

**Title :** Experimental Production of 70% Alcohol Solution and Validation of Ethanol Analysis Methods.

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## ABSTRACT

This project aimed to experimentally produce 70% alcohol solution and evaluate an analytical method for assessing the quality of ethanol, focusing on the validation of organic impurity analysis in ethanol using Gas Chromatography (GC), in accordance with the ICH Q2(R2) guideline. The initial phase involved testing the produced 70% alcohol solution. Results showed that the ethyl alcohol content (69.93 – 70.32 %v/v), absorbance at 640 nm (0.2 – 0.3), and pH (5.12 – 6.54) all met the established standard criteria. The study evaluated system suitability, specificity, linearity, limits of detection and quantitation (LOD/LOQ), and precision. The method validation results confirmed compliance with all ICH Q2(R2) acceptance criteria. The analytical method demonstrated high specificity, yielding a resolution value between acetaldehyde and methanol of 1.607 (criterion: NLT 1.5). Good linearity was observed with a correlation coefficient (R) of greater than 0.990 for all target compounds. Furthermore, the Precision, reported as percent relative standard deviation (%RSD), ranged from 0.000% to 7.092%, which is lower than the specified acceptance criteria of 7.3%. The signal-to-noise ratio (S/N) for the LOQ solution was confirmed to be greater than 10.0. In conclusion, the developed method is effective, highly reliable, and suitable for the quality control of ethanol, supporting future drug registration processes.

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