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DEVELOPMENT OF NEW AND NOVEL ANALYTICAL METHODS OF AND ITS VALIDATION OF VALSARTAN IN PURE AND PHARMACEUTICAL DOSAGE FORM BY UV-SPECTROMETRY METHOD

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ABSTRACT

Objective: Using a UV-spectrometry method, develop new and innovative analytical techniques and validate them for use with pharmaceutical dosage forms of valsartan. **Methods:** Wavelength selection Stock solution preparation 40 mg of the medicine were dissolved in ethanol to create the standard stock solution for Valsartan, which was then further diluted with distilled water. Once the solution had a concentration of 10, 20, 30, 40, 50, or 60 g/ml, it was further diluted. Between 200 and 400 nm in the UV spectrum, the solutions were scanned. range for Beer's law concentration By dissolving 100 mg of the drug in ethanol, mixing it with the same solvent, and then diluting it further with distilled water, a standard stock solution of valsartan was created with a concentration range of 1 to 100 g/ml. The solutions were scanned in the 200-400 nm range of the UV spectrum, and their absorbance was determined at 250.0 nm. A calibration curve was created between 10 and 60 g/ml using absorbance values versus concentrations. **Results:** The wavelength with the highest absorbance was chosen as the wavelength after preparing a concentration of 10-60 g/ml standard stock solution and observing the absorbance at various wavelengths. **Conclusion:** The article presents a UV Spectrophotometric approach for Valsartan dosage estimation in both pure and pharmaceutical form.

KEYWORDS: Valsartan, UV Spectroscopy, Method development, Validation, and Estimation are some of the key phrases.

INTRODUCTION

Chemically speaking, valsartan is N-(1-Oxopentyl)-N-[[2'-(1H-tetrazol-5-yl) [1, 1'-biphenyl]-4-yl]methyl].-L-valine.It is also known as an ARB (angiotensin receptor blocker) since it is used as a hypertension medication that lowers blood pressure by inhibiting the action of angiotensin II solely at the AT1 receptor.

MATERIALS AND METHODS

Experimental Procedure

The techniques for taking Spectrophotometric measurements are illustrated in the simulation that follows. First, a blank's light transmission is evaluated for intensity. The quantity of photons per second is the intensity. The sample solution and the blank are both solutions, but the blank is devoid of the substance that absorbs light. Because the cell itself scatters some light, this measurement is required. Second, a measurement of the light's intensity as it traverses the test solution is made. (In actuality, instruments gauge light power as opposed to intensity. The product of intensity (photons per second) and energy per photon yields the power, which is measured in terms of energy per second.

Third, the experimental data is used to calculate two quantities: the transmittance (T) and the absorbance (A).

$$T=I/I_o$$

$$A= - \log 10$$

T The transmittance is simply the fraction of light in the original beam that passes through the sample and reaches the detector. The remainder of the light, 1-T, is the fraction of the light absorbed by the sample. (Do not confuse the transmittance with the temperature, which often is given the symbol T.)

In most applications, one wishes to relate the amount of light absorbed to the concentration of the absorbing molecule. It turns out that the absorbance rather than the transmittance is most useful for the purpose. If no light is absorbed, the absorbance is zero (100% transmittance).

Each unit in absorbance corresponds with an order of magnitude in the fraction of light transmitted. For A=1, 10% of the light is transmitted (T=0.10) and 90% is absorbed by the sample. For A=2.1% of the light is transmitted and 99% is absorbed.

Analytical Method Development

In the discovery, development, and production of pharmaceuticals, analytical method development and validation are crucial processes. To assure the identification, purity, potency, and effectiveness of drug goods, quality control laboratories use the official test procedures that come as a result of these processes. The recent development of methodologies has significantly benefited from advancements in analytical instrumentation. Particularly for chromatographic detectors, this is true. The principal methods for the examination of non-volatile active medicinal components and contaminants have developed to be isocratic and gradient reverse-phase high performance liquid chromatography.

The photo-diode array detector is the HPLC detector of choice for many types of technique development since it may be utilized for both qualitative and quantitative analysis. Recent guidance on chiral drug products and contaminants from the US Food and Drug Administration (FDA) and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) has presented additional difficulties for method developers. But recent developments in the use of chiral HPLC columns have significantly accelerated this field's growth.

