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Validation for Residual Solvents in Bisoprolol Fumarate by Gas Chromatographic Technique

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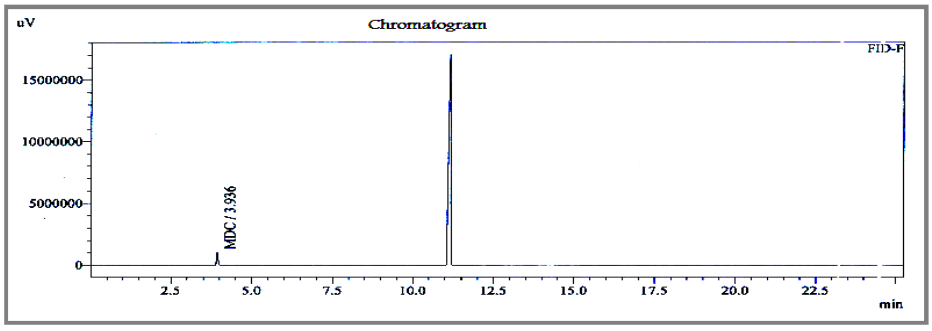
ABSTRACT

Validation is important technique for detection, progress and estimation of drugs for pharmaceutical analysis. Aim of this article was to check the progress and validation of the method employed for the Residual Solvents in Bisoprolol Fumarate by Gas Chromatographic technique. The objective of this protocol is to validate a GC method of analysis for detection and Quantification of Residual Solvents Methanol, Acetone and Methylene dichloride in Bisoprolol Fumarate. In the pharmaceutical industry, validation policy is more important for documented of validation, types of validation and validation policy. The method was developed accurately and validation parameters are explained. Chromatographic condition was GC- 2014, gas chromatograph equipped with FID detector, column: 30 m x 0.32 mm ID x 1.8 µm DB - 624 capillary column or equivalent and column temperature was 45°C (hold 7 minutes) to 250°C @ 40°C/minutes, hold at 250°C for 3 minutes. The parameters such as Accuracy, Specificity, Precision, Linearity and Range, Limit of detection (LOD), Limit of quantitation (LOQ), ruggedness, robustness and system suitability testing with residual solvent such as Methanol, Acetone and methylene dichloride. All validation parameters are used in the routine and stability analysis.

Graphical Abstract



GC of Methylene Dichloride.

Keywords: GC, Validation, Bisoprolol Fumarate, LOD, LOQ and Linearity.