USP 35	100,4
Total Nitrogen	N/A	
FA & E, as ML OF 0.5N NaOH	USP 35	< 0,3%
Opalescence / Turbidity	Visual (50% H2O)	PASSED
THERMOSTABILITY		
Original Sample	MA 15-1510 Rev 2 / ASTM D 1209	Color Pt- Co < 5
Treated sample	MA 15-1510 Rev 2 / ASTM D 1209	Color Pt – Co 50
VOLATILE IMPURITIES		
1.1.1 Trichloroethane	AD HOC GC USP 621	<14 ppm
1.2 – Dichloroethane	AD HOC GC USP 621	<5 ppm
1.1 – Dichloroethane	AD HOC GC USP 621	<10 ppm
Carbon Tetrachloride	AD HOC GC USP 621	<7 ppm
Benzene	AD HOC GC USP 621	<5 ppm
PH		
PH	50% H2O	Between 6 and 8
MICROBIOLOGICAL		
Gram negative bacilli	F.A.	< 10 CFU/g
Staphylococcus Aureus	F.A.	< 10 CFU/g
Total Aerobic count	F.A.	< 10 CFU/g
Yeast and Mold	F.A.	< 10 CFU/g
CHARACTERISTIC ODOR	Required by Customer	PASSED

(*) Note
USP specifies ASSAY 99-101%, and refers to glycerol on a dry basis
Glycerol dry basis = [glycerol x (100/ (100-water content))]
In addition to the ASSAY level Renova guarantees a glycerol content of 99.7%

(**) Note
USP specifies 1.249. Under request Renova could guarantee 1.26

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