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Physicochemical Analysis, Identification and Characterization of drug Irbesartan and Triamterene

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ABSTRACT

The study paper focuses on the physicochemical analysis and structural elucidation of two pharmacologically important compounds: Irbesartan, an angiotensin II receptor antagonist, and Triamterene, a potassium-sparing diuretic. The identification and characterization were carried out using various analytical and spectroscopic techniques including UV-Visible spectroscopy, FTIR (Fourier Transform Infrared Spectroscopy), and melting point determination. Organoleptic properties such as color, odor, and appearance were also assessed. The λmax of both drugs was determined in appropriate solvents to establish their UV absorption profiles. FTIR analysis confirmed the presence of functional groups characteristic to each drug, providing molecular fingerprint confirmation. Melting point analysis further supported the purity and identity of the samples. These characterization studies are essential for ensuring the quality, efficacy, and safety of pharmaceutical formulations containing Irbesartan and Triamterene, and they provide a strong foundation for further formulation development and quality control.

Keywords: *Drugs, Identification, FTIR*

1. INTRODUCTION

Identification and characterization of a drug are fundamental steps in the development of any pharmaceutical dosage form. These processes involve confirming the identity, purity, and chemical structure of the active pharmaceutical ingredient (API) through a range of analytical techniques such as UV-Visible spectroscopy, FTIR, NMR, HPLC, and mass spectrometry. Characterization also includes the evaluation of physical properties like solubility, melting point, and partition coefficient, which are critical for understanding the drug's behavior in different environments. Proper identification ensures that the correct compound is used, while thorough characterization helps in selecting suitable excipients, designing stable formulations, and predicting drug release and absorption profiles. Ultimately, these steps are crucial for ensuring the safety, efficacy, and quality of the final pharmaceutical product, as well as for meeting regulatory requirements during drug approval. [1]

Irbesartan is an angiotensin II receptor blocker (ARB) used primarily in the management of hypertension and diabetic nephropathy. It selectively inhibits the binding of angiotensin II to the AT1 receptor, thereby preventing vasoconstriction and reducing blood pressure. Irbesartan is known for its high oral bioavailability and long duration of action, allowing once-daily dosing. It is well-tolerated in most patients, with a favorable safety profile and minimal side effects. Chemically, Irbesartan is a white to off-white crystalline powder that is slightly soluble in alcohol and methanol but practically insoluble in water. Due to its effectiveness in controlling blood pressure and protecting renal function in diabetic patients, Irbesartan is widely used either as monotherapy or in combination with other antihypertensive agents. [2]

Triamterene is a potassium-sparing diuretic commonly used in the treatment of hypertension and edema, particularly when associated with conditions such as congestive heart failure, liver cirrhosis, or nephrotic syndrome. It acts on the distal convoluted tubule of the nephron, inhibiting sodium reabsorption while conserving potassium, thereby helping to maintain electrolyte balance. Triamterene is often combined with thiazide diuretics to counteract potassium loss typically caused by these agents. Chemically, it appears as a bright blue crystalline powder, practically insoluble in water but soluble in dilute acid and alcohol. Due to its potassium-sparing action, Triamterene is particularly valuable in patients at risk of hypokalemia, making it an important component in combination therapies for long-term management of cardiovascular and renal disorders. [3]

2. MATERIAL AND METHODS

Procurement o Active Pharmaceutical Ingredient (API)

Based on literature review the drugs viz., Irbesartan and Triamterene was selected for present investigation. The API was obtained as gift sample from the Phamaceutical Industry. All other ingredients were used of analytical grade without any further modification

Identification and Characterization of drug

Organoleptic properties

The organoleptic properties like physical appearance, color and odor of the Irbesartan and Triamterene were studied by visual observation and smelling the drug powder. [4]

Melting point determination

It was determine dusing the capillary tube method. Irbesartan and Triamterene powder was filled into a capillary tube (previously sealed at one end) and then tube was inserted into sample holder of the melting point apparatus. The temperature at which drug substance started melting was recorded. [5]

Determination of λmax by U.V. spectrophotometric analysis

Absorbance maxima of Irbesartan and Triamterene was determined by scanning its solutions (100µg/ml) in distilled water/Methanol at wavelength range of 200-400nm against blank on spectrum mode of double beam U.V. visible spectrophotometer. [6]

