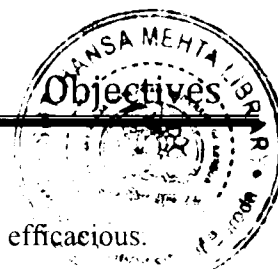


# **Chapter 2**

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## **Objectives**

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### OBJECTIVES OF THE STUDY

A patient taking a pharmaceutical product expects the product to be safe and efficacious.

Due to abundance of pharmaceutical agents available in the pharmaceutical market in various various dosage forms either as a single drug component or in combination with other drugs and also due to potency of the most of the drugs, it becomes necessary to quantitate these agents in their formulations in a precise manner.

Pharmaceutical regulatory agencies worldwide demand that the product retains its quality, purity, and potency for the time the product is commercially available. Consequently the agencies expect to see stability data supporting the proposed expiration date of the product in the marketing submission. In the broader sense the stability studies that are conducted should provide evidence of how the quality of the drug substance and drug product changes over time when subjected to various environmental conditions, such as temperature, humidity, and light.

It has also been observed that mainly in case of the cream formulations ,interference by cream components by cream base components hamper the analysis of active constituents ,which makes it a challenging task.

Therefore there is always a need to develop validated analytical methods which are precise, accurate, selective, and sensitive and can be used for routine analysis and stability studies of the drug products.

The objective of the present work was to develop validated analytical methods with the help of which we can separate and simultaneously quantitate drug components from the pharmaceutical formulations.

The specific aim of the work undertaken was:

- To develop validated analytical method based on HPLC for Racecadotril as a single component in bulk and in a commercial powder formulation. Racecadotril was selected because it was recently introduced in the Indian market and no method was available in the literature for estimation of the drug in the formulation at the time of undertaking the study.
- To study applicability of developed HPLC method for the determination of racecadotril in presence of its degradation products.
- To develop validated HPLC method for simultaneous analysis of Butenafine hydrochloride and Betamethasone dipropionate in bulk and in cream formulation. This combination was selected for study as the cream formulations are always difficult to analyze and butenafine

was recently introduced in the market at the time of undertaking the project.. Also not a single analytical method was reported in the literature for simultaneous estimation of the butenafine hydrochloride and betamethasone dipropionate.

- To develop validated HPTLC method for simultaneous analysis of Butenafine hydrochloride and Betamethasone dipropionate in bulk and in a cream formulation.
- To develop validated HPLC method for simultaneous analysis of Escitalopram oxalate and Etizolam in bulk and in a tablet formulation..Etizolam is not official in any pharmacopoeia and not a single analytical method was reported for the simultaneous estimation of these drugs in the formulation. The literature survey also revealed that no stability indicating method was available for this combination of drugs.
- To apply developed validated developed HPLC method for the determination of Escitalopram oxalate and Etizolam in presence of their degradation products.
- To study applicability of developed HPLC method for dissolution studies of Escitalopram oxalate and Etizolam in a tablet dosage form..
- To develop validated HPTLC method for the simultaneous analysis of Albendazole and Ivermectinin in bulk and in a tablet dosage form .This combination was selected for study because ,although analytical methods for indivisual drugs were available,but not a single method was reported for the simultaneous estimation of this these drugs in combined dosage form at the time of selection. Also proportion of ivermectin to albendazole (12:400) in tablet dosage form was also found to be challenging.
- To develop IR method for the simultaneous analysis of Albendazole and Ivermectin in bulk and in a tablet dosage form. Solubility of albendazole in mineral acid was the measure concern in the simultaneous method development as ivermectin is sensitive to mineral acid degradation. Therefore it was decided to take the advantage of IR for estimation of drugs in solid dosage form without much sample preparation.
- To develop validated HPLC method for simultaneous analysis of Fluocinolone acetonide and Miconazole nitrate in bulk and in an ointment. This combination was selected because, although analytical methods for individual drugs were available, not a single method was reported for the simultaneous estimation of this these drugs in combined dosage form.Also proportion of fluocinolone acetonide to miconazole nitrate (1:200) was also found to be challenging.

- To develop validated HPLC method for simultaneous analysis of Hydrocortisone acetate and Miconazole nitrate in bulk and in a cream formulation. This combination was selected because, although analytical methods for individual drugs were available, not a single method was reported for the simultaneous estimation of these drugs in combined dosage form.
- To overcome typical challenges encountered while developing and validating methods for pharmaceutical products containing single and more than one active ingredients.