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Estimation of Irbesartan in Bulk and Dosage Forms by New Simple UV Spectrophotometry Using Hydrotropic Technique

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Abstract

Irbesartan, chemically, a non peptide tetrazole derivative, has anti hypertensive property. It is an angiotensin II antagonist that selectively blocks the binding of an angiotensin II to the angiotensin I receptor. In present work, a selective, specific, sensitive and economical hydrotropic agent assisted spectroscopic method using 1M sodium bicarbonate and 2M urea (50:50% v/v), as hydrotropic agent; to increase the solubility of poorly water-soluble Irbesartan, has been developed for the estimation of Irbesartan in Bulk and its pharmaceutical dosage forms. An absorption maximum was found to be at 246.4 nm where sodium bicarbonate, urea and other excipients did not show any absorbance above 228 nm and thus no interference in the estimation. Irbesartan was obeyed Beer's law in the concentration range from 10-35 µg / ml. Proposed method was validated according to ICH guidelines and values of accuracy, precision and other statistical analysis were found to be in good accordance with the prescribed values with correlation coefficient of 0.9998. The percentage recovery of Irbesartan ranged from 99.4-101.3% in pharmaceutical dosage form. Results of the analysis for accuracy, precision, LOD, LOQ and were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.

Keywords: Irbesartan; UV spectrophotometry; Tablets; Estimation

Introduction

Irbesartan, chemically, 2-butyl-3-({4-[2-(2H-1,2,3,4-tetrazol-5-yl)Phenyl]phenyl}methyl)-1,3-diazospiro[4.4]non-1-en-4-one. Irbesartan, a non peptide tetrazole derivative, has anti hypertensive property [1]. It is an angiotensin II antagonist that selectively blocks the binding of an angiotensin II to the angiotensin I receptor [2]. The chemical structure of Irbesartan is shown (Figure 1).

Irbesartan is practically insoluble in water so hydrotropic agents utilized to increase the water solubility [3]. Urea and sodium bicarbonate are the most common examples of hydrotropic agents. The solubility of various poorly water-soluble drugs was increased by hydrotropic solubilization phenomenon [4]. Literature survey reveals that various analytical methods had been developed such as HPLC [5], UV-Visible spectrophotometry [6], liquid chromatography [7] in biological fluids and in pharmaceutical formulations. To the best of our knowledge, there is no work in the literature reported about the Spectrophotometric method for the analysis of Irbesartan using hydrotropic agent. Therefore, it was thought worth wile to employ these hydrotropic solutions to extract out the drug from fine powder of tablets to carry out Spectrophotometric estimation.

Experimental Details

Materials and methods

Instrumentation: Spectrophotometer used was Double beam UV-Visible spectrophotometer with 10mm matched quartz cell Model-UV-1700 PHARMASPEC. Make – shimadzu, Japan and Analytical balance: shimadzu, Japan AX 200.

Chemicals and reagents: Irbesartan was procured from Smilax Laboratories Limited, Jeedimetla, Hyderabad-500055. All the reagents and chemicals used were of Analytical grade.

Method development

Preparation of standard stock solution and calibration curve: Standard stock solution of Irbesartan 100 µg/ml was prepared in mixed hydrotropic solution comprises 1 M sodium bicarbonate and 2 M urea (50:50% v/v). From this stock solution, appropriate dilution was made and scanned in the UV range 200-400 nm against the blank (Figure 2 and 3). The absorbance of Irbesartan was found to be 246.4 nm. The solubility of Irbesartan was increased more than 20 times in mixed hydrotropic solution as compared with distilled water. Aliquots of in the range of 10-35 µg /ml were prepared with the same solvent and scanned under Photometric mode for Absorbance at 246.4 nm. A calibration curve was plotted taking an absorbance on Y-axis against concentration of standard solution on X-axis (Table 1). The method

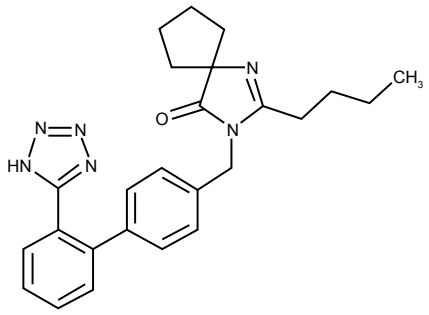

Figure 1: Chemical structure of Irbesartan.

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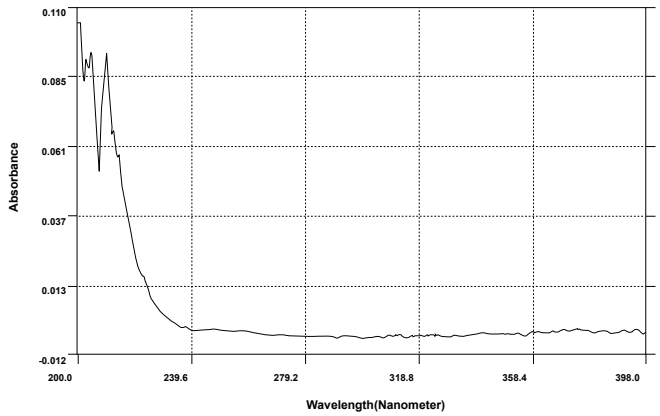

Figure 2: Spectrum of $NaHCO_3$ and Urea.

