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Stability Indicating Assay Method Development and Validation for Ondansetron hydrochloride and Prantoprazole sodium in Bulk and Pharmacetical Dosage Form

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Abstract

This thesis presents the development and validation of a stability-indicating assay method for the simultaneous estimation of ondansetron hydrochloride and pantoprazole sodium in bulk and pharmaceutical dosage forms, utilizing high-performance liquid chromatography (HPLC). The method development focused on optimizing the chromatographic conditions, which included the selection of an appropriate column, mobile phase composition, flow rate, and detection wavelength. . This validated method is suitable for routine quality control and stability testing of ondansetron hydrochloride and pantoprazole sodium in bulk and pharmaceutical formulations.

Keywords: Validation, Stability, Assay

Introduction

Nausea and vomiting may be manifestations of many conditions. A useful mnemonic for remembering causes of nausea and vomiting is VOMIT. Vestibular Obstruction (opiates), Mind (dysmotility), Infection (irritation of gut),Toxins (taste and other senses).

By integrating the medicinal properties of many drugs into a single formulation, pharmaceutical goods that include more than one drug are able to fulfill patients' needs that were previously unfulfilled. These products are often known as combination products. The analytical chemist tasked with creating and validating analytical procedures (Spectrophotometric, HPLC & HPTLC) for pharmaceutical goods comprising several active ingredients may encounter difficulties while working with these combination items. Quality control labs employ the approved test procedures that come from these processes to guarantee that drug items are authentic, pure, effective, and safe to use.

Quantitative Analysis

The quantitative analysis finds out how many of each element there are in the material and what their relative abundances are. Assuring the drug's identification, safety, effectiveness, and quality is a primary responsibility of pharmaceutical analysts. In a nutshell, the rationale for the creation of more modern approaches to drug analysis. It is possible that no pharmacopoeia recognizes the medicine or medication combination in question. A competent analysis process for the literature according to patent rules. The drug's formulation may render analytical procedures unavailable owing to interference from the formulation's excipients. It is possible that there are no analytical procedures that can be used to measure the drug's concentration in biological fluids. It is possible that analytical procedures are not yet available for a medicine when used in conjunction with other drugs.[1-2]

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Selection of Analytical Method

Before beginning any quantitative investigation, method selection is a must.. Careful evaluation of the following factors is necessary for this.

The sort of analysis necessary.

Difficulties stemming from the characteristics of the researched substance.

Potential interference caused by material components.

We need to explore the concentration range.

The amenities that are being offered.

The amount of time needed to do the analysis.

The amount of comparable analyses that need to be carried out. Finally, the sample's complexity and the quantity of its components always dictate the choice of approach.

There are two main groups into which analytical procedures fall.

Instrumental

Separate from the tool

In the former, the sample is examined using traditional physico-chemical characteristics, whereas in the latter, a physical property is measured to ascertain the substance's composition.

High Performance liquid chromatography[8,9]

One technique for separation is (HPLC), which makes use of a stationary phase composed of solid material and a mobile phase made of liquid. The HPLC can evaluate the majority of the medication in the procedure due to its multi-component dose form. This approach has a number of benefits, such as being quick, specific, accurate, precise, and easy to automate. There is no need to do extraction or isolation using the HPLC approach. Among the many benefits are:

- Quickness (the whole analysis takes no more than twenty minutes).
- Enhanced sensitivity (a variety of detectors will be available)
- Enhanced clarity (several different stationary phases)
- "Reusable columns" are costly, but they may be utilized for several analyses.
- To use with chemicals that have a low volatility
- Simple sample collection, processing, and upkeep Repeatable and exact
- Integral itself does the calculations.
- Work well with larger-scale

The two modes of operation for (HPLC) are the Normal Phase and the Reverse Phase.

Normal-Phase:

Silica particles of varying sizes are dispersed throughout the column, which is then immersed in a non-polar solvent like hexane. The typical dimensions of a column are 150–250 mm in length and 4.6 mm in inner diameter. Unlike non-polar chemicals, polar silica will cling to any polar compounds in the mixture for a longer duration as it passes through the column. This causes the non-polar chemicals to go through the column at a faster rate.

Reverse-Phase:

In this process, long hydrocarbon chains, usually consisting of 8 or 18 carbon atoms, are attached to the surface of the silica in order to render it non-polar. One example of a polar solvent used in RP-HPLC is a water-and-alcohol combination, or methanol. In this case, there will be a significant attraction between the polar molecules and the polar solvent. The polar drug molecules in solution will have less of an attraction toward the hydrocarbon chains attached to the stationary phase silica. This means the polar molecules in the mixture will elute faster.

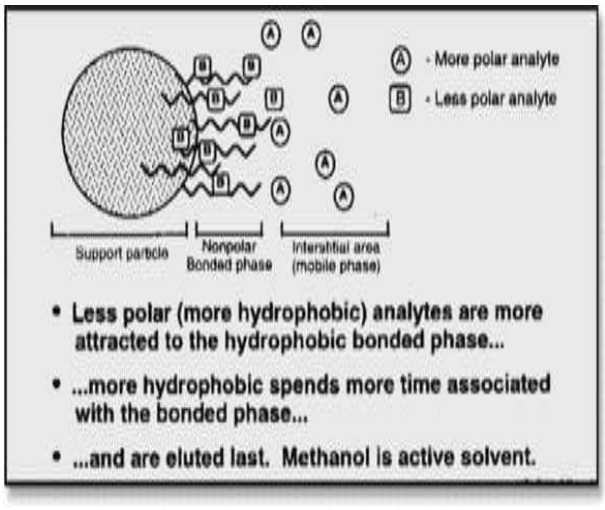

Figure1.4.1: Reverse Phase Mechanism in HPLC

Objectives of Validation:
Validation verifies an analytical process's suitability.Proper validation and reporting of results are expected after method development, prior to communication or transfer between labs, because Different test timings, days, reagent lots, instruments, equipment, and ambient conditions (temperature) might alter any given procedure.
The following organizations and bodies provide guidance for the validation of pharmaceutical analytical methods.

