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Development and validation of simple, precise UV spectroscopic method for the estimation of valsartan in bulk and marketed tablet

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Abstract

Two new simple and accurate solvent blends have been presented for the estimation of Valsartan (VAL) in bulk and its tablet dosage form. The developed analytical method was validated and established in ICH Q2 (R1). Valsartan exhibit 250 nm and 251 nm for Solvent A, Solvent B respectively and found was linear for a range of 1 µg/ml – 50 µg/ml. The goodness of fit study suggests good correlation coefficient R^2 - 0.9998 and 0.9985 for proposed solvent blends. The validity of Beer's law with intercept response < 2% calculated by the least square method indicating functional linearity between the concentration of analyte and the absorbance. The (LOD) and limit of quantification (LOQ) of Valsartan was within the quantifiable with % RSD < 2. The analytical method validation of proposed solvent blends was performed by carrying out precision and accuracy studies. The Accuracy percentage recovery on three different levels i.e. 50%, 100% and 150% was found to be within the acceptable limits with % RSD < 2. The proposed solvent blends were validated for specificity, precision, ruggedness, accuracy and robustness. Overall study suggest that the proposed solvent blends can be used for estimation of Valsartan in bulk and its tablet dosage form and can be applied for the everyday quality control analysis.

Keywords: Valsartan; UV spectroscopy; Validation; Accuracy; Precision

1. Introduction

Valsartan (VAL) is a new potent, highly selective and orally active antihypertensive drug belonging to the family of angiotensin II type I receptor antagonists. VAL widely used in the treatment of hypertension, heart failure, myocardial infarction and diabetic nephropathy. It is available as single and in combination with other antihypertensive drugs. Chemically Valsartan is N-(1-oxopentyl)-N-[[2-(1H-tetrazol-5- yl) [1, 1- biphenyl]-4-yl] methyl]-l-valine figure 1. Many analytical methods have been reported in the literature for the determination of VAL in pharmaceutical formulations alone and in combinations viz., UV spectroscopy[1-3], HPLC[4,5], RP-HPLC[6-8], HPTLC[9-10], LC[11], absorption ratio method[12-13], Voltammetry[14], HPLC-MS/MS[15], LCMS/ MS[16]. The reported methods were found to be tedious and expensive so there is a need for a simple, rapid, cost effective and reproducible method for quantification. Therefore, it was thought of interest to develop simple, accurate, fast and cost effective method for the estimation of VAL in bulk and its marketed tablets.

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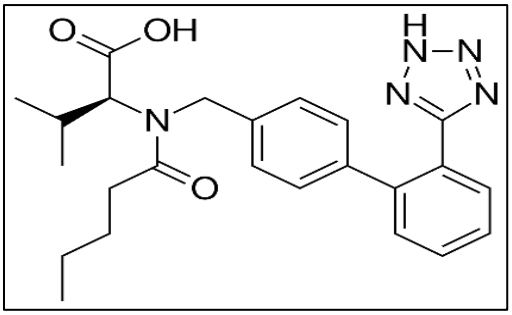

Figure 1 Chemical structure of VAL

2. Materials

Valsartan (VAL) obtained as gift sample from Caplin Point Laboratories, Chennai. Valsartan 80 mg and Valzaar 40 mg tablets procured from local community pharmacy. All reagents, solvents used were of analytical grade. Spectrophotometric measurement was performed by using a double beam UV-Visible Spectrophotometer (Shimadzu UV-1900/PC, Japan, Hitachi UV Spectrophotometer) connected to a compatible computer and supported with UV Probe software.

2.1. Methods

2.1.1. Screening of the solvents

Selection of solvent blends were done by screening the various solvents comprising organic solvents, aqueous solvents at varied pH and distilled water alone and in combination at different ratios. Two ideal solvent blends viz., Solvent A (Methanol: pH 6.8 at 1:3) and Solvent B (Acetonitrile: pH 6.8 at 1:3) were selected based on solubility and stability for quantification of model drug VAL.