Preparation of calibration curve of Irbesartan and Triamterene

Standard Curve of Irbesartan (IBT)

Accurately weighed 100 mg IBT was dissolved in 100 ml of water in 100 ml volumetric flask to get the stock solution of 1000 µg/ml. From stock solution 5 ml was pipetted out and further diluted up to 50ml with ethanol to get 100 µg/ml solutions. From 100µg/ml solution take 5ml and diluted to 50ml to get 10µg/ml solution from this aliquots of 2, 4, 6, 8, 10, 12 ml were withdrawn and diluted to 10 ml to obtain a concentration range of 2-10µg/ml. The absorbances of the solutions were measured at 244 nm by using UV-Vis spectrophotometer. A graph of Concentration vs. Absorbance was plotted. [6]

Standard Curve of Triamterene (TMT)

Accurately weighed 100 mg TMT was dissolved in 100 ml of methanol in 100 ml volumetric flask to get the stock solution of 1000 µg/ml. From stock solution 5 ml was pipetted out and further diluted up to 50ml with ethanol to get 100 µg/ml solutions. From 100µg/ml solution take 5ml and diluted to 50ml to get 10µg/ml solution from this aliquots of 2, 4, 6, 8, 10, 12 ml were withdrawn and diluted to 10 ml to obtain a concentration range of 2-10µg/ml. The absorbances of the solutions were measured at 369 nm by using UV-Vis spectrophotometer. A graph of Concentration vs. Absorbance was plotted. [6]

Solubility determination

The solubility of Irbesartan and Triamterene was determined using the saturation solubility method. A surplus quantity of Irbesartan and Triamterene was added to 10ml of distilled water, phosphate buffer pH 6.8, methanol and dimethyl sulphoxide (DMSO) separately in a glass vials. The content of vials was agitated vigorously for 30 minutes and further solutions were shaken mechanically. After 72 hours, the content of each vial was centrifuged for 10 minutes at 2500 rpm. The supernatant of each vial was filtered through 0.45µ membrane filter and then filtrate was diluted suitably with solvent. The concentration of Irbesartan and Triamterene was analyzed by double beam UV visible spectrophotometer at suitable wavelength respectively against blank. [7]

FTIR study

FTIR spectrum of the Irbesartan and Triamterene were separately recorded using FTIR spectrophotometer. Pellets for sampling purposes were prepared by mixing 9 mg of above mentioned sample with 300 mg of KBr. Prepared samples were scanned over the wavelength range of 4000 to 400cm^{-1} to record the spectrums and were analyzed. [8]

3. RESULTS AND DISCUSSION

The observed organoleptic properties of the Irbesartan and Triamterene were shown below in table 1 and results were found to be matched with the standards. Observed melting point of Irbesartan and Triamterene was found to be 181±0.5°C and 317±0.5°C respectively and it was matched with that of standard value. U.V. spectrum indicating the λmax or absorbance maxima of Irbesartan and Triamterene is shown in figure 1 and 2. Obtained value was 244 nm and 369 nm respectively it was found to have closeness with that of standard value. Calibration curve for both the drug were prepared and were given in figure 3 and 4. Saturated solubility of and Triamterene in different solvent systems is shown in table 4. Fourier transform infrared (FTIR) spectroscopy (Figure 5 & 6) analysis to find out any possible chances of interaction and incompatibility

between the Irbesartan & Triamterene and excipients.

Table 1: Organoleptic properties of Irbesartan and Triamterene

Organoleptic properties	Observations	
	Irbesartan (IBT)	**Triamterene (TMT)**
Physical appearance	Crystalline Powder	Crystalline Powder
Color	White to off-white	Bright yellow
Odor	Odorless	Odorless

