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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF IRBESARTAN: REVIEW

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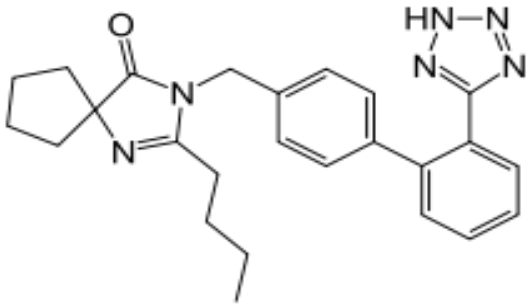
ABSTRACT

Analytical method development and validation are the uninterrupted and symbiotic tasks associated with the research and development. A quality control and quality assurance department associated with quality research and provides quality assurance. An analytical procedure plays a vital role in equivalence, risk assessment and management. It helps in establishment of product specific acceptance criteria and stability of results. Validations demonstrate that the analytical procedure is suitable for its intended purpose. Literature survey reveals that the analytical methods based on UV spectrometry, RP-HPLC & HPTLC for the determination of Irbesartan individually and in combination with other drugs. The methods were validated according to ICH guideline in terms of accuracy, precision, robustness, and other aspects of analytical validation. The developed methods are simple, sensitive and reproducible and can be used for the routine analysis of Irbesartan in bulk and Tablet dosage form.

KEYWORDS: Irbesartan, Literature Survey, Method Development, Validation, ICH Guidelines.

INTRODUCTION

Irbesartan is an angiotensin II receptor antagonist used mainly for treatment of hypertension. It was developed by Sanofi research. It is jointly marketed by sonafi-Aventis and Bristol-Myers Squibb under the trade names Aprovel, Karvea, and Avapro.[1] Irbesartan is an oral medication that is used to treat high blood pressure (hypertension) and diabetic nephropathy or kidney disease.[2]



IRBESARTAN

Irbesartan is chemically 2-butyl-3-({4-[2-(2*H*-1,2,3,4-tetrazol-5-yl)phenyl]phenyl}methyl)-1,3-diazaspiro[4.4]non-1-en-4-one, is an angiotensin II receptor antagonist, Is used mainly for the treatment of hypertension. It is an orally active non-peptidetetrazole derivative and selectively inhibits angiotensin II receptor type 2.It has a molecular formula of $C_{25}H_{28}N_6O$ and molecular weight of 428.53g/mol. IRB is practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. Brand name of Irbesartan is Avapro.

REVIEW OF LITERATURE

1. Srinath Nissankararao[3] et al., Have 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.

2. Annapurna[4] *et al.,* Have been developed and validated for the simultaneous determination of Irbesartan and Hydrochlorothiazide in pharmaceutical formulations (Tablets) by two methods i.e. simultaneous equation method and absorbance ratio method (Q-analysis) in phosphate buffer (p^H 7.5). Irbesartan and Hydrochlorothiazide have shown linearity over the

concentration range 5-35 µg/ml and 0.2-40 µg/ml in both the methods.

3. Gunjan Kalyani[5] *et al.,* To develop a simple, sensitive, accurate, precise and rapid first order derivative Spectrophotometric method for the estimation of irbesartan in pure form. For the estimation of irbesartan, solvent system employed was 50% v/v aqueous ethanol and wavelength of detection was 237 nm. The linearity was obtained in the range 8 -18µg/ml, with a regression coefficient, $R_2 = 1$.

4. ParasVirani1[6] *et al.,* A simple, accurate and precise spectroscopic method was developed for simultaneous estimation of Irbesartan and atorvastatin in synthetic mixture using simultaneous equation Method. In this spectroscopic method, 226.00 nm and 246.00 nm wavelengths were selected for measurement of absorptivity. Both the drugs show linearity in a concentration range of 05-30 µg/ml at their respective λmax. Accuracy, precision and recovery studies were done by QC samples covering lower, medium and high concentrations of the linearity range. The relative standard deviation for accuracy, precision studies were found to be within the acceptance range (<2%). The limit of determination was 0.033µg/ml and 0.125µg/ml for Irbesartan and atorvastatin respectively. The limit of quantification was 0.1008µg/ml and 0.3792µg/ml for Irbesartan and atorvastatin respectively. Recovery of Irbesartan and atorvastatin were found to be 99.75 % and 99.52% respectively confirming the accuracy of the proposed method.

5. Mohamed M. Baraka[7] *et al.,* Two simple and sensitive Spectrophotometric methods are described for determination of irbesartan, losartan, hydrochlorothiazide and atenolol in bulk and tablet forms. Method (I) depends on formation of the colored chromogen by condensation reaction between irbesartan, losartan and atenolol and vanillin in acidic conditions and the product was measured at λmax 546,552 and 560 nