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A REVIEW ON DEVELOPMENT AND ESTIMATION OF PHARMACEUTICAL FORMULATION BY GAS CHROMATOGRAPHY(C-18)

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ABSTRACT
Gas chromatography is a sensitive, accurate, reproducible, quantitative and versatile tool well adapted for the analysis of complex mixtures. Analytical method development plays a crucial role in ensuring the quality and safety of pharmaceutical formulations. In the present work a gas chromatographic method was developed and optimised for the estimation of a pharmaceutical formulation. The study focused on systemic optimization of chromatographic conditions to achieve effective separation, reproducible retention, behaviour and reliable quantification of the analyte. Method development involved the selection of appropriate column characteristics, carrier gas flow conditions and temperature programming to enhance sensitivity and peak resolution. The development method was validation in accordance with ICH guidelines validation parameters such as linearity accuracy, precision limit of detection, limit of quantification and robustness were evaluated and found to be within acceptable limits. The proposed gas chromatography method demonstrate satisfactory performance for the estimation of pharmaceutical formulations and can be effectively applied for routine quality control analysis.

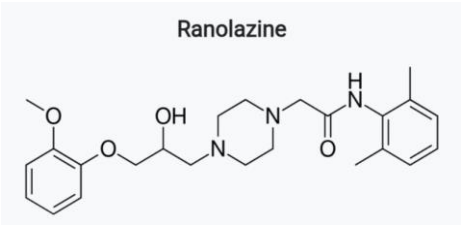
KEYWORDS: LOD: limit of detection, LOQ: limit of quantification, GC: Gas chromatography.

INTRODUCTION

Gas chromatography (GC) is a widely used analytical technique for the separation, identification, and quantification of volatile and semi-volatile compounds in pharmaceutical formulations. It plays a crucial role in quality control by ensuring the purity, safety, and efficacy of active pharmaceutical ingredients (APIs) and excipients. The development of a GC method involves optimization of parameters such as column type, carrier gas, temperature program, and detector conditions to achieve accurate and reproducible results. Method validation is performed according to ICH guidelines, including evaluation of specificity, linearity, accuracy, precision, limit of detection (LOD), and limit of quantification (LOQ). GC-based estimation is particularly useful for analyzing plant-derived compounds and essential oils, such as β-caryophyllene in clove extract, which possess significant pharmacological activities. Therefore, a validated GC method serves as a reliable tool for the routine analysis and quality assessment of pharmaceutical formulation. Mechanism of action of Ranolazine works by inhibiting the late inward sodium current in cardiac cells during ischemia. This reduces intracellular sodium and subsequently decreases calcium overload. Lower calcium levels improve myocardial relaxation, reduce wall tension, and decrease oxygen demand, thereby relieving anginal symptoms without significantly affecting heart rate or blood pressure.[1,2]

Adverse Drug Reactions: Dizziness, headache, constipation, nausea, Palpitations, hypotension, syncope**:** QT prolongation → risk of arrhythmias **Drug Interactions**

- CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin) → ↑ Ranolazine levels
- CYP3A4 inducers (e.g., rifampicin, phenytoin)
- Other QT-prolonging drugs → ↑ risk of arrhythmias
- Digoxin → increased levels (monitor)
- Simvastatin → increased concentration (dose adjustment needed).[3]



Applications: The developed Gas Chromatography method for the estimation of Ranolazine finds significant applications in pharmaceutical analysis

1. It is employed for the quantitative determination of Ranolazine in bulk drug and pharmaceutical dosage forms.
2. The method is useful in quality control analysis to ensure the consistency, purity, and potency of the formulation.
3. It facilitates the detection and quantification of impurities and degradation products, thereby ensuring drug safety.
4. The method can be applied for residual solvent analysis in accordance with regulatory guidelines.
5. It is suitable for stability studies, enabling monitoring of drug degradation under various environmental conditions.
6. The developed method can be routinely used in pharmaceutical industries and analytical laboratories for reliable drug estimation.[4]

