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Various Analytical methods for estimation of Cinitapride- A Review

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ABSTRACT:
Cinitapride is a benzamide with gastroprokinetic and antiemetic properties typically used for the treatment of gastrointestinal motility disorders such as gastroesophageal reflux disease, non-ulcer dyspepsia, and delayed gastric emptying. There is no any official method of analysis of Cinitapride. Several UV spectrophotometric, HPLC methods in pure form, pharmaceutical formulation and plasma have been reported to determine.This review provides an overview of various analytical techniques used for Cinitapride determination both in a single preparation and mixed with other substances.

KEYWORDS: Cinitapride, spectrophotometric, HPLC,

I. INTRODUCTION [1-3]

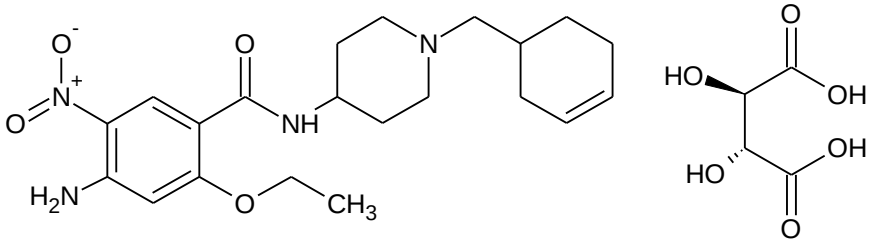

Fig 1. Structure of Cinitapride hydrogen tartrate.

IUPAC Name is 4-amino-N-[1-(cyclohex-3-en-1-ylmethyl)piperidin-4-yl]-2-ethoxy-5-nitrobenzamide.Molecular Formulais$C_{25}H_{36}N_4O_{10}$.It's molecular weightis552.57 g/mol.The appearance is Yellow coloured powder.Freely soluble in methanol, sparingly soluble in water. Coming under the category of antiemetics, it is a gastroprokinetic agent and antiulcer agent of the benzamide class. It acts as an agonist of the 5-HT1 and 5-HT4 receptors and as an antagonist of the 5-HT2 receptors.HavingHalf life of 3-5 h. There are UV, colorimetry and HPLC methods for cinitapride estimation.

II. VARIOUS ANALYTICAL METHODS

Spectrophotometry methods:

A new, rapid, precise, accurate and sensitive analytical method was developed for the UV spectrophotometric assay of cinitapride. The drug obeyed the Beer's law and showed good correlation. It showed absorption maxima at 260 nm in methanol. The linearity was observed between 5-40 µg mL^{-1}. The results of analysis were validated by recovery studies. The recovery was more than 99%. The proposed method is the only method available for spectrophotometric determination of the drug. It is simple, precise, sensitive and reproducible and can be used for the routine quality control testing of the marketed formulations [4].

The a research work the development of a UV estimation method for Cinitapride was given. This was simple, fast, accurate and cost efficient and reproducible. Spectrophotometric method has been developed for the estimation of Cinitapride at in bulk and tablet formulations. The wave length (λ max) selected for the Cinitapride at was 263 nm. The linearity for this drug at the selected wavelength is lies between 0.2 to1µg/ml. Beer's law obeyed in this concentration range with correlation coefficient of 0.9999. The proposed method was successfully applied to the determination of cinitapride in pharmaceutical formulations without any interference from common excipients [5].

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Cinitapride and Pantoprazole are available as capsule dosage forms in the ratio 1:13.33. A simple reproducible and efficient method for the simultaneous determination of cinitapride and pantoprazole in marketed formulation was developed. The proposed method was based on the Q-analysis UV-Spectrophotometric method. The absorbance maximum of cinitapride and pantoprazole were found to be 265.5 nm and 268 nm respectively in water. In Q-analysis, the isoabsorptive point for both the drugs was found at 236 nm. The linearity range lies between 5-30 µg/ml for cinitapride and pantoprazole at their respective wavelengths. Both the drugs obey Beers law. The recovery studies confirmed the accuracy of the proposed method [6].

This work describes two sensitive, accurate and precise chemometric spectrophotometric methods for the simultaneous determination of Cinitapride hydrogen tartarate and Pantoprazole sodium in bulk powder and capsules without prior separation. Multivariate calibration chemometric methods are proposed for simultaneous determination of two drugs. The chemometric methods applied are Principal Component Regression and Partial Least Squares. These approaches are successfully applied to quantify both drugs using the information included in the absorption spectra of appropriate solutions. In these multivariate methods, calibration sets of standard samples composed of different mixtures of these two drugs have been designed. The methods were validated according to TheInternational Conference on Harmonization guidelines. The specificity of the proposed methods were tested using laboratory-prepared mixtures. The developed methods were successfully applied for the determination of Cinitapride hydrogen tartarate and Pantoprazole sodium in bulk powder and dosage form combination [7].