Analytical Method Development is required for

- Herbal Products
- New process and reactions
- New molecules
- Active ingredients (Macro analysis)
- Residues (Microanalysis)
- Impurity Profiling
- Component of Interest in different matrices

Analytical method validation

Analytical Approach Validation is "the gathering and assessment of data from the process design stage through production, which establishes scientific evidence that a process is capable of reliably producing high-quality products. When something is validated, it is demonstrated that it functions as predicted under a specific set of conditions and has the necessary accuracy, precision, sensitivity, ruggedness, etc.

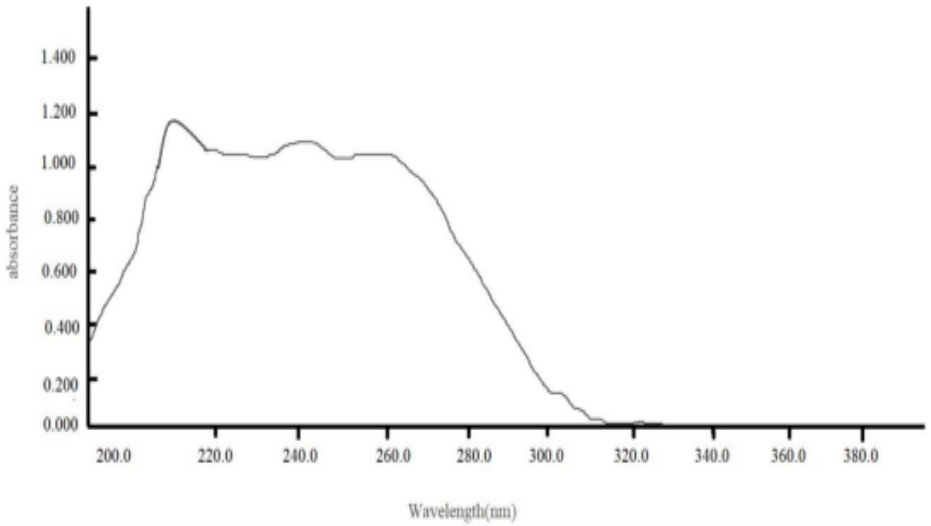
RESULT AND DISCUSSION

UV SPECTROMETRY METHOD

Wavelength selection

The 10-60 g/ml standard stock solution was made, and the wavelength with the highest absorbance was chosen after observing the absorbance at several wavelengths.

S.NO	Concentration	Wavelength (nm)	Absorbance
1	10	250.0	0.263
2	20	250.0	0.523
3	30	250.0	0.779
4	40	250.0	1.041
5	50	250.0	1.297
6	60	250.0	1.534