2.1.2. Preparation of VAL standard stock solution

50 mg of VAL was weighed accurately and transferred into 50 ml volumetric flask which is previously contains 40 ml of Solvent A. The mixture was shaken for 1 hr and sonicated for 10 min, further makeup the volume to 50 ml with Solvent A to get 1000 µg/ml. Similarly, VAL standard stock solution was prepared in Solvent B to get 1000 µg/ml.

2.1.3. Preparation of VAL working standard solution

VAL working standard solution were prepared in both the Solvent blends under the study, during preparation 5.0 ml of respective standard stock solutions were diluted with 50 ml with Solvent A and Solvent B respectively in a separate 50 ml volumetric flask to get 100 µg/ml.

2.1.4. Assay procedure for tablets

Two marketed brands viz., Valsartan 80 mg and Valzaar 40 mg were chosen for the study. The sample solution for assay of VAL in marketed tablets were prepared by crushing 10 tablets to a fine powder, further powder equivalent to 50 mg of VAL was extracted separately with 50 ml of solvent blends under the study in a two 50 ml volumetric flask for 1 hr and sonicate for 30 min. The extracted mixture was filtered through Whatman filter paper no. 41, then filtrate was appropriately diluted with solvent blends under the study in a series of 10 ml volumetric flask for further study.

2.2. Method development

2.2.1. Determination of absorption maxima (λ max)

The working standard solution was appropriately dilute with Solvent A and Solvent B solution separately in 10 ml volumetric flask to get 10 µg/ml solution, both solutions were scanned in the range of 200 to 400 nm using double beam UV spectrophotometer, and observe the characteristic peak at standard wavelength (nm).

2.2.2. Range

Appropriately dilute the VAL working standard solution with Solvent A in a series of 10 ml volumetric flask to obtain 1-50 µg/ml concentrations and measure the absorbance at 250 nm, similarly prepare series of VAL working standard

solution i.e. 1-50 µg/ml concentrations in Solvent B solution, measure the absorbance at 251 nm keeping respective solvent blends as blank.

2.2.3. Linearity

The linearity is the ability of analytical procedure to produce test results, which are proportional to the concentration (amount) of analyte in samples within a given concentration range. Appropriately dilute VAL working standard with Solvent A in a series of 10 ml volumetric flask to obtain 2, 4, 6, 8, 10, 12, 14, 16, 18 and 20 µg/ml concentrations and the absorbance were measured at 250 nm. Similarly prepare series of VAL working standard solution viz., 1, 3, 5, 7, 10, 14, 16, 18 and 22 µg/ml concentrations in Solvent B, measure the absorbance at 251 nm, keeping respective solvent blend as blank, plot the concentration vs absorbance curve and regression equation was computed.

2.2.4. LoD and LoQ

Limit of detection (LoD) is the lowest amount of an analyte detected in a sample and Limit of quantitation (LoQ) is the lowest amount of an analyte quantified in a sample with a suitable precision and accuracy. Both are determined based on standard deviation (SD) of response and slope (S) by using the following equations,

$LoD = 3.3 \times SD/S$; $LoQ = 10 \times SD/S$

2.2.5. Precision

Precision of proposed analytical method was carried out at different concentrations prepared by diluting appropriately the VAL working standard solution in Solvent A and Solvent B under the study and express the results in terms of % RSD, similarly interday and intraday precision were performed.

2.2.6. Robustness

A robustness study performs to check the influence of method parameters varied intentionally on the proposed method results. Change in the experimental parameter viz., varied wavelength ± 2 nm and ± 5 nm and measure the recovery and interpret the results in terms of % RSD.

2.2.7. Ruggedness

A ruggedness study performs to check the influence of process parameters varied intentionally on the proposed method viz., different analyst. Interpret the results in terms of % RSD.

2.2.8. Accuracy

The most common technique for determining accuracy in analytical method development studies is the recovery method, recovery defined as the ratio of the observed result to the expected result expressed as a percentage. Standard addition method was applied for recovery studied, in which a sample assayed with spiked amount of VAL (50%, 100% and 150%) to the test working standard solvent blends under the study, and the sample assayed as percent recovered in terms of % RSD.

