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A Review on Chromatographic Technique of RP-HPLC Method for The Estimation of Olanzapine and Samidorphan in Pharmaceutical Dosage Form and Bulk Form

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ABSTRACT:
A complex, long-term mental illness, schizophrenia is typified by a wide range of symptoms, such as hallucinations, delusions, disordered speech or behaviour, and cognitive impairment. An outline of the analytical methods utilized to identify olanzapine and samidorphan by rphplc is given in the current work. Both official compendia and scientific publications in worldwide literature were searched to gather data.Pharmaceutical medications, contaminants, and biological samples can be identified and separated quickly, safely, and precisely using high-performance liquid chromatography (HPLC) in conjunction with ultraviolet (UV), photodiode array detectors (PDA), and other technologies. Pharmaceuticals can be quantified more quickly and with greater flexibility using HPLC than with more traditional liquid chromatography methods. Pharmaceutical medications are essential to human life since they help treat a variety of illnesses. Consequently, the main analytical activity is now the development of analytical procedures. People have been searching for safe and efficient treatments for viral infections since ancient times. In the current setting, the discovery of drugs to treat fungal infections is becoming equally crucial due to the advent of new fungal illnesses.to improve therapeutic efficacy and reduce unfavourable side effects, combination medication is becoming more and more popular for treating mental health issues. According to clinical research, olanzapine and samidorphan medication together led to noticeably less weight gain than olanzapine alone.

Key Words: Olanzapine and Samidorphan, HPLC, Pharmaceutical analysis.

I. INTRODUCTION

Bipolar 1 disorder is a mental illness that causes psychological distress and interferes with day-to-day functioning. It is characterized by recurring manic episodes that alternate with depressive episodes and intervals of euthymia.[1] Both schizophrenia and bipolar disorder require effective treatments to achieve the treatment goals of lowering the debilitating symptomology, improving social functioning and quality of life, and raising the chances of recovery.[2,3] Bipolar 1 disorder has been identified as primarily biological, and the disease course and symptomology can vary greatly depending on psychological and environmental social factors.[4,5,6]An important turning point was the FDA's approval of the olanzapine/samidorphan combination for the treatment of bipolar I disorder and schizophrenia. The clinical trials detailing the side effects and clinical effectiveness of the olanzapine/samidorphan combination are compiled in this article along with an evaluation of their bias.[7]

A subfield of practical chemistry known as pharmaceutical analysis comprises a variety of techniques for identifying, determining, quantifying, and purifying substances as well as for separating the components of a mixture or solution or figuring out the chemical makeup of compounds.[8] The material could be one component, a mixture of compounds, or both, and it could be present in any dose form. Pharmaceuticals use a wide range of manmade materials as well as microbes, minerals, plants, and animals. Achieving pharmaceuticals with

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sufficient levels of quality, efficacy, and safety is the industry's main goal.[9]The development of a new medicine product involves several pharmaceutical procedures, including analytical testing. The resulting analytical data enable future decisions on how development should go or offer information on whether a therapeutic product should be released. The application of analytical techniques is one of the most crucial stages in the production and development of pharmaceutical goods. They are essential to assisting other development and production activities at every stage of a drug product's life cycle.[11,12,13] For an analytical technique to be suitable for the task at hand, it must be exact, accurate, and reliable,the separation of analytes contained in a sample is, for the most part, the main principle of operation of an analytical method. Liquid chromatography methods such as HPLC or UPLC are most employed, typically in reversed-phase mode with UV absorbance detection.[14] The goals of the analysis are influenced in many ways by the number, significance, and relationship of the analytes that need to be identified. The most utilized analytical procedures are those for evaluating an active pharmaceutical ingredient (API) or determining its associated substances and degradation products.[15]

Chemistry of Olanzapine and Samidorphan

Olanzapine and samidorphan, an opioid receptor antagonist, are being developed together to treat bipolar I disorder and schizophrenia. The goal of the single-tablet combo medication is to reduce weight gain linked to olanzapine while maintaining its effectiveness.[16]