A new visible spectrophotometric method has been developed for the estimation of cinitapride and pantoprazole in bulk and capsule dosage form. The method makes use of diazotization followed by complexation for cinitapride and redox cum complexation for pantoprazole. The complex of cinitapride showed Lambda max at 399nm and that of pantoprazole showed at 477nm. A good linearity with correlation coefficient within the limit was observed for the drugs at the concentration range of 10-60µg/ml for cinitapride and 0.4 – 2.4 µg/ml for pantoprazole. The reagents used were optimized. The developed methods were assessed for precision, accuracy, sensitivity.Thus a simple easy to perform and economical precise and accurate visible spectrophotometric methods have been developed for the estimation of cinitapride and pantoprazole [8].

Current research attempts to develop simple, cost effective, and time saving, validated UV spectrophotometric method for the simultaneous estimation of Rabeprazole and Cinitapride in tablet formulations by simultaneous equation method. The sampling wavelengths for Rabeprazole and Cinitapride are 284.5 nm and 267 nm respectively. Assay results showed 10.008 mg of Rabeprazole and 2.974 mg of Cinitapride were found in the tablet dosage form. The method was validated as per ICH guidelines. Linearity was obtained in the concentration range of 3-8 µg/mL for Rabeprazole and 2-7 µg/mL for Cinitapride. The %RSD for intraday and interday variations of Rabeprazole was found to be 0.183±0.002 and 0.317±0.001 respectively. An intraday and interday variation of Cinitapride was found to be 0.194±0.002 and 0.298±0.001 respectively. In both cases values were within the acceptance limit of < 2%. The mean percent recovery for Rabeprazole and Cinitapride were found to be 98.57 % and 99.43 % respectively, within the acceptance limit of 98% to 102%. From the high recovery values (> 98%) it can be inferred that the method is free from the interference of excipients used in the formulation. Based on the results obtained the proposed method can be regarded as simple, accurate, precise, reliable and cost effective which can be employed for routine quality control of these drugs in combined tablet dosage forms[9].

Cinitapride and Pantoprazole are available as capsule dosage forms in the ratio 1:13.33. A simple reproducible and efficient method for the simultaneous determination of cinitapride and pantoprazole in marketed formulation was developed. The proposed method is based on the Q-analysis UV-Spectrophotometric method. The absorbance maximum of cinitapride and pantoprazole were found to be 265.5 nm and 268 nm respectively in water. In Q-analysis, the isoabsorptive point for both the drugs was found at 236 nm. The linearity range lies between 5–30 µg/ml for cinitapride and pantoprazole at their respective wavelengths. Both the drugs obey Beers law. The recovery studies confirmed the accuracy of the proposed method[10].

Three simple, selective and rapid spectrophotometric methods have been established for the determination of cinitapride hydrogen tartrate (CHT) in pharmaceutical tablets. The

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proposed methods are based on the diazotization of CHT with sodium nitrite and hydrochloric acid, followed by coupling with resorcinol, 1-benzoylacetone and 8-hydroxyquinoline in alkaline medium for methods A, B and C, respectively. The formed azo dyes are measured at 442, 465 and 552 nm for methods A, B and C, respectively. The parameters that affect the reaction were carefully optimized. Under optimum conditions, Beer's law is obeyed over the ranges 2.0-32.0, 1.0-24.0 and 1.0-20.0 µg mL^{-1} for methods A, B and C, respectively. The calculated molar absorptivity values were 1.2853×10^4, 1.9624×10^4 and 3.92×104 L mol^{-1} cm^{-1} for methods A, B and C, respectively. The results of the proposed procedures were validated statistically according to ICH guidelines. The proposed methods were successfully applied to the determination of CHT in Cintapro tablets without interference from common excipients encountered[11].

Two simple spectrophotometric methods have been developed for simultaneous estimation of Omeprazole (OMZ) and Cinitapride (CNT) in combined dosage forms has been developed. Method-I simultaneous equation method involves the measurement of absorbances at two wavelengths 267 nm (λmax of Cinitapride) and 302 nm (λ max of Omeprazole) in Methanol, Method-II involves, formation of Q-absorbance equation at 283 nm (isoabsorptive point) and 267nm (λmax of Cinitapride).The linearity lies between 3-18 µg/ml for both Omeprazole and Cinitapride for both methods. The accuracy and precision of the methods were determined and validated statically. Both methods showed good reproducibility and recovery with % RSD less than 2. Both method were found to be rapid, specific, precise and accurate and can be successfully applied for the routine analysis of Omeprazole and Cinitapride in combined dosage form [12].