2.2.9. Solution stability

The stability of stock solutions of VAL in proposed mediums studied at different temperature (45°C) and refrigerated temperature (2-8°C). The samples were stored in tightly sealed glass containers protected from light. Appropriately dilute the standard stock solutions of proposed methods in a series of 10 ml volumetric flask and the absorbance measured at 24 hr and 48 hr time interval.

3. Results and Discussion

The absorption maxima were found to be 250 nm for Solvent A and 251 nm for Solvent B solution with characteristic peak as shown in figure 2. The linearity curve was constructed for Solvent A and Solvent B, same was shown in figure 3. The linearity curve data was given in table 1.

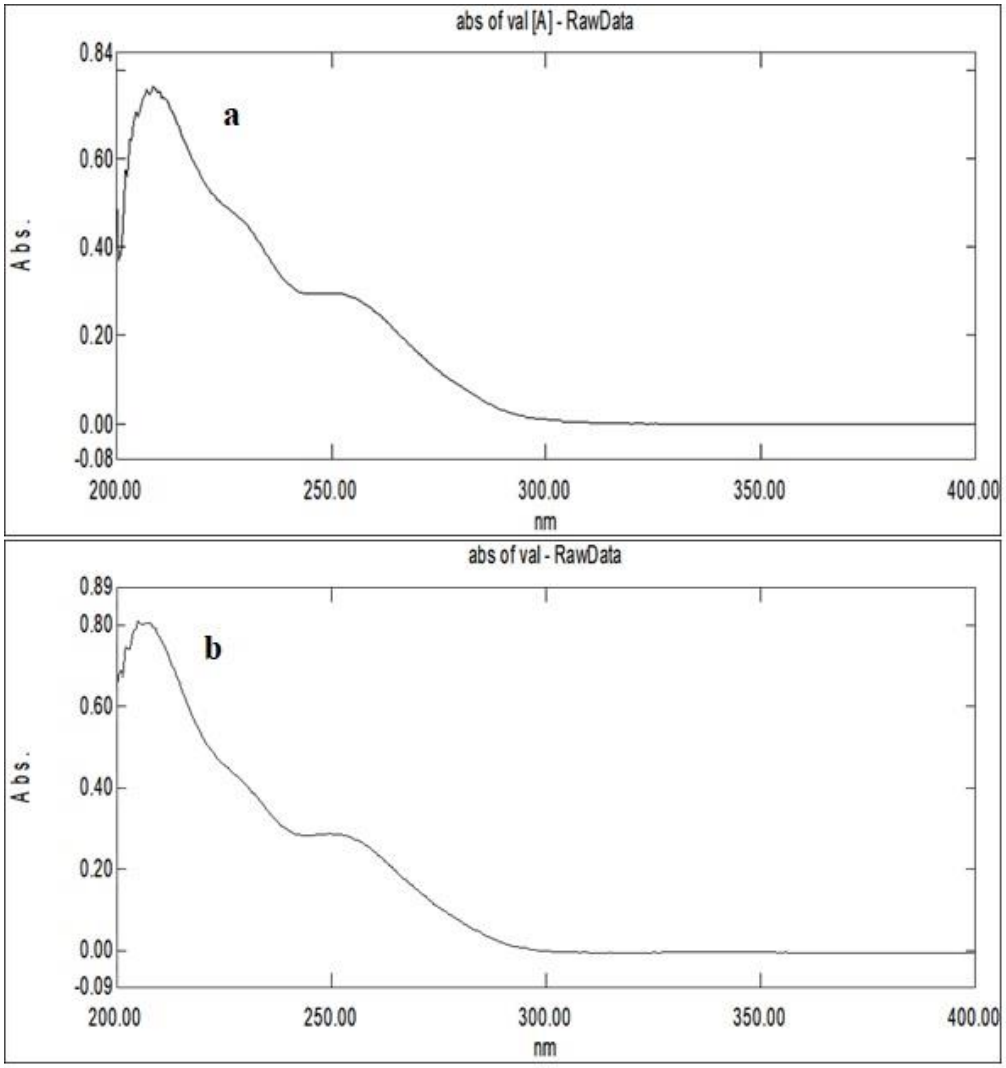

Figure 2 Absorption maxima of VAL in a) Solvent A and b) Solvent B

A linear relationship found in the concentration range of 1-50 µg/ml for both solvent A and Solvent B. The correlation coefficient R^2 was 0.9998 and 0.9985 for Solvent A and Solvent B shows the validity of Beer's law with intercept response < 2% calculated by the least square method indicating functional linearity between the concentration of analyte and the absorbance. Based on standard deviation of the response and slope, the LOD values for Valsartan for the proposed mediums found to be 0.002229 µg/ml, 0.1271 µg/ml and LOQ values found to be 0.06759 µg/ml, 0.3853 µg/ml with % RSD values less than 2.