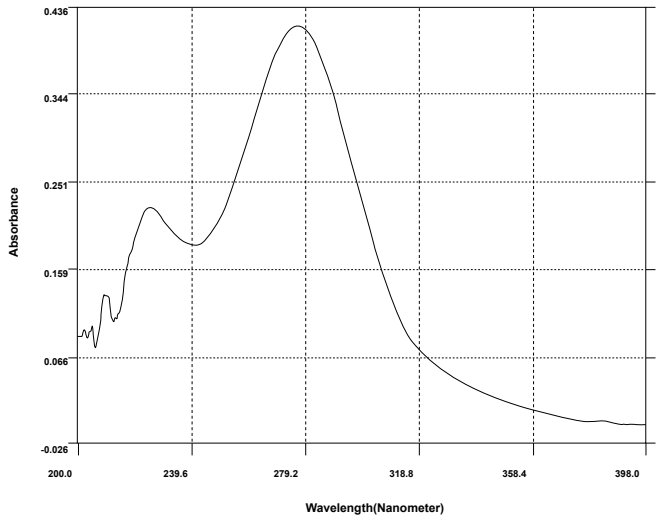

Figure 3: Spectrum of Irbesartan in $NaHCO_3$ and Urea.

Parameter	value
Absorption maxima (nm)	246.4 nm
Beer's law limit (µg/ml)	10-35 µg/ ml
Correlation coefficient (r)	0.9998
Regression equation (Y= mX+c)	Y= 0.0341x -0.1062
Slope (m)	0.0341
Intercept (c)	0.1062
Standard Deviation	0.0075
LOD (µg / ml)	1.23
LOQ (µg / ml)	3.72

Table 1: Optical characteristics of the proposed method.

was applied for Test sample solution and was found to be satisfactory for the analysis of dosage forms (Table 2).

Method validation

The method was validated for different parameters like Linearity, Accuracy and Precision.

Linearity: Fresh aliquots were prepared from the stock solution (100 µg/ml) ranging from 10-35 µg/ml. The samples were scanned in UV-Visible spectrophotometer using 1 M sodium bicarbonate and 2 M urea (50:50% v/v) in water as blank. It was found that the selected drug shows linearity in the range of 10-35 µg/ml.

Accuracy: Accuracy of the method confirmed by studying recovery at 3 different concentrations for 80, 100, and 120% of these expected, in accordance with ICH guidelines, by replicate analysis. Standard drug solution was added to a pre analyzed sample solution and percentage drug content was measured. The results from study of accuracy were reported (Table 3). %Recovery = [(ct –cu)/ ca] × 100. Where ct is the total conc. of the analyte found; cu is the conc. of the analyte present in formulation; and ca is the conc. of the pure analyte added to the formulation.

Precision: Precision (intra-day precision) of the method was evaluated by carrying out the five independent test samples of Irbesartan. The intermediate precision (inter-day precision) of the method was also evaluated using two different analyst, and different days in the same laboratory. The percent relative standard deviation (%RSD) and assay values obtained by two analysts were found to be good (Table 4).

Results and Discussion

From the optical characteristics (Table 1) of the proposed method, Irbesartan was shown its λ_{max} at 246.4 nm in the solvent mixture of hydrotropic agents of 1M sodium bicarbonate and 2M urea (50:50% v/v) with a good correlation coefficient 0.9998. The percentage purity and relative standard deviation from the Assay of the tablet dosage forms (Table 2) were found to be within the limits. The accuracy data of the drug (Table 3) was shown good percentage recovery and %RSD with the range of 99.4 -101.3 and 0.2-0.4 respectively. The Inter-day and Intra-day (Table 4) precision values were found to be 0.79 and 0.57 respectively.

Conclusion

The proposed method for the estimation of Irbesartan was found

Dosage form	Label claim (mg)	Amount found * ± SD
Irbest	300	300.04 ± 0.072
Irovel	150	149.93 ± 0.055

*An average of three samples for each concentration

Table 2: Assay of IRBESARTAN tablets.

Sample ID	Concentration µg /ml		(%)Recovery* ± S.D	RSD (%)
	Pure drug drug	Formulation		
80%	80	100	101.3±0.308	0.305
100%	100	100	99.4±0.397	0.40
120%	120	100	99.9±0.222	0.223

*An average of three samples of each concentration

Table 3: Accuracy data of the drug.

Assay of Irbesartan as percent of labeled amount		
Sample no	**Intra-day precision**	**Inter-day precision**
1	99.78	100.32
2	101.52	101.32
3	100.36	99.88
4	101.24	100.22
5	99.87	99.98
Mean	100.54	100.34
%RSD	0.79	0.57

Table 4: Precision of the Irbesartan working standards.

to be simple, sensitive and reliable with good precision and accuracy. The method is specific while estimating the commercial formulations without interference of excipients and other additives.

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