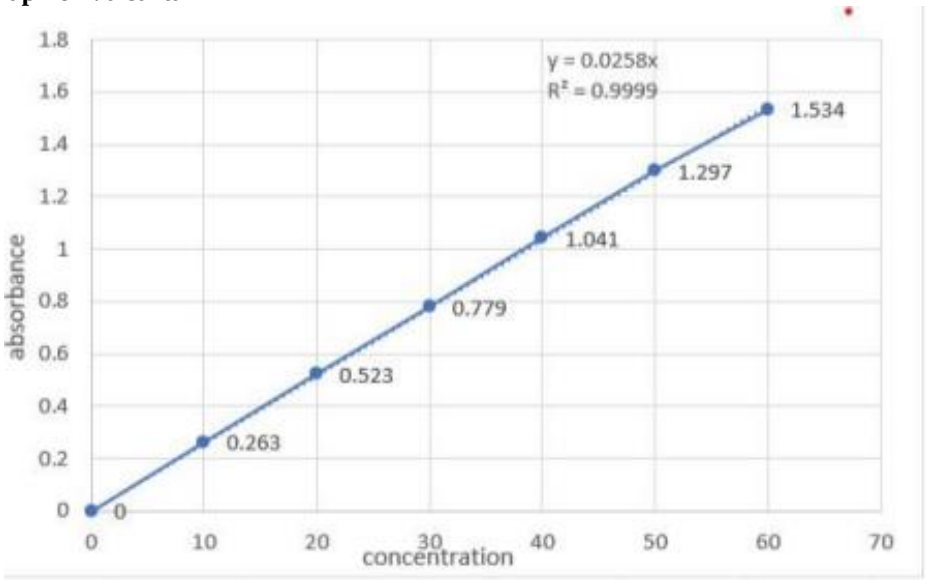


Spectrum of Valsartan

Beer's law range

The solutions' absorbance was determined at 250.0 nm after being scanned in the UV area between 200 and 400 nm. Beer's law is observed by Valsartan between 10-60 g/ml when a calibration curve was plotted from the graph using absorbance values against concentrations.
The data was given in Table-2.

Calibration graph of Valsartan



Beer's law range

Quantitative estimation of Valsartan Tablets

By using concentrations of 20–60 g/ml, a quantitative estimation of tablet formulations was conducted. According to the formulation's brand, the range of w/w percentage purity values is 104.45 to 110.37%. The values for the percentage deviation ranged from 4.4 to 0.3. The data was given in Table-3.

Quantitative Estimation of Valsartan Tablets

S.no	Concentration (µg/ml)	Label Claim (mg/tablet)	Amount Present (mg/tablet	Percentage Label claim(%w/w)	Percentage Deviation
1	20	40	44.15	41.78	±0.3
2	40	40	42.43	106.07	±6.0
3	40	40	41.78	104.45	±4.4

Valsartan Tablet Statistical Data Estimation: To determine the standard deviation and standard error values, statistical analysis was performed on the given quantitative results. Low standard error values demonstrate the correctness of the approach, and the relative standard deviation values shown below indicate the methodology's precision.
The data was given in Table-4.

Statistical Data of Valsartan Tablets

S.no	Concentration (µg/ml)	Percentage Label claim (%w/w)	Standard Deviation (SD)	Relative Standard Deviation (RSD)	Standard Error of Mean (SE)
1	20	110.37	2.41	2.25	1.39
2	40	106.07	0.62	0.57	0.35
3	60	104.45	1.77	1.65	1.02

Repeatability studies

The assay procedures with many varied concentrations validated the reproducibility of the approach. 100.75 to 102.37% w/w is the range of repeatable values. The repeatability test results demonstrate the accuracy of the suggested approach. Table 5 contained the information.

Repeatability Studies

S.no	Concentration (µg/ml)	Label Claim (mg/tablet)	Amount Present (mg/tablet	Percentage Label claim(%w/w)	Percentage Deviation
1	20	40	40.95	102.37	±2.3
2	40	40	40.72	101.8	±1.8
3	60	40	40.03	100.75	±0.7

Recovery studies

Recovery studies further supported the proposed method's validity. Recovery rates range from 102.3 to 105.0% weighted average. This is a reliable indicator of the study's accuracy and reproducibility. Table 6 contained the information.

Recovery Studies

S.no	Concentration (µg/ml)	Amount Added (mg)	Amount Recovered (mg)	% Recovery	% Deviation
1	20	10	10.3	105.0	±5.0
2	40	20	20.5	102.5	±2.5
3	60	30	30.7	102.3	±2.3

CONCLUSION

Uv Spectrometry Method

For the determination of valsartan in pure and pharmaceutical dosage form, a UV Spectrophotometric approach is reported. The solvent and wavelength were initially chosen for procedure standardization. The absorbance peak was discovered at 250.0 nm after several concentration solutions were made and scanned in the UV range between 200 and 400 nm. A calibration curve was built utilizing the absorbance measurements against concentrations. According to the graph, Valsartan follows Beer's rule between 10-60 g/ml.

According to the formulation's brand, the range of w/w percentage purity values is 104.45 to 110.37%. The values for the percentage deviation ranged from 4.4 to 3.3. 100.75 to 102.37% w/w is the range of repeatable values. The repeatability test results demonstrate the accuracy of the suggested approach. Recovery rates range from 102.3 to 105.0% weighted average. This is a reliable indicator of the study's accuracy and reproducibility.

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