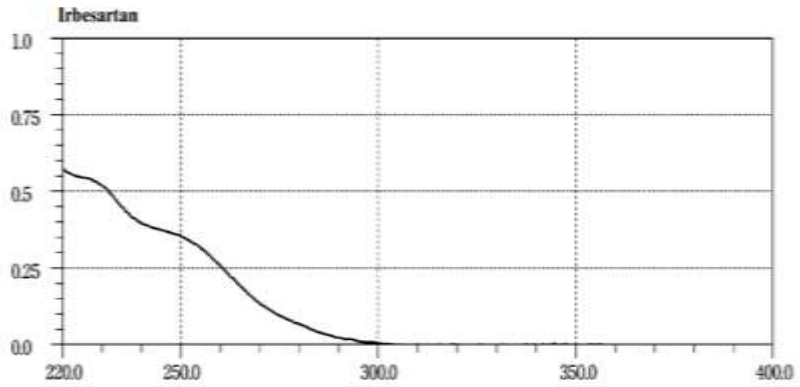

Fig. 1: UV Spectra of Irbesartan

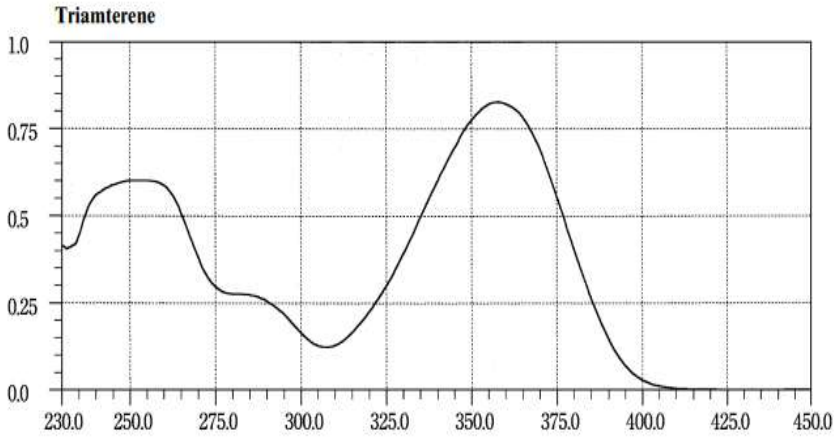

Fig. 2: UV Spectra of Triamterene

Table 2: Absorbance of Different Dilutions of Irbesartan IBT

S/No.	Concentration (µg/ml)	Absorbance
1.	0	0
2.	2	0.152

3.	4	0.268
4.	6	0.396
5.	8	0.526
6.	10	0.656
7.	12	0.802

Table 3: Absorbance of Different Dilutions of Triamterene (TMT)

S/No.	Concentration (µg/ml)	Absorbance
1	0	0
2	2	0.192
3	4	0.318
4	6	0.439
5	8	0.556
6.	10	0.682
7.	12	0.739