Types of Analytical Procedures to be validate
Tests for identification. Chemical contamination concentration measurements using quantitative methods. Keep an eye on pollutants by doing limit testing. Analytical testing of pharmaceutical substances, medicinal products, or individual components for their active ingredients. There are a number of supplementary analytical methods that are not included in the introductory literature on ensuring that analytical methods are legitimate. Drug product dissolution testing is one such example. and drug material particle size measurement are not included. A brief summary of the many types of tests covered in this publication is provided below: To ensure that the analyte in a sample can be definitely identified, laboratories use identification tests. One common method is comparing the sample's spectra, chromatographic patterns, chemical reactivity, or any other property to a reference standard. There are two main ways to find out whether an impurity is in a sample: a quantitative test and a limit test. The intended purpose of these tests is to determine the material's purity characteristics with great precision. The requirements for validating quantitative tests and limit tests are distinct. Here are some typical validation factors to keep in mind.
Precision, accuracy, and repeatability
Level of Accuracy: Intermediate
Limit of Detection
Determination Bound
Precision Scale

The most essential validation features for various kinds of analytical methods are listed in the table. The analytical processes described are often included in this list, but any deviations should be handled individually. Even if it isn't in the chart, robustness is something to think about when it's time to build.

Aim of work

- The combined tablet dosage forms of Ondansetron hydrochloride and Pantoprazole sodium are commonly used and available in market for treatment of Nausea and vomiting associated with radiotherapy and cytotoxic chemotherapy.
- Literature survey reviews that there is no stability indicating assay method reported for the simultaneous determination of Ondansetron hydrochloride and pantoprazole Sodium.
- The present study is to make an attempt to establish simple, sensitive and accurate methods for the estimation of Ondansetron hydrochloride and pantoprazole Sodiumin their combined tablet dosage form in the presence of degradation products
- To develop stability indicating assay method for simultaneous estimation of Ondansetron hydrochloride and pantoprazole Sodium in Tablet Dosage form by HPLC
- To Develop HPTLC method for Estimation of Ondansetron Hydrochloride and Pantoprazole Sodium in Bulk and Pharmaceutical Dosage Form
- To validate the developed analytical methods as per ICH guideline (Q2-R1) for various parameters like Accuracy, Precision, Limit of Detection (LOD), Limit of Quantification (LOQ), Linearity, Range, etc.

Alkali Hydrolysis
Forced degradation in alkaline media was performed by taking 2 mL stock solution of PAN, 2 mL stock solution of OND and 2 mL stock solution of synthetic mixture were transferred to their respective to 10 mL volumetric flask. Add 2 mL of 0.1 N NaOH in eachvolumetricflaskandkeptatroomtemperatur efor5hrs.Thenneutralized itwith0.1 N HCl and diluted up to the mark with mobile phase. All solutions have strength of 100 µg/mL of PAN and 10 µg/mL of OND.

Neutral hydrolysis

Forced degradation was performed by taking 2 mL stock solution of PAN, 2 mL stock solution of OND and 2 mL stock solution of synthetic mixturewere transferred to their respectiveto10 mLvolumetricflask.Add2 mLofHPLCWater ineachvolumetricflask and kept at room temperature for 24 hrs. All solutions have strength of 100 µg/mL of PAN and 10 µg/mL of OND

Oxidative degradation

Forced degradation in oxidative mediawas performed by taking 2 mLstocksolution of PAN,2mL stocksolutionofONDand2mL stocksolutionofsyntheticmixture were transferredtotheirrespectiveto 10mLvolumetricflask.Add2mLof3%H_2O_2 ineach volumetric flask and kept at room temperature for 5 hrs. and diluted up to the mark with mobile phase.

Experimental Work Done

InRP-HPLC method, chromatographic separation was achieved on Phenomenex,C8 (250× 4.6 mm i.d, 5□) column using Methanol:ACN:Water (20:30:50) as the mobile phase with detection at 216 nm. Both the drugs were subjected to acid, alkali,oxidative, thermal and photolytic stress conditions individually and in combination whereas tablet formulation was subjected to thermal andphotolyticstress conditions. Both the methods were validated as per ICH guidelines.

In HPTLC method, chromatographic separation was optimized on TLC plate precoated with silica gel 60F254 using Dichloromethane:Methanol (9.0:0.7) as mobile phase and scanning the plate at 290 nm.

Results and Discussion

RP-HPLC method showed adequate linearityfrom 100-600 µg/mLfor PAN and 10- 60 µg/mL for OND. The mean recoveries for all methods were found in between 98 %- 102 % for both the drugs. The RP-HPLC method successfully separated Pantoprazole and Ondansetron from degradation products formed under stress conditions like acidic, alkali, oxidative, photolytic and thermal.

PANdegradedsignificantlyunder acidic,neutral,oxidative,photolyticandthermal conditions and gave 1 degradation products respectively, whereas OND degraded significantlyunderoxidativeconditionsandgave1degradationproducteachconditions. Both the drugs were found to be stable under alkali conditions.

HPTLCmethodshowedadequatelinearityfrom200-1200ng/bandforOND and 2000-12000 ng/band for PAN.

Conclusion

The suitable chromatographic methods (RP-HPLC, HPTLC) were developed and validated for estimating OND and PAN in tablet dosage form. HPLC method was stability indicating as it achieved separation of both drugs from potential degraded products. More degradation has been observed for either of drugs in combination than degradation of such single drug.

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