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. The precision data in terms of repeatability, intra and inter day of the proposed solvent blends were given table 2, and were studied for two fixed amounts with six replicates, the % RSD was less than 2 indicate the Solvent blends under the study were precise and reproducible over the period of 72 hr.

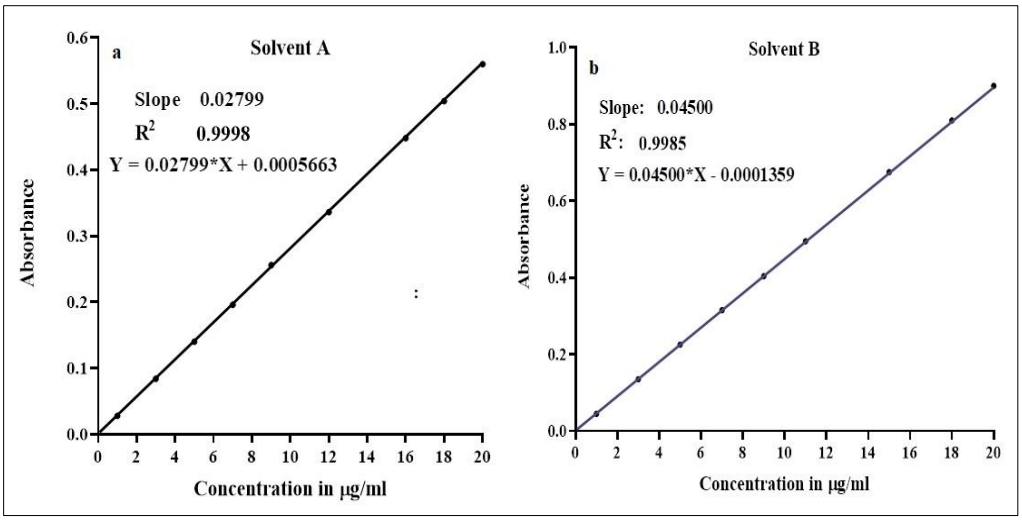

Figure 3 Linearity curve of VAL in a) Solvent A and b) Solvent B

Table 1 Linearity curve data of VAL in Solvent A and Solvent B

Solvent A			**Solvent B**		
Concentration µg/ml	Absorbance Mean ± SD	% RSD	Concentration µg/ml	Absorbance Mean ± SD	% RSD
1	0.028±0.0005	1.770	1	0.045±0.0082	1.814
3	0.085±0.0081	0.258	3	0.135±0.00500	0.369
5	0.139±0.0050	0.357	5	0.225±0.00158	0.558
7	0.196±0.0081	0.416	9	0.404±0.00129	0.319
9	0.252±0.0081	0.324	11	0.495±0.00170	0.344
12	0.335±0.0050	0.149	15	0.675±0.00577	0.854
16	0.448±0.0081	0.183	18	0.810±0.00163	0.201
18	0.504±0.0057	0.115	20	0.901±0.00012	0.328
20	0.562±0.0047	0.835			

In accuracy studies the Solvent A and Solvent B were analyzed for assay in two marketed VAL tablet formulations viz., VALSARTAN 80 mg; VALZAAR 40 mg at fixed labelled claim and data was given in table 3, 4. The percentage recovery was found to be between 99.53±0.2887 to101.5±0.2505. Further the recovery study was performed by standard addition method and the % recovery found within the permissible limits with % RSD was less than 2% indicate non-interference of the excipients in the formulations. The accuracy results indicate VAL content of two marketed products determined by the proposed solvent blends were in good agreement with the label claim with % RSD less than 2.