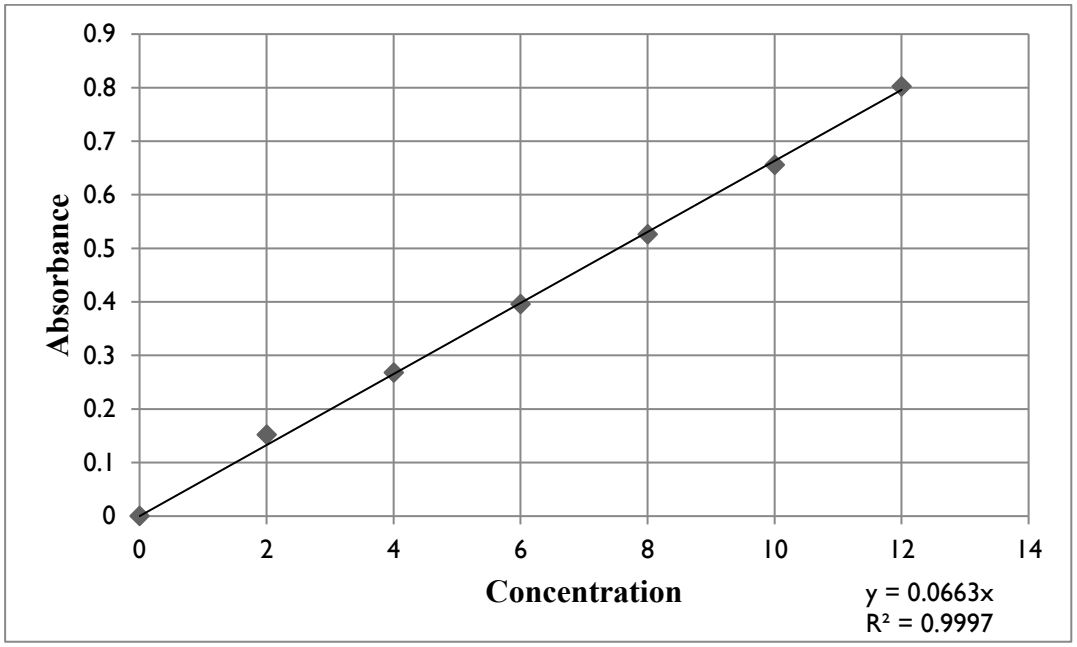

Fig. 3: Calibration Curve of Irbesartan (IBT)

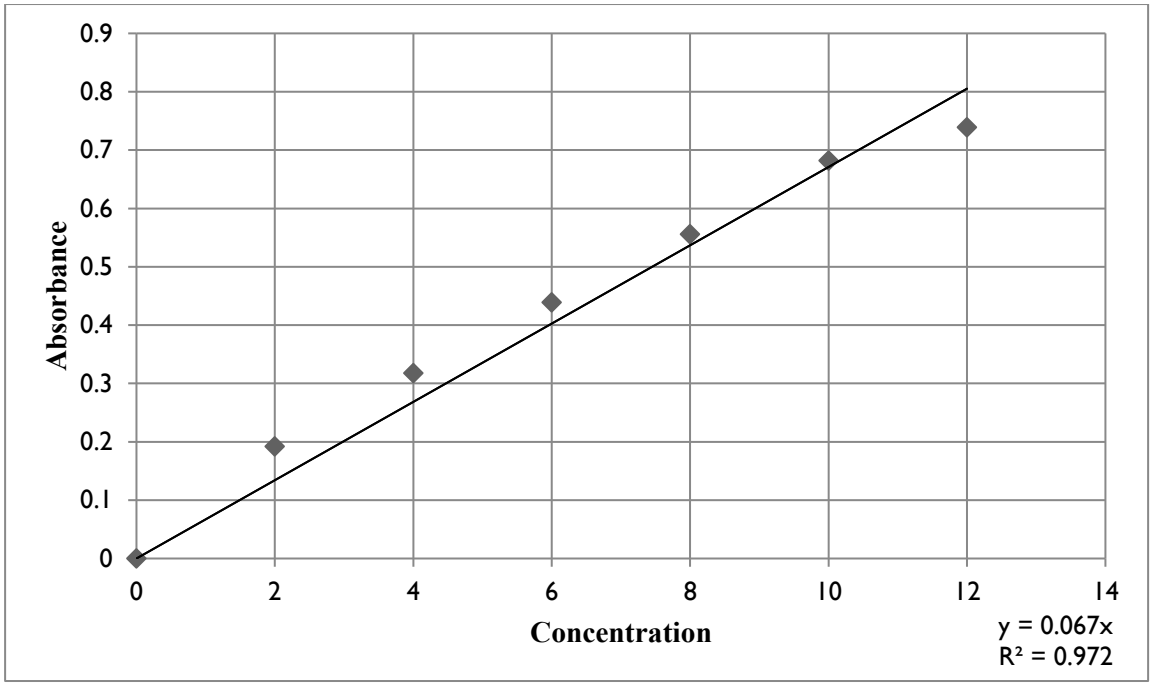

Fig. 4: Standard Calibration Curve of Triamterene (TMT)

Table 4: Saturated solubility data of drugs in different solvents (n=3)

S/ No.	Solvent	Solubility	
		Irbesartan (mg/ml)	Triamterene (mg/ml)
1	Distilled Water	14.6±0.14	0.0038 ±0.16
2	Phosphate buffer pH 6.8	3.48 ±0.16	5.17 ±0.08
3	DMSO	10.24 ±0.28	7.39 ±0.18
4	Methanol	0.16 ±0.31	12.49±0.11

