

# **Development and Validation of Analytical Method for Estimation of 1,4-Dioxane in Herbal Shampoo by Gas Chromatography**

Submitted By

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## **ABSTRACT**

1, 4-dioxane is a man made chemical used primarily as an industrial solvent and also found as organic volatile impurity in cosmetic products. A rapid, simple, accurate and precise method has been developed for the estimation of 1,4 dioxane in herbal shampoo by gas chromatography coupled with flame ionization detector. Good resolution and sharpness of peak were achieved by using Rtx 5 capillary column (30m x 0.25mm) with stationary phase crossbond 5% diphenyl 95% dimethyl polysiloxane. 1, 4-dioxane was extracted out by simple and rapid liquid-liquid extraction method using methanol and dichloromethane. The amount of 1, 4-dioxane was found 9.32 ppm at retention time 3.52 mins in Trichup herbal shampoo.

The method validation was carried out with regard to the guidelines for analytical procedures demanded by the International Conference on Harmonization (ICH Q2R1). The lower limit of detection (LOD) and lower quantification limit (LOQ) were obtained 0.10ppm and 0.30 ppm, respectively. The linearity was over the range of 0.5 ppm to 20 ppm with regression coefficients higher than 0.997. The interday and intraday precision of the method was achieved within 2% relative standard deviation (RSD) with % recoveries between 98 to 102%. The robustness of the method done by changing levels of parameters and results were achieved within 2% relative standard deviation (RSD). In specificity study, there was no peak observed at the retention time of the 1,4-dioxane in placebo.

**Keywords:** 1, 4-dioxane, Gas chromatography, Herbal shampoo