High-Performance Liquid chromatography

The aim of this research is method development and validation of Reversed-Phase High-Performance Liquid chromatography (RP-HPLC) method for simultaneous determination of Cinitapride hydrogen tartrate and Pantoprazole sodium in its pharmaceutical dosage form. The method is simple, precise, economic, less time consuming and suitable for routine quality control analysis of both the drugs in formulation. The chromatographic separation was achieved on Thermoscientific BDS Hypersil C18 (250 × 4.6 mm, 5µl) column using a mixture of methanol and 0.1% v/v triethylamine (pH 6) in the ratio 85: 15 % v/v at a flow rate of 1.0 ml/min and UV detection at 264 nm. The retention times of Cinitapride and Pantoprazole were found to be 4.73 and 2.86 min respectively. The method shows linearity in the concentration range of 0.5-1.3 µg/ml for both the drugs with r2=0.9922 for Cinitapride and r2 =0.9974 for Pantoprazole. The LOD of Cinitapride and Pantoprazole were found to be 0.00164 µg/ml and 0.00042 µg/ml respectively. The LOQ of Cinitapride and Pantoprazole were found to be 0.00496 µg/ml and 0.00126 µg/ml respectively. The percentage recovery was found to be within the limits. The method for the determination of assay was below 2.0% RSD. Hence the developed HPLC method was applied for the estimation of Cinitapride and Pantoprazole in its pure form as well as in tablet dosage form and results was found to be in good agreement with the labeled claim. The developed method was found to be simple, accurate, precise, and specific and is useful in the quality control of bulk and pharmaceutical formulations [13].

A rapid, specific, reverse phase high performance liquid chromatography [RP-HPLC] method has been developed for assaying Cinitapride Hydrogen Tartarate (CHT) in pure and pharmaceutical formulations. The assay involved an gradient elution of CHT in a Symmetry C18 (4.6 × 150 mm) column using a mobile phase composition of acetonitrile and Phosphate buffer pH 2.5 (68 : 32). Detection was carried out by UV at 264 nm. The flow rate was 1 mL/min and the analyte monitored at 264 nm. The assay method was found to be linear from 10 to 60 µg/mL and met all specifications as per ICH guidelines. Statistical analysis revealed that this method can be used in routine quality control studies of Cinitapride Hydrogen Tartarate in pure and its formulations [14].

Six simple and sensitive spectrophotometric methods (A, B, C, D, E, F and G) have been developed for the quantitative estimation of cinitapride in bulk drug and pharmaceutical dosage forms. Method A and B is based on the oxidation followed by coupling reaction of cinitapride with 1, 10 phenanthroline and 2, 2′ bipyridyl in presence of ferric chloride to form orange-red coloredchromogens respectively. Method C, D, E and F are based on the diazotization cinitapride with nitrous acid followed by its coupling in situ with N -(1-naphthyl) ethylenediaminedihydrochloride form pinkish purple coloredchromogen(C), with phloroglucinol

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to form orange coloredchromogen (D), with diphenylamine to form pink coloredchromogen (E) and with chromo tropic acid to form orange coloredchromogen (F) respectively. The results of analysis for the six methods have been validated statistically and by recovery studies [15].

Two simple, sensitive and highly accurate UV spectrophotometric methods (A and B) have been developed for the determination of Cinitapride Hydrogen Tartarate in pure drug and its pharmaceutical formulations. Method A is based on the diazotization of CHT with nitrous acid to form diazotized CHT, followed by its coupling with β-Naphthol to form red coloured chromogen, which shows absorption maximum at 552 nm and obeys beers law on the concentration range of 1-5 µg/mL. Method B is based on the diazotization of CHT with nitrous acid to form diazotized CHT, followed by its coupling with Chromotropic acid to form pink coloured chromogen which shows maximum absorption at 511 nm and obeys beers law in the concentration range of 4-20 µg/mL. The methods have been successfully applied for the assay of drug in pure and in pharmaceutical formulation. No interference was observed from common pharmaceutical additives. The developed methods were validated by determining its sensitivity, accuracy and precision as per ICH guidelines[16].