Method validation

It is an essential part of analytical method development. It ensures that the developed analytical method is reliable, accurate, and suitable for its intended purpose. Validation demonstrates that the method consistently produces precise and accurate results under defined experimental conditions. In this study, method validation was performed to confirm that the developed analytical procedure using Gas Chromatography is suitable for the estimation of the drug in pharmaceutical formulations. The validation was carried out by evaluating key parameters such as linearity, accuracy, precision, specificity, sensitivity, and robustness. These parameters ensure that the method provides dependable results for routine analysis and quality control.[5]

Preparation of Standard Solution

A known quantity of the drug reference standard was accurately weighed and transferred into a volumetric flask. It was dissolved in a suitable solvent and diluted to obtain a primary stock solution. From this, serial dilutions were prepared to obtain different working concentrations used for calibration.

Preparation of Sample Solution

The pharmaceutical formulation was finely powdered and a quantity equivalent to the labeled amount of drug was weighed. The drug was extracted using a suitable organic solvent, sonicated to ensure complete extraction, and then filtered through a membrane filter. The filtrate was suitably diluted to bring the concentration within the calibration range.[6]

Chromatographic Conditions

The analysis was carried out using a Gas Chromatography system. A capillary column was employed as the stationary phase. An inert gas was used as the carrier gas and maintained at a constant flow rate. The injector and detector temperatures were optimized to obtain sharp peaks. The oven temperature was programmed to allow proper separation of the drug and possible impurities. A Flame Ionization Detector was used for detection.

Calibration curve

A series of standard solutions were injected under identical chromatographic conditions. The peak area was recorded for each concentration. A calibration curve was constructed by plotting peak area against concentration. Linearity was evaluated by regression analysis.[7]

Sample Analysis

Prepared sample solutions were injected into the chromatographic system under the same conditions used for the standard. The concentration of the drug in the formulation was calculated using the calibration curve.

Stationary Phase

For the analysis of Ranolazine using Gas Chromatography, a non-polar fused-silica capillary column coated with 5% phenyl – 95% dimethylpolysiloxane was selected as the stationary phase. This phase was chosen to achieve better separation efficiency, symmetrical peak shape, and adequate retention of the analyte.[9]

Mobile Phase

An inert carrier gas such as helium or nitrogen was used as the mobile phase. The carrier gas was selected due to its chemical inertness, ensuring that it transports the vaporized analyte through the column without interaction, allowing accurate detection and quantification.[10]

Column

For the estimation of Ranolazine by Gas Chromatography, a fused-silica capillary column was used. The inner surface of the column is coated with a thin layer of stationary phase (commonly 5% phenyl –

95% dimethylpolysiloxane). The sample vapour passes through the column along with the carrier gas (helium or nitrogen). Separation occurs because different components interact differently with the stationary phase and travel at different speeds through the column.[11]

S.No	Parameters	Typical condition
1.	Column type	Fused- silica capillary column
2.	Stationary phase	5%phenyl-95% dimethylpolysiloxane
3.	Column length	~30m
4.	Internal diameter	~0.25mm
5.	Film thickness	~0.25mu m
6.	Carrier gas(Mobile Phase)	Helium/Nitrogen
7.	Flow rate	~1.0mL/min
8.	Injector temperature	~250°C
9.	Detector temperature	~280°C
10.	Oven program	Optimized for clear separation

CONCLUSION

In the present study, a gas chromatographic method was successfully developed for the estimation of Ranolazine in pharmaceutical formulations. Appropriate chromatographic conditions were optimized using a non-polar capillary column as the stationary phase and an inert carrier gas as the mobile phase to achieve efficient separation. The developed method was validated in accordance with standard analytical parameters including linearity, accuracy, precision, specificity, and robustness. The validation results confirmed that the method is reliable and reproducible. The method demonstrated good sensitivity and selectivity, making it suitable for routine pharmaceutical analysis. The developed gas chromatographic method proved to be simple, accurate, precise, and robust for the estimation of Ranolazine in pharmaceutical formulations. The method exhibited excellent separation efficiency and reliable quantification. Validation studies confirmed its suitability for routine quality control and stability analysis. Therefore, the proposed method can be effectively applied in pharmaceutical industries for ensuring the quality, safety, and efficacy of the drug.

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