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Analytical Validation of Itraconazole by UV Method

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ABSTRACT :

There are two straightforward, accurate, precise, and cost-effective spectrophotometric methods have been developed for the simultaneous estimation of Itraconazole in bulk drug and pharmaceutical dosage forms by using methanol as a solvent. Method A is a Second- order derivative method, which involves the measurement of absorbances at selected wavelength 262 nm for the estimation of Itraconazole.The Q absorbance ratio is Method B and is based on the measurement of absorbances at two selected wavelengths 270nm (Isosbestic point) and 283 nm for the estimation of Itraconazole. A small number of protocols for pharmaceutical formulation quality assurance and stability testing published, although itraconazole is not yet formally included in any pharmacopoeia. For the purpose of determining the amount of itraconazole in formulations, two sensitive zero order UV spectroscopic methods (approach A) and a first order derivative approach (Method B) have been developed and verified. using phosphate buffer (pH 2.0)[1]. The medication displayed its maximum absorbance at 255 nm (Method A), and Method B measured the amplitude between 245 and 270 nm. The medication complied with linearity between 5 and 60 µg/mL.. The drug obeyed linearity in the range of 5–60 µg/mL.[1] The present methods were validated as per International Conference on Harmonization.The goal of this study is to create a spectrophotometric method that is easier, more affordable, and more accurate for analysing itraconazole in pill and bulk dosage forms with improved precision, accuracy, and sensitivity[15].The UV spectroscopic determination was also performed with Chloroform as the solvent at 267 nm, the maximum absorption wavelength.

Keywords : - Itraconazole , UV spectroscopy

Materials and methods :

Experimental

Chemicals and reagents: Throughout UV spectrophotometric technique, development and validation methanol was used [16].

Instrumentation

UV spectrophotometric technique was performed on a double beam UV-visible spectrophotometer having two matched quartz cells with a 1 cm light path[16]

Selection of solvent

For the analysis of Itraconazole, methanol had been selected as the ideal solvent for spectrophotometry [20].

Preparation of standard stock solution (1000µg/ml) :

A volumetric flask containing a precisely weighed quantity of 100 mg itraconazole reference standard was dissolved and diluted with methanol to produce a stock solution with a strength of 1000µg/ml. 100 µg/ml working standard solution was prepared bydiluting 1 ml of stock solution to 10 ml with methanol[17].

Preparation of sample stalk solution (100µg/ml) :

Twenty capsules were weighed, and the mean weight was found, in order to establish the ITZ content of each capsule (the label claims 100 mg ITZ per capsule, Itaspor capsules)[16]. The powder weighing 100 mg ITZ was put into a 100 ml volumetric flask with 50 ml of methanol. After 30 minutes of sonication, the mixture was diluted to 100 ml with methanol (1000 µg/ml). To achieve a concentration of 100µg/ml, 1 millilitre of the filtered solution was diluted ten times.[18]

Methodology :

Method A (Second order derivative method)

The second-order derivative method involves the measurement of absorbances at selected wavelength. i.e. 262nm for the estimation of Itraconazole. By Using a UV Spectrophotometer, the drug standard solutions are scanned in the spectrum mode between 400 and 200 nm. With the aid of UV probe software's derivative mode, these spectrums were transformed into second order derivative spectra. In order to eliminate the interference caused by absorbing species, the resulting absorbance spectra were derivatized.[5]. The two wavelengths that are chosen should be such that there is as much of an absorbance difference between the components at each wavelength.[19]. From the examination of the Second order derivative spectra of Itraconazole 262 nm is selected as working wavelengths for the second-order derivative spectroscopy.

Method B (Q-Analysis or Absorbance ratio method)

The simultaneous equation method serves as the foundation for the absorbance ratio approach[20].It depends on the property of the substance, which obeys Beer's law at all wavelengths, the ratio of absorbance at any wavelength is a constant value independent of concentration or wavelength. Another name for this ratio is a Q-value **[20].** In the quantitative assay of two components in admixture by the absorbance ratio method, absorbances were measured at two wavelengths. One being the λmax of one of the components (λ2) and other being a wavelength of equal absorptivity of the two components (λ1), i.e. an iso-absorptivity point (Pernarowski1961).

From the above Stock solutions, both the drugs are scanned in the wavelength range of 400- 200nm using UV-Spectrophotometer. With the help of an overlay spectrum absorbance of the solutions was measured at 262.0 nm (λmax of ITRA).

Introduction -

Itraconazole is indeed a potent antifungal medication belonging to the triazole class. It can be administered orally or intravenously, depending on the severity of the fungal infection and the patient's condition[7].