In robustness the experimental variations viz., change in λ max of ± 5 nm and ± 2 nm to the actual λ max was studied on Solvent A and Solvent B, data was given in table 5. The result suggests the both proposed solvent blends were highly robust. In ruggedness, analysis by different analyst indicates the proposed solvent blends were significantly rugged as shown in table 6. The stability of proposed solvent blends was studied and % recovery was found to be within the acceptable limits indicate stable at stored temperature viz., 40°C and 4-8°C over the period of 24 hr.

Table 2 Precision data of VAL in Solvent A and Solvent B

Precision	**Solvent A**				**Solvent B**			
	Labelled claim µg/ml	Amount recovery µg/ml	Mean % Recovery ±SD N=6	% RSD	Labelled claim µg/ml	Amount recovery µg/ml	Mean % Recovery ±SD N=6	% RSD
	14	13.97	99.80±0.1549	0.1552	18	18.27	101.5±0.1732	0.1706
	18	18.01	100.0±0.0516	0.0516	20	20.2	101.0±0.1000	0.0990
Intraday Precision								
24 hr	14	13.96	99.70±0.3000	0.3009	18	18.28	101.6±0.1637	0.1612
24 hr	18	17.99	99.97±0.2887	0.2888	20	20.33	101.6±0.2082	0.2048
Interday Precision								
0 hr	14	14.11	100.8±0.6557	0.6505	18	18.31	101.7±0.1000	0.0983
	18	17.9	99.60±0.2342	0.2353	20	20.28	101.4±0.2646	0.2609
24 hr	14	14.16	101.1±0.6028	0.5960	18	18.31	101.7±0.2517	0.2474
	18	18.03	101.2±0.1732	0.1730	20	20.33	101.6±0.2082	0.2048
48 hr	14	14.08	100.6±0.1155	0.1148	18	18.27	101.5±0.1732	0.1706
	18	17.96	99.97±0.3512	0.3513	20	20.2	101.0±0.1000	0.0990
72 hr	14	14.11	100.8±0.6557	0.6505	18	18.30	101.7±0.1528	0.1502
	18	17.9	99.60±0.1343	0.1342	20	20.33	101.6±0.2082	0.2001

Table 3 Drug content data of VAL in two marketed tablets

Assay	**Solvent A**			
Brand name	Labelled claim µg/ml	Amount recovery µg/ml	Mean % Recovery± SD N=3	% RSD
VALSARTAN 80 mg	12	11.96	99.87 ±0.8083	0.8094
	14	14.02	100.1 ±0.4041	0.4036
	18	17.92	99.67 ±0.1155	0.1159
VALZAAR 40 mg	12	12.03	100.4±0.6351	0.6323
	14	13.93	99.53±0.2887	0.2900
	18	18.03	100.2±0.1323	0.1321
Assay	**Solvent B**			
VALZAAR 40 mg	3	3.04	101.4±0.5021	0.7913
	5	5.11	102.2±0.4509	0.4411
	9	9.02	102.3±0.7367	0.7367
VALSARTAN 80 mg	3	2.98	100.9±1.529	1.526
	5	5.08	101.8±0.4509	0.4431
	9	9.04	100.5±0.2505	0.2505

