



PRODUCT SPECIFICATIONS SHEET

Product Name Ethyl Alcohol 17.5% made with Water for Injection (WFI)
 Catalog # Grain Derived Ethanol
 111WFI350

TEST	MONO-GRAPH	SPECIFICATION	TYPICAL RESULT
Assay (v/v)	Internal	17.0 % – 18.0 %	17.48 %
Assay (wt/wt)	Internal	13.8 % – 14.6 %	14.21 %
Specific Gravity	Internal	0.9779 – 0.9789 @ 15.56°C	0.9785
Specific Gravity	Internal	0.9773 – 0.9784 @ 20.00°C	0.9779
Acidity	Internal	To Pass Test	Pass
Appearance	Internal	Clear liquid, free from sediment	Pass
Color (Pt-Co)	Internal	10 max.	1
Odor	Internal	Characteristic	Pass
Bioburden – Plate Count	Internal	≤ 10 CFU/100 mL	LT 10 CFU/100 mL
Bioburden – Yeast & Mold	Internal	≤ 10 CFU/100 mL	LT 10 CFU/100 mL
Bacterial Endotoxins	Internal	≤ 19.2 EU/mL	LT 0.15 EU/mL

This product is made with USP Grade Ethyl Alcohol and USP grade Water for Injection.

This product is for further commercial manufacturing, laboratory, or research use, and may be used as an excipient or a process solvent for pharmaceutical purposes. This product is not intended for use as a sterile product. Not for parenteral use, nor for injection, wound irrigation, or infusion. It is not intended for use as an active ingredient in drug manufacturing nor as a medical device or disinfectant. Appropriate/legal use of this product is the responsibility of the user.