It describing its role as a synthetic broad-spectrum triazole fungistatic agent. It acts by selectively inhibiting the fungal cytochrome P450 3A enzyme, altering membrane fluidity and interfering with membrane-associated enzymes, ultimately leading to the inhibition of replication. Itraconazole's complex structure contributes to its lipophilic nature and limited water solubility, characteristics important for its antifungal activity. The molecule's synthesis yields a racemic mixture containing four diastereomers, each with three chiral centers[12]. It's a very weak base (pKa =3.7) that only ionises at very low pH levels Concerning its analytical determination, there are some works in literature describing the analysis in human plasma, alone or in the presence of other azoles, and in dog serum applying liquid chromatography with UV or mass spectrometry detectors (Kim et al., 2000, Kim et al., 2003; Shen et al.

2007; Chhun et al., 2007; Cunliffe et al., 2009; Alffenaar at al., 2010; Ekiert et al., 2010; Reddy et al., 2011; Beste et al., 2012)[15].

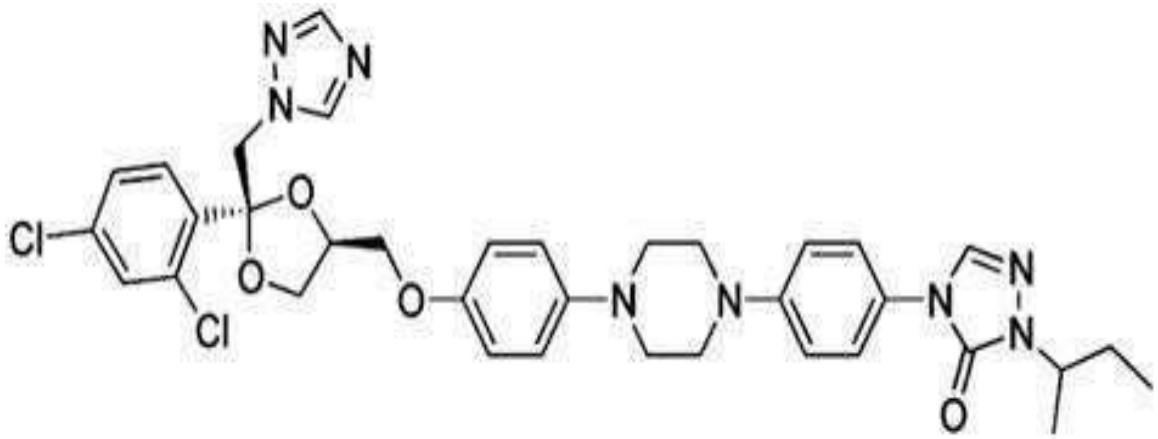

Fig 1 : - structure of itraconazole

UV-VIS spectroscopy indeed has been a valuable analytical tool for examining solvents and compounds over the past 37 years. Its popularity, particularly among small-scale enterprises, is attributed to its cost-effectiveness and lower maintenance requirements. The technique measures the amount of monochromatic light absorbed by colourless molecules in the 200–400 nm near ultraviolet spectrum [11].

UV Spectroscopy Principle :

The Beer-Lambert Law describes the relationship between the concentration of a solution, the path length of the sample, and the absorbance of light at a specific wavelength. UV spectrophotometers utilize this principle to quantify the concentration of absorbing substances in a solution by measuring the absorbance of light passing through it. This equation can be used to express this law:

$A = \log (I0/I) = ECI$

A represents absorbance, I0 denotes light intensity entering a sample cell, l denotes light intensity leaving the sample cell, C denotes solute concentration, L denotes sample cell length, and E denotes molar absorptivity[21].

Based on the Beer-Lambert law, it has been determined that the amount of light absorbed increases with the number of molecules that can absorb light at a given wavelength.[21].

Advantages and limitations of uv spectroscopy :

Advantages:-

- Because the method is non-destructive, the sample can be processed or analysed further or used again.
- Quick measurement makes it simple to incorporate into experimental protocols.
- The instruments are user-friendly and don't require much training before use.
- Again, not much processing is usually needed for data analysis, which means less user training is needed**.**

Since the instrument is typically affordable to purchase and run, many laboratories can use it [22].