Table 4 % Recovery data of VAL in two marketed tablets

% Recovery studies	**Solvent A**					
	Labelled claim µg/ml	% Addition	Amount add	Amount recovery µg/ml	Mean % Recovery ± SD N=6	% RSD
VALSARTAN 80 mg	14	50	7	7.11	101.7±1.067	1.049
	14	100	14	14.15	101.1±0.1155	0.1143
	14	150	21	21.1	100.5±0.05774	0.05743
VALZAAR 40 mg	14	50	7	7.09	101.3±0.2771	0.2735
	14	100	14	13.9	99.7±1.950	1.9555
	14	150	21	21.06	100.5±1.172	1.1666
% Recovery studies	**Solvent B**					
VALZAAR 40 mg	9	50	4.5	4.54	100.4±0.9298	0.9257
	9	100	9	8.99	99.9±0.4388	0.4388
	9	150	27	26.87	99.47±0.1155	0.1161
VALSARTAN 80 mg	9	50	4.5	4.48	99.60±0.6928	0.6956
	9	100	9	8.99	100.3±0.7371	0.7352
	9	150	27	27.10	100.4±1.172	1.167

Table 5 Robustness data for VAL in Solvent A and Solvent B

λmax	**Labelled claim µg/ml**	**Amount recovery µg/ml**	**Mean %Recovery ± SD N=6**	**% RSD**
± 2	**Solvent A**			
250	14	14.11	100.8± 0.6557	0.6505
	18	18.01	100.5±0.1350	0.1317
252	14	14.38	101.9±1.340	1.365
	18	18.29	101.5±0.2000	0.1936
248	14	13.38	98.08±0.4696	0.478
	18	17.92	99.60±0.2517	0.2579
250	14	14.11	100.8± 0.6557	0.6505
	18	18.01	100.5±0.1350	0.1317
255	14	14.2	101.7±0.5774	0.5324
	18	18.35	100.7±0.3055	0.2883
245	14	14.01	100.2±0.8505	0.9221
	18	17.91	98.03±0.2000	0.1761
± 5	**Solvent B**			
251	18	18.18	101.6±0.4099	0.3995

	20	20.44	99.99±0.1102	0.1102
253	18	18.18	101.0±0.3550	0.3292
	20	19.88	99.43±0.1386	0.124
249	18	17.86	99.2±0.7100	0.7310
	20	20.8	102±0.08083	0.0850
251	18	18.18	101.6±0.4099	0.3995
	20	20.44	99.99±0.1102	0.1102
256	18	17.86	99.2±0.4099	0.3628
	20	19.86	99.3±0.1400	0.1314
246	18	18.36	102±0.5488	0.6019
	20	20.46	99.99±0.1102	0.1102

Table 6 Ruggedness data for VAL in Solvent A and Solvent B

Analyst	**Labelled claim µg/ml**	**Amount recovery µg/ml**	**Mean % Recovery ± SD N=6**	**% RSD**
Solvent A				
Analyst -1	14	13.97	99.80±0.1732	0.1736
	18	18.01	100.6±0.1155	0.1148
Analyst -2	14	14.08	101.8±0.5774	0.05772
	18	18.16	101±0.02309	0.2287
Solvent B				
Analyst -1	18	18.31	101.7±0.2517	0.2474
	20	20.33	101.6±0.2048	0.2082
Analyst -2	18	18.31	101.7±0.1000	0.0983
	20	20.29	101.4±0.2646	0.2609

4. Conclusion

The results demonstrate that the proposed solvent blends viz., Solvent A and Solvent B were found to be simple, specific, accurate and precise. Therefore, this method can use for the estimation of VAL in tablet dosage formulations without interference with commonly used excipients and related substances by UV spectroscopic method.

Compliance with ethical standards

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Disclosure of conflict of interest

No conflict of interest

Authors Contribution

The collaborative efforts of all authors have successfully led to the Development and validation of simple precise UV spectroscopy method for the estimation of Valsartan in bulk and marketed tablet. Ashritha and HM Swathi under the mentorship of Dr. N. Srinivasulu, conducted the development and validation of the technique. Dr. Y. Anand Kumar provided guidance in crafting the manuscript and structuring the research paper in accordance with the journal's guidelines.

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