

Item Number	E1068	Lot Number	3GC0038
Item	Dehydrated Alcohol, 200 Proof, USP, EP, BP		
CAS Number	64-17-5		
Molecular Formula	C ₂ H ₅ OH	Molecular Weight	46.07

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (by VOLUME)	99.5 %		99.99%
CLARITY OF SOLUTION	TO PASS TEST		PASSES TEST
COLOR OF SOLUTION	TO PASS TEST		PASSES TEST
ACIDITY OR ALKALINITY	TO PASS TEST		PASSES TEST
RELATIVE DENSITY @ 20 °C	0.790 - 0.793		0.791
SPECIFIC GRAVITY @ 15.56 °C		0.7962	0.7937
UV ABSORPTION	TO PASS TEST		PASSES TEST
240 nm		0.40	0.28
250nm-260nm		0.30	0.11
270nm-340nm		0.10	0.01
UV SPECTRUM	The spectrum shows a steadily descending curve with no observable peaks or shoulders		PASSES TEST
ORGANIC IMPURITIES / VOLATILE IMPURITIES	TO PASS TEST		PASSES TEST
METHANOL		200 PPM	NONE DETECTED
ACETALDEHYDE AND ACETAL		10 PPM	NONE DETECTED
BENZENE		2 PPM	NONE DETECTED
SUM OF ALL OTHER IMPURITIES		300 PPM	7 PPM
NONVOLATILE RESIDUE / RESIDUE ON EVAPORATION	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
RESIDUAL SOLVENTS	TO PASS TEST		
CLASS 2, METHANOL		3000 PPM	< 3000 PPM
CLASS 3, 2-PROPANOL		5000 PPM	< 5000 PPM
APPEARANCE			CLEAR,COLORLESS LIQUID
RETEST DATE			03-JAN-2020
MANUFACTURE DATE			03-JAN-2017

RESIDUAL SOLVENTS: USP, Chapter <467> limits the residual solvent content of a drug product to the permitted daily exposure (PDE) level given in that chapter. This Spectrum Certificate of Analysis reports any residual solvents that are likely to be present in the material as a result of manufacturing and/or processing. Residual solvents of Class 1 are identified and quantified when present in the material. Residual solvents of Class 2 or Class 3 are identified and the maximum limit is reported unless Class 2 solvents are present at levels greater than Option 1 limits or Class 3 solvents are present at levels greater than 0.5%. It is the responsibility of the producer of a finished dosage form to ensure that the aggregate residual solvent content meets applicable requirements set forth in USP, Chapter <467>.



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