Mechanism of action

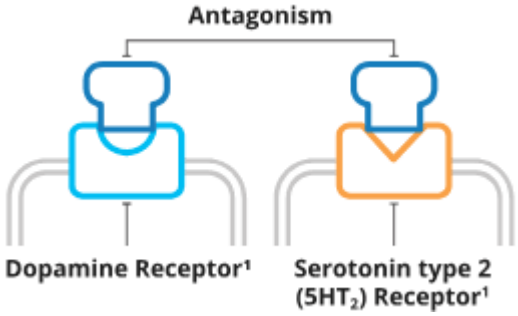

Figure no 1 Mechanism of action

Samidorphan functions as a partial agonist at k-opioid and δ-opioid receptors, while olanzapine is thought to act as an antagonist to dopamine D2 receptors and have rapid ligand-receptor dissociation kinetics, which helps to reduce extrapyramidal symptoms. The precise mechanism of action of olanzapine as a therapeutic agent in schizophrenia is not well understood.[17]

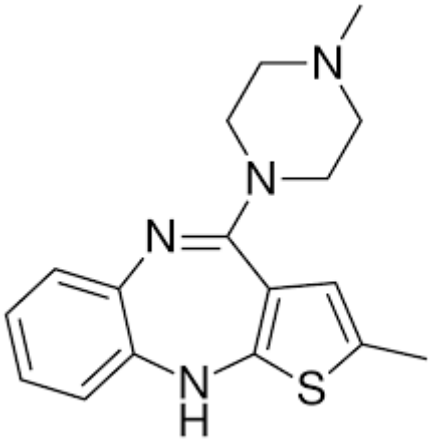

Figure no 2Structure ofOlanzapine

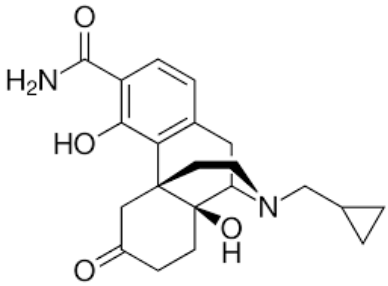

Figure no 3Structure of Samidorphan

HPLC methods for Olanzapine and Samidorphan in combinations

For the evaluation of drug products, the separation, detection, and quantification of pharmaceuticals and drug-related degradants, HPLC is an essential analytical tool. Method performance features and limitations are established through validation, which also identifies factors that affect these qualities.[18] Strategies for the development and validation of HPLC methods are covered in this article.Total seven methods reported for estimation of Olanzapine and Samidorphan in combination dosage form by using HPLC methods.

S. Vinod et al., estimated the analysis by rphplc ofOlanzapine and Samidorphan through c18 column,for olanzapine (15 µg/mL) and samidorphan (10 µg/mL), the procedure was linear across the concentration range. Olanzapine and samidorphan, the active pharmaceutical ingredients (API), had recoveries that ranged from 98.00 to 102.00%, **Divyasri Pillamari et al.,** In this context of analysis of olanzapine and samidorphan there elution of analytes found to have retention times of 3.108 and

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2.365 minutes respectively. The percentage RSDs for olanzapine and samidorphan were determined to be 0.4% and 0.6%, respectively. % Recovery rates for olanzapine and samidorphan were 100.46% and 100.29%, respectively. The regression equations for olanzapine and samidorphan yielded LOD and LOQ values of 0.29, 0.89, and 0.04, 0.12, respectively. % assay results for samidorphan and olanzapine were 99.71% and 99.58%, respectively, **Roja Priya et al..,**developed for the simultaneous estimation of the Olanzapine and Samidorphan,the assay results for olanzapine and samidorphan were 99.19% and 99.81%, respectively. For Olanzapine and Samidorphan, the recovery percentages were 99.49% and 99.49%, respectively. values for LOD and LOQ derived using regression equations of the corresponding values for olanzapine and samidorphan were 0.21, 0.63, and 0.09, 0.23, **Ibrahim Baje Syed et al..,**A regression value of R2 > 0.999 indicates that the calibration charts' linearity was within acceptable bounds. The proposed method is quick, easy, feasible, and affordable under test conditions, **JagadeswaranChandraseka et al..,**It was created for the quantitative investigation of samidorphan and olanzapine in pharmaceutical dosage forms. The relative standard deviation (RSD) for samidorphan was 0.3 and for olanzapine, it was 0.60. Regression coefficients for Olanzapine and Samidorphan were 0.9998 and 0.9999, respectively, after linearity was demonstrated by creating different concentrations ranging from 5 ppm to 30 ppm. Using six dilutions at 20 µg/mL and a %RSD of 2, precision was verified. The mean recoveries for Olanzapine and Samidorphan were 99.83% and 99.84%, respectively, when accuracy was evaluated at 50%, 100%, and 150% concentration levels. For Olanzapine, the limits of detection (LOD) and quantification (LOQ) were found to be 0.6 µg/mL and 0.3 µg/mL, while for Samidorphan, they were 2 µg/mL and 1 µg/mL, **Padmavathi Sakinala et al..,**Olanzapine's elution time is 2.054, while samidorphan is 3.940. RSD is between 0.30% and 0.52%. For the linearity research, different concentration solutions of 5 ppm, 10 ppm, 15 ppm, 20 ppm, 25 ppm, and 30 ppm were prepared. Tailing factors 1.21, 1.16 Regression values are 0.99947, 0.99986. % RSD for precision results using concentrations of 6 dilutions at 20µg/ml. precision percentage concentration 50%, 100%, 150% average recovery Samidorphan 2 µg/ml, 1 µg/ml, 100.9 lod&loq 0.6 µg/ml, 0.3 µg/ml. Samidorphan was 100.2% and olanzapine was 99.4% in the assay, **Rafi Syed et al..,**In 15 minutes, the analysis was completed over an honest linearity in the concentration range of 1–15 µg/ml of Samidorphan and 2–30 µg/ml of Olanzapine. System suitability parameters were examined by injecting the standard six times, and the results fell significantly short of the acceptance criterion. The results of the precision and recovery studies were found to be within the appropriate range.