Six simple and sensitive spectrophotometric methods (A, B, C, D, E and F) have been developed for the quantitative estimation of cinitapride in bulk drug and pharmaceutical dosage forms. Method A and B is based on the oxidation followed by coupling reaction of cinitapride with 1, 10 phenanthroline and 2, 2' bipyridyl in presence of ferric chloride to form orange- red coloredchromogens respectively. Methods are based on the diazotization of cinitapride with nitrous acid followed by its coupling in situ with N- (1- naphthyl) ethylenediaminedihydrochloride to form pinkish purple coloredchromogen(C), with phloroglucinol to form orange coloredchromogen (D), with diphenylamine to form pink coloredchromogen (E) and with chromo tropic acid to form orange coloredchromogen (F) respectively. The results of analysis for the six methods have been validated statistically and by recovery studies[17].

A new visible spectrophotometric method has been developed for the estimation of cinitapride and pantoprazole in bulk and capsule dosage form. The method makes use of diazotization followed by complexation forcinitapride (CNP) and redox cum complexation for pantoprazole (PNP). The complex of cinitapride showed λmax at 399nm and that of pantoprazole showed at 477nm. A good linearity with correlation coefficient within the limit was observed for the drugs at the concentration range of 10-60µg/ml for cinitapride and 0.4 – 2.4 µg/ml for pantoprazole. The reagents used were optimized. The developed methods were assessed for precision, accuracy, sensitivity.Thus a simple easy to perform and economical precise and accurate visible spectrophotometric methods have been developed for the estimation of cinitapride and pantoprazole [18].

A precise and reliable reversed-phase high-performance liquid chromatographic method with ultraviolet detection was developed and validated to determine cinitapride in human plasma. After liquid-liquid extraction, chromatographic separation was achieved on a Nucleosil C18 (25 cm × 4.6 mm, 5 µm) column with an isocratic elution consisting of 10 mM ammonium acetate (pH 5.2), methanol, and acetonitrile, 40 : 50 :10, v/v/v. The developed method was validated as per US FDA guidelines for its linearity, selectivity, sensitivity, precision, accuracy, and stability. Satisfactory findings were obtained from the validation studies. e linearity range of the method was 1 to 35 ng/mL while the extraction recovery of cinitapride in human plasma was more than 86%. e percent coefficient of variation of both intraday and interday precision was ≤7.1% [19].

A reversed-phase-liquid chromatographic (RP-HPLC) method was developed for the determination of Cinitapride and Pantoprazole Sodium in their marketed formulation. A reversed-phase C- 18 column (250 mm × 4.60 mm i.d., particle size 5 µm) with mobile phase consisting of acetonitrile : water : Triethylamine (80:20:0.05) was used. The flow rate was 1.2 ml/ min and effluents were monitored at 260 nm. The retention times of Cinitapride and Pantoprazole Sodium were found to be 5.26 ± 0.10 min and 1.72 ± 0.10 min, respectively. The method was validated in terms of linearity, range, accuracy, precision, limit of detection (LOD) and limit of quantitation (LOQ). The method showed good linearity in the range of 12-28 µgm/ml for Cinitapride and 24-56 µgm/ml for Pantoprazole Sodium. The % recoveries of Cinitapride and Pantoprazole Sodium were found to be between 99.52 - 99.85% and 99.38 – 99.74 % respectively. The percentage RSD for the method precision was found to be less than 2%. The proposed method was successfully applied to the

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estimation of Cinitapride and Pantoprazole Sodium in combined capsule dosage forms [20].

Cinitapride and Pantoprazole are available as capsule dosage forms in the ratio 1:13.33. A simple reproducible and efficient method for the simultaneous determination of cinitapride and pantoprazole in marketed formulation was developed. The proposed method is based on the Q-analysis UV-Spectrophotometric method. The absorbance maximum of cinitapride and pantoprazole were found to be 265.5 nm and 268 nm respectively in water. In Q-analysis, the isoabsorptive point for both the drugs was found at 236 nm. The linearity range lies between 5-30 µg/ml for cinitapride and pantoprazole at their respective wavelengths. Both the drugs obey Beers law. The recovery studies confirmed the accuracy of the proposed method [21].

A simple stability indicating UV-spectrophotometric method has been developed and validated for the determination of cinitapride hydrogen tartrate (CHT) in bulk and solid pharmaceutical dosage form. Drug absorption was measured in different analytical mediums however; maximum absorption was seen in 0.1 N HCl at wavelength (λmax) of 266 nm. The calibration curve was found to be linear over the concentration range from 6 to14µg/mL with the correlation coefficient value (r) of 0.999. The LOD and LOQ were estimated to be 0.1019µg/ml and 0.309µg/ml respectively. The accuracy was evaluated by determining the percent drug recovery, performed at three different levels of 50%, 100% and 150%. The% recovery was found to be in the range of 99.96–100.64%. The precision of the method was determined by inter-day and intra-day variations[22].

