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Method Development and Validation for the Simultaneous Determination of Methyl Sulphonyl Methane in Sold Dosage Form by Gc

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Abstract
A Gas chromatographic method has been developed for the analysis of Methyl Sulphonyl Methane in solid dosage form. Perkin Elmer Clarus 500 GC with Nitrogen as carrier gas was utilised at the flow rate of 5.0 mL/min and FID detection was carried out. The separation was achieved using BP-624-20 column (30m X 0.53 mm I.D., particle size 1µm). The method was linear over the concentration rangefor Methyl Sulphonyl Methane. The analytical recovery obtained was 99.88%. The validation of method carried out as per ICH guidelines. The described GC method was successfully employed for the analysis of pharmaceutical formulations containing Methyl Sulphonyl Methane in solid dosage form and can be employed for bioequivalence study in future for the same formulations.

Keywords:- GC, Methyl Sulphonyl Methane, Method Development.

I. Introduction And Material And Methods

Introduction

Methyl Sulphonyl Methaneis a white crystalline solid at (m.p. = 109 °C) and is a organosulfur compound with the formula $(CH_3)_2SO_2$. It occurs naturally in some primitive plants, is present in small amounts in many foods and beverages, and is marketed as a dietary supplement. It is also commonly found in the atmosphere above marine areas, where it is used as a carbon source by the airborne bacteria *Afipia*,[2] and is found distinctively in human melanoma cells.

A literature survey reveals that Nuclear magnetic resonance (NMR) studies have been demonstrated that oral doses of MSM are absorbed into the blood and cross the blood/brain barrier. As only a few methodshave been developed for the quantification of individual drug Methyl Sulphonyl methane in Multiple Ingredients dosages that too only by very Sophisticated Instruments like NMR techniques & no easy , accurate & fast techniques by GC were available, hence the method was thought to be developed by GC,. There were no simple and reproducible methods so far reported for simultaneous determination of Methyl Sulphonyl Methane by GC in solid dosage form.It was essential to develop simple, precise, accurate GC method for determination of this drug in solid dosage form. Therefore, in this study we developed reproducible method which can be used in laboratory. GC method can be applied in future for estimation of same drugs even from biological samples. The validation of this method carried out as per ICH guidelines.

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MATERIAL AND METHODS

Experimental

Reagents and Materials

Pharmaceutical grade Methyl Sulponyl Methane wasused. All chemicals and solvents are of AR grade and were purchased from Qualigens fine Chemicals, Mumbai, India.

Instrumentation of GC

Perkin Elmer, Clarus 500GC system was used, GC system used consisted of:Integrator: Total Chrom Navigator.

The column used was BP-624-20 (30 m X 0.53mm i.d., 1µm particle size), max temperature 300°c . Different flow rates & gas were utilised in order to find the best conditions.

The optimal conditions of GC was consisted of Hydrogen Gas flow at 30ml/min and Air flow rate of 300ml/min and FID detection was carried out.

The Injector temperature was maintained 250°c & detector temperature was maintained 270°c
The Injector Volume loaded was 1µl.

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Preparation of working solutions

Stock solution was prepared by dissolving 100 mg of Methyl Sulphonyl Methane (WS) in 25 mL volumetric flask and added 10ml of ethanol and mixed& further diluted by ethanol to volume.

All solutions were stored at + 20^0C, these solutions were shown to be stable during the period of study. From the above stock solutions, dilutions were made to working standard and final concentration of 1.0mg/ml was prepared.

A volume of1 µL of the working standard was injected into column. All measurements were repeated five times for each concentration and calibration curve was constructed by plotting the peak area ratios of analyte versus the corresponding drug concentration.

Analysis of tablets

To determine the content of Methyl Sulphonyl Methane in tablets (label claim: 250 mg); twenty tablets were weighed; their average weight determined and were finely powdered in mortar & pestle . The correct amount of powder equivalent to 100mg of Methyl Sulponyl Methane wasWeighed in 100ml Volumetric flask & further dissolved in ethanoland sonicated for 10 min., the final volume was madeup with ethanol and mix.

The excipients were separated by filtration. After filtration, an appropriate amount of. 1.5ml was taken in autosampler to get working standard solution containing 1.0 mg/ml of Methyl Sulponyl Methane.

This sample solution was injected five times and recorded the chromatograms. The amount of Methyl Sulponyl Methane was determined.

To check the accuracy of the developed methods and to study the interference of formulation additives, analytical recovery experiments were carried out by standard addition method at 80, 100 and 120 % level.

From the total amount of drug found, the percentage recovery was calculated.

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Conclusion:

After the review of Analytical Method Validation report & observing the results obtained, it is summarized that the methods discussed in the present work provide a convenient and accurate way for analysis of Methyl Sulponyl Methane in its Dietary Supplement tablet dosage form.

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