Table 1 lists various HPLC techniques and their characteristics as they are described in the literature review.

Table 1: Performance attributes of HPLC method[19-25]

Author	Pharmaceutical or Biological Matrix	Stationary phase	Chromatographic Conditions	Wave length
S Vinod et al..,	Bulk and Pharmaceutical Dosage form	Azilent C18 150x 4.6mm, 5µm	50:50 % (V/V) Acetonitrile: 0.1% Orthophosphoric Acid Flow rate- 1.0ml/Min Run time- 6 Minutes	226nm
Divyasri Pillamari et al..,	pharmaceutical Dosage Form	BDS 150 x 4.6 mm, 5mm	0.01N Potassium dihydrogen phosphate: Methanol taken in the ratio 80:20 %v/v. Flow rate- 0.9ml/min Run time- 6 minutes	278 nm
Kethavat Roja Priya et al..,	tablet dosage form	Std Zorbax 150 x 4.6 mm, 5µm	Buffer 0.01N Sodium hydrogen phosphate: Acetonitrile taken in the ratio 60:40 %v/v. Flow rate- 1.0ml/min	268nm

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			Run time- 6 minutes	
Ibrahim Baje Syed et al..,	Bulkand Pharmaceutical Dosage	Inertsil ODS 250x4.6 mm x 5µm	acetonitrile/0.1 percent ortho phosphoric acid (50:50). Flow rate- 1ml/min Run time- 5 minutes	261nm
JagadeswaranChandraseka et al..,	Pure and Pharmaceutical Dosage Forms	C18(100 ×4.6 mm, 5µm)	Acetonitrile and Mono basic potassium phosphate in a ratio of 50:50% v/v Flow rate- 1ml/min Run time- 6 minutes	280
Padmavathi Sakinala et al..,	Dosage Forms	Luna phenyl hexyl250X4.6 mm, 5µm	Ammonium formate pH-3.2/ formic a cid& ACN in the ratio of 20:80% v/v Flow rate- 1ml/min Run time- 5 minutes	280nm
Rafi Syed et al..,	Dosage Form And Bulk	Symmetry C18 column (150x4.6mm, 3.5 µ	buffer and acetonitrile within the ratio of 60:40	261nm

II. CONCLUSION:

The current review discussed hplc analytical techniques that were used to assess separation quantification of analytes from pharmaceutical dosage form and bulk. Numerous tests have been conducted through HPLC to assess the effectiveness of Olanzapine and Samidorphan in combination derived from pharmaceutical formulation and pure bulk form using hplc, Liquid chromatography with UV detection was the most widely studied method for estimating Olanzapine and Samidorphan in pharmaceutical dosage forms,This analysis of the HPLC method for quantifying samidorphan and olanzapine indicates that a trustworthy method for precise quantification of the substances. Olanzapine and Samidorphan quantitative analysis in pharmaceutical formulations has been developed with precision and accuracy. This method was used to verify the accuracy, precision, linearity, LOD, LOQ, and repeatability. All the parameters' RSD values were determined to be less than 2%, demonstrating the method's validity and the outcomes it produced.

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