A new, simple, precise, accurate, rapid as well as cost effective reverse phase HPLC method was developed for simultaneous estimation of cinitapride and pantoprazole in pharmaceutical dosage form. Chromatographic separation achieved isocratically on a C18 column by utilizing mobile phase Methanol: Water: Triethylamine (90: 10: 0.2v/v/v) at the flow rate of 1ml/min with UV detection at 277nm. The retention time of cinitpride and pantoprazole are 4.80min and 2.40min respectively. The method is accurate (99.2-102.9%), and linear within range 3-15µg/ml and 4-20µg/ml for ciitapride and pantoprazole respectively. The correlation coefficient was found to be r2= 0.999 and 0.997 for CNP and PNP respectively. The LOD for cinitapride and pantoprazole 0.223µg/ml and 0.498µg/ml respectively and LOQ are 0.675µg/ml and 1.509µg/ml respectively. The proposed method is applicable for routine analysis of simultaneous estimation of cinitapride and pantoprazole in combine pharmaceutical dosage form [23].

An accurate, Precise, Simple and Economical High Performance Liquid Chromatographic method for the estimation of Omeprazole and Cinitapride was developed and validated. The determination was performed by the using of two phases one is stationary phase it's a Thermo BDS Hypersil C18 column having 250 x 4.6mm 5µ, and another one is mobile phase containing 0.1N phosphate buffer and Acetonitrile at the ratio 50:50%v/v. The flow rate was 1ml/min and effluents were monitored at 282nm. The retention time of Omeprazole and Cinitapride was 3.5 and 5.4 min respectively. The developed method was validated for specificity, system suitability, precision, linearity, accuracy, Limit of Detection, Limit of Quantification, robustness, and ruggedness. Recovery of Omeprazole and Cinitapride in formulations was found to be in the range of 99%, 100%, and 101% respectively. And the correlation coefficient was 0.999. Hence, it was concluded that the developed method is suitable for routine analysis of these combination due to its less analysis time[24].

A simple, precise and accurate isocratic high-performance liquid chromatography method is developed for the simultaneous estimation of omeprazole and cinitapride in bulk drug and pharmaceutical dosage form. The separation and quantification is carried out using Phenomenex C18 (150 mm × 4.6 mm; 5µm) analytical column. The mobile phase comprises of 0.1% orthophosphoric acid and methanol (55:45 v/v). The flow rate is 1.0 mL/min. The eluent is monitored at 256 nm. The retention time of omeprazole and cinitapride are 2.564 min and 3.904 min, respectively. The method is validated in terms of linearity, sensitivity, precision, accuracy, specificity, selectivity and robustness. The stress testing is carried out under acidic, alkaline, oxidation, photolytic and thermal degradation conditions. The degradation products are well resolved from the omeprazole and cinitapridepeaks[25].

HPTLC Method

A simple, precise, specific and accurate high performance thin layer chromatographic method has been developed for the simultaneous determination of Cinitapride (CNT) and Omeprazole (OMZ) in pharmaceutical dosage

form. The separation was carried out on Merck HPTLC aluminum plates of silica gel G60 F254, (20 × 10 cm) with 250 µm thickness using chloroform : ethyl acetate: methanol (7.3: 2: 0.7, v/v/v) as mobile phase. HPTLC separation of the two drugs followed by densitometric measurement was carried out in the absorbance mode at 277 nm. The drugs were resolved satisfactorily with Rf values of 0.46 ± 0.01 and 0.68 ± 0.01 for CNT and OMZ, respectively. The linear regression analysis data for the calibration plots showed good linear relationship with R2=0.999 and 0.999 for CNT and OMZ, respectively in the concentration range of 30-180 ng/spot for CNT and 200-1200 ng/spot for OMZ. The method was validated for accuracy, precision, specificity and robustness. The limit of detection and quantitation were 2.79 and 8.46 ng/spot, respectively for CNT and 18.22 and 55.1 ng/spot, respectively for OMZ. The proposed developed HPTLC method can be applied for identification and quantitative determination of OMZ and CNT in bulk drug and drug formulation[26].

III. CONCLUSION:

Overall, various analytical methods have been used to determine cinitapride levels. Spectrophotometry, HPTLC, high-performance liquid chromatography methods are simple and easy to apply. However, the HPLC analysis methods are often used in research because it can detect samples with low concentrations. The HPLC methods can be applied in mixture of candesartan cilexetil with other drugs.

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