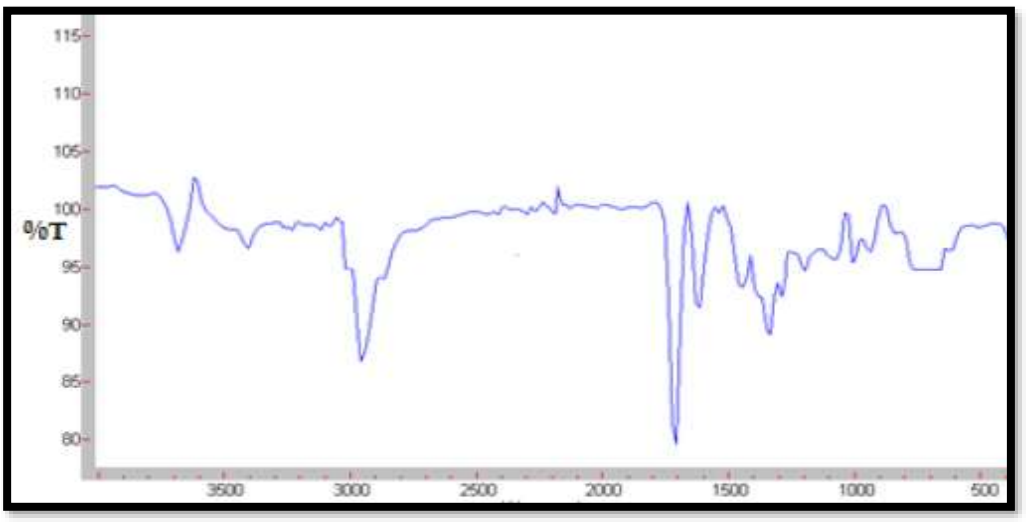

Fig. 5: FTIR of Irbesartan (IBT)

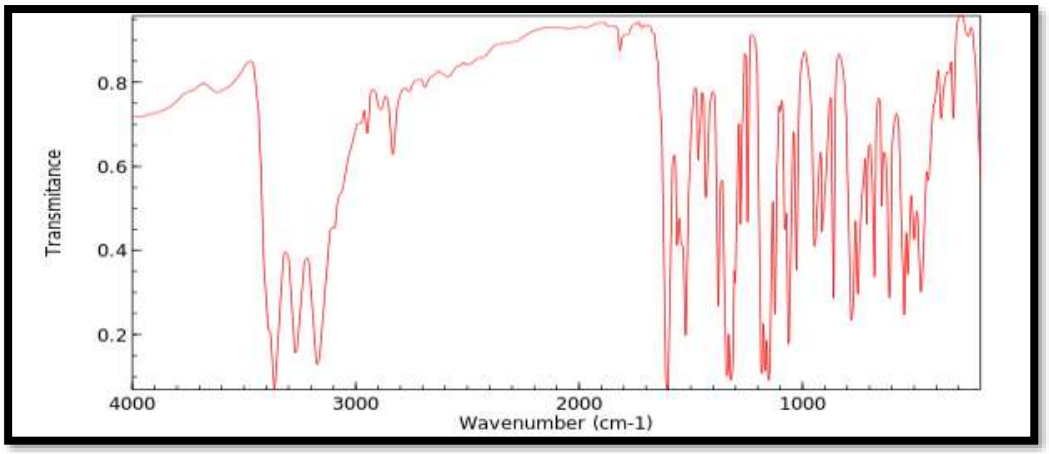

Fig. 6: FTIR of Triamterene (TMT)

4. CONCLUSION

The study on the *Physicochemical Analysis, Identification, and Characterization of the drugs Irbesartan and Triamterene* successfully established the identity, purity, and key physicochemical properties of both compounds. Through various analytical techniques, including organoleptic evaluation, UV-Visible spectroscopy, FTIR analysis, and melting point determination, the drugs were accurately identified and their structural and functional attributes confirmed. These characterization findings not only verify the authenticity of the active pharmaceutical ingredients but also provide critical data necessary for the formulation development process. Understanding the solubility, thermal behavior, and functional group presence of Irbesartan and Triamterene contributes significantly to the design of stable, effective, and safe pharmaceutical dosage forms. Overall, the study lays a strong foundation for further research, formulation, and quality control of these therapeutically important drugs.

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