Limitations :-

- **Stray light** - A small amount of light from a wide wavelength range may still be transmitted from a real instrument due to imperfect wavelength selector,Which possibly causing serious measurement errors. Additionally, stray light can originate from the surroundings or an instrument's loosely fitting compartment [22].
- **Light scattering** - Scattered solids in liquid samples are a common source of light scattering and can lead to significant measurement errors. Results are not repeatable if there are bubbles in the cuvette or sample because they scatter light [22].
- **Interference from multiple absorbing species** - For instance, different forms of the green pigment chlorophyll may be present in a sample. When analysed together in the same sample, the spectra of the various chlorophylls will overlap. Each chemical species needs to be taken out of the sample and looked at separately in order to conduct a proper quantitative analysis [22].
- **Geometrical considerations** - Any one of the instrument's components that is not positioned correctly could lead to inaccurate and irreproducible results, particularly the cuvette that holds the sample. As a result, it is crucial that each part of the instrument be positioned consistently and aligned in the same direction for each measurement. Therefore, it is usually advised to receive some basic user training to prevent misuse [22].

Mechanism of action : -

Itraconazole inhibits the 14-α demethylase enzyme in fungi, disrupting ergosterol synthesis and compromising the integrity of the fungal cell membrane, leading to increased permeability and subsequent leakage of cellular contents. It is effective against a variety of fungal infections due to this mechanism. It is an antifungal medication. The details you mentioned cover various aspects of its mechanism of action, including effects on respiration, membrane phospholipids, yeast transformation, purine uptake, and lipid biosynthesis. Additionally, taking itraconazole with food enhances its oral bioavailability and increases plasma concentrations compared to fasting intake. It provided information about itraconazole metabolism, mentioning its primary metabolism in the liver via the cytochrome P450 3A4 isoenzyme system, leading to the formation of hydroxyl itraconazole[10]

Therapeutic significance in antifungal management : -

Itraconazole at 100mg once daily has shown efficacy in fungal diseases like chronic mucocutaneous candidiasis and chromomycoses. However, as you mentioned, longer treatment durations are often required. Future research will be crucial to assess its ability to sustain remission in challenging cases, especially in chronic mucocutaneous candidiasis patients.

Itraconazole's reported anti-cancer effects in pancreatic cancer, including inhibition of epithelial-mesenchymal transition and modulation of the transforming growth factor-β signaling pathway, highlight its potential therapeutic role. The observed impacts on invasion, migration, colony formation, and apoptosis in Panc-1 and BxPC-3 cells further underscore its multifaceted influence on pancreatic cancer cells[6].

Simultaneous Estimation Method Development

A. Challenges in Simultaneous Estimation

Challenges in Simultaneous Estimation, especially when using UV spectroscopy, demand careful consideration to ensure accurate and reliable results. Several factors contribute to the complexity of developing methods for the simultaneous estimation of vildagliptin and metformin[2].

1. **Overlapping Spectra:**

- One of the primary challenges is the overlapping spectra of Itraconazole. Their absorption peaks may coincide, making it difficult to distinguish between the two components (Santosh et al., 2013)[1].

2. Variable Molar Absorptivity:

- Differences in the molar absorptivity of itraconazole can pose challenges in achieving a balanced calibration curve. Unequal response factors can affect the accuracy of simultaneous estimation (United States Pharmacopeia, 2020)[3].

3. Matrix Interference in Formulations:

- Pharmaceutical formulations often contain excipients that can interfere with UV measurements. Overcoming matrix effects while maintaining specificity for Itraconazole is a significant challenge (International Conference on Harmonization, 2005)[5].

4. Sensitivity and Lower Limits of Detection:

- Achieving the required sensitivity, especially at lower concentrations, is challenging. Sensitivity becomes crucial for accurate simultaneous estimation, particularly in pharmacokinetic studies (Miller and Miller, 2010) [10].

5. Selectivity and Interference from Degradation Products:

- Stability studies may lead to the formation of degradation products. Selectivity challenges arise in distinguishing these products from the parent compounds during simultaneous estimation (ICH, 2003)[16].

6. Method Robustness Across Instruments and Laboratories:

- Ensuring the robustness of the developed method across different UV spectrophotometers and laboratories is essential for method transferability and reproducibility (ICH, 2005) [13].

7. Chromophore Similarity:

- Vildagliptin and metformin may share similar chromophores, making it challenging to design a method that selectively measures each component without interference from the other (Srivastava et al., 2011)[13].

In addressing these challenges, method developers often employ advanced chemometric techniques, such as partial least squares (PLS) regression, to overcome issues related to overlapping spectra and variable molar absorptivity (Câmara e. Methodological Approaches and Considerations.

1. Choice of Solvents:

- The selection of an appropriate solvent is crucial for UV spectroscopy. Common solvents such as methanol or acetonitrile may be suitable for ensuring good solubility of Itraconazole without interference (Ishii et al., 2017)[9].

2. Wavelength Selection:

- Identifying suitable wavelengths for quantification is vital. Analyzing the UV absorption spectra of Itraconazole helps in selecting wavelengths with maximum absorbance and minimal interference, ensuring accurate simultaneous estimation (Thapliyal et al., 2014)[12].

3. Use of Derivative Spectrophotometry:

- Derivative spectrophotometry can be applied to enhance the resolution of overlapping spectra, which is particularly useful in the simultaneous estimation of Itraconazole. Analyzing the first or higher-order derivatives aids in peak resolution (Thapliyal et al., 2014)[12].

4. Application of Chemometric Techniques:

- Chemometric techniques, such as principal component regression (PCR) or partial least squares (PLS), can enhance the accuracy of simultaneous estimation methods for Itraconazole (Dinç et al., 2016)[11].

5. Method Validation Parameters:

- Rigorous method validation is essential. Parameters like specificity, linearity, accuracy, and precision should be thoroughly evaluated to ensure the reliability of the simultaneous estimation method for Itraconazole (ICH, 2005).t al., 2020)[14].

6. Forced Degradation Studies:

- Forced degradation studies help assess the stability of Itraconazole under stress conditions. This aids in identifying potential degradation products and ensuring method selectivity in simultaneous estimation[16].

7. Internal Standard or Reference Substance:

- The use of an internal standard or reference substance can enhance precision and accuracy in simultaneous estimation. Adding a substance that does not interfere with Itraconazole absorption can serve as a reference for quantification (Ishii et al., 2017)[17].

8. Method Transferability:

- Ensuring method transferability is vital. Robustness and reproducibility across different instruments and laboratories should be demonstrated for practical application of the simultaneous estimation method for Itraconazole[9].

In summary, a strategic approach involving solvent selection, wavelength optimization, and the application of advanced analytical techniques is crucial for the successful development of simultaneous estimation methods for Itraconazole using UV spectroscopy[8].

Uv spectroscopic methods for estimation of itraconazole :

Analytical method validation :

The method developed was validated according to International conference of Harmonization (ICH) guidelines. The parameters that were determined are linearity, accuracy, precision, quantitation limit, detection limit [19].

Selectivity :Selectivity is defined as the capacity to measure the analyte with absolute certainty in the presence of other elements that are anticipated to be present, such as degradants, matrices, and impurities[20].

Specificity: Since there is no excipient in the raw material, specificity was shown by analysing the spectra that were obtained using the sample matrix (methanol) between 200 and 400 nm [20].

Linearity: The linearity was evaluated across the range of analytical procedure by analyzing a series of solutions prepared using phosphate buffer pH 2.0. Beer-Lambert's law was obeyed in the concentration range 5-60µg/mL for both methods [17].

Accuracy: The pre-analysed powder for infusion samples was spiked with various concentrations of pure drug within the analytical concentration range of the suggested method to conduct recovery studies and determine accuracy at three different set at levelof 80%, 100% and 120%. At each level, the amount of itraconazole was determined, and the percentage of recoveries was computed [23].

Precision: The amount of variation between several measurements made after a homogenous sample was sampled again under specific guidelines. A true, homogeneous sample should ideally measure precision. Alternatively, precision can be measured using an artificial sample or sample solution. Additionly, this characteristic has three levels that, when applicable, the ICH advices reporting together [24].

Repeatability: It is the degree of variation over a given day while operating under the same conditions[24]

Intermediate Precision: It is a certain amount of variation from day to day in a laboratory, ideally with different analysts and, if feasible, different equipment [24].

Reproducibility: There is some variation in the degree between laboratories [24].

Robustness :

Robustness looks at how changes in operational parameters affect the analytical outcomes.

- pH
- Temperature
- Operational parameters in chromatographic analysis, such as flow rate, injection volume, detection wavelength, or mobile phase composition [25].

To examine the robustness of the method, intentional variation within a reasonable range is necessary. Following the intentional modifications, the analysis's findings ought to fall within the tolerance ranges given by the technique. Although method validation might seem like a laborious and time-consuming task, once it is done before being adopted, the method won't fail you in any situation [26]

Applications of u.v. spectroscopy :

1) **Impurity Detection:** One of the best techniques for identifying impurities in organic molecules is UV absorption spectroscopy. Impurities in the sample may cause additional peaks to show up, which can be compared to raw material standards. The contaminants can be found by measuring the absorbance at a particular wavelength as well.
2) **Quantitative analysis :**Compounds that absorb UV radiation can be quantitatively determined using UV absorption spectroscopy. The following formula, known as Beer's Law, is used to calculate it:

1/ T = – log A = log I0 / It = log T = abc = εbc Where:

b-is the cell length used in the UV spectrophotometer, c-is the concentration, and ε- is the extinction coefficient [27].

3) **Qualitative analysis :** Compounds that absorb UV radiation can be identified using UV absorption spectroscopy. By contrasting the absorption spectrum with the spectra of a known compound, identification is accomplished [27].

4) **Chemical kinetics :** UV spectroscopy can also be used to study reaction kinetics. The UV radiation is passedthrough the reaction cell and the absorbance changes can be observed [27].

5) **Detection of functional groups :** This method is used to determine whether a functional group is present in a compound at a specific wavelength, which is thought to be evidence of the group's absence [27].

6) **Quantitative analysis of pharmaceutical substances :** Many medications are available as formulations or as raw materials. By preparing a suitable drug solution in a solvent and measuring the absorbance at a particular wavelength, they can be assayed.The wavelength at which 0.5% H2SO4 in methanol can be used to analyse a diazepam tablet is 284 nm [27].

7) **Structure elucidation of organic compounds :**UV spectroscopy is helpful in determining the presence of heteroatoms, the degree of unsaturation, and the structure of organic molecules. One can infer information about the compound's saturation and unsaturation, the presence or absence of heteroatoms, and other factors based on the location and combination of peaks [27].

8) **Molecular weight determination :** By making the appropriate derivatives of these compounds, one can use spectrophotometry to measure the molecular weights of these compounds.For instance, amine is transformed into amine picrate in order to calculate the molecular weight of the amine. After that, a litre of solution containing a known concentration of amine picrate is dissolved, and its optical density is measured at λmax 380 nm [28].

RESULTS AND DISCUSSION

It appears that the estimation of itraconazole in both bulk and pharmaceutical formulation is accurate and reproducible, with a linearity range of 3-15 µg/ml for both methods. The high correlation coefficients (0.9999 for method A and 0.9998 for method B) suggest a strong linear relationship between concentration and response in each method. It conducted a comprehensive analysis of optical characteristics and regression parameters for two methods. If you have specific questions or if there's anything you'd like assistance with regarding the results in Table

1. It sounds like the recovery studies yielded accurate and reliable results, with standard deviation values within an acceptable range. The % RSD (relative standard deviation) being less than 2 indicates good precision and accuracy in the method [20].

Table No. 1: Optical and validation parameters of UV Spectrophotometric methods.

Spetroscopy Parameters	**Third Order Derivative Method ITRA**	**Q Absorbance Ratio Method ITRA**
Linearity Range (ug/ml)	3-15	3-15
λmax / wavelength range (nm)	262	270
Coefficient of correlation	0.9998	0.9999
Slope (m)	0.0267x	0.0404X
Intercept*(c)	0.002	0.0101
Accuracy (% RSD)	0.4943	0.2253
Precision (% RSD)	Intra Day-1.2083 Inter Day - 0.9297	Intra Day- 0.3063 Inter Day - 0.2832
Limit of Detection (µg/ml)	0.1562	0.2818
Limit of Quantification (µg/ml)	0.4732	0.8541

CONCLUSION

It's great to hear that the developed second-order derivative and Q-Absorbance ratio methods for analyzing Itraconazole are simple, precise, specific, and accurate. The validation according to ICH guidelines further strengthens the reliability of these methods.The method is also validated according to ICH guidelines so that the existing UV spectrophotometric device can also be used in bulk and solid dosage form for routine quality control analysis of Itraconazole and is found to be linear, accurate and precise [20].

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Appendix

"Analytical validation of Itraconazole by UV method"

Using methanol as a solvent, two straightforward, exact, accurate, and cost-effective spectrophotometric methods have been developed in this work for the simultaneous estimation of itraconazole in pharmaceutical dosage forms and bulk drugs. In order to estimate itraconazole, Method A, a second-order derivative method, measures absorbances at a

chosen wavelength of 262 nm. In order to estimate ittraconazole, Method B, a Q Absorbance ratio method, measures absorbances at two chosen wavelengths: 283 nm and 270 nm

(the isosbestic point). Although itraconazole is not yet officially included in any pharmacopoeia, a few protocols for quality control and stability testing in pharmaceutical formulations have been published. In order to ascertain the quantity of itraconazole in.

Errata