Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2023, 12 (1): 42-52

(International Peer Reviewed Journal)

Method of Validation for Residual Solvents in Brimonidine tartrate by GC-HS

Sunil Lakhmapure[1], Sandip A Telavane[1], Seema Kothari[1] and Manohar V. Lokhande[2]*

1. Department of Chemistry PAHER University, Udaipur-313003, Rajasthan, **INDIA**
2. Department of Chemistry, Sathaye College, Mumbai-400057, Maharashtra, **INDIA**

Email: manohar2210@gmail.com

Accepted on 20th January, 2022

ABSTRACT

GC-HS is vital method for recognition, development and valuation of drugs in pharmaceutical analysis. Aim of this article was to check the progress and validation of the method employed for the Residual Solvents in Brimonidine Tartrate by Gas Chromatography Headspace technique. The objective of this protocol is to validate a GC-HS method of analysis for detection and Quantification of Residual Solvents Acetone, Benzene, Dichloromethane, Ethyl Acetate, Toluene, Isopropyl alcohol and bromobenzene in Brimonidine Tartrate. In the pharmaceutical industry, validation policy is more important for documentation for types of validation and validation policy. The method was developed accurately and validation parameters were explained. Chromatographic condition was Clarus 600 with parkin Elmer instrument, column: 30m x 0.53 mm-lD, 3.0 pm GS-TEK-624 column or equivalent (G-35) or equivalent and column temperature was 45°C (hold 15 min) to 250°C @ 40°C min^{-1}, hold at 250°C for 3 min. The parameters such as Specificity, Limit of detection (LOD) and Limit of quantitation testing with residual solvent such as Acetone, Benzene, Dichloromethane, Ethyl Acetate, Toluene, Isopropyl alcohol and Bromobenzene. All validation parameters are used in the routine and stability analysis.

Keywords: Brimonidine tartrate, GC-HS, Specificity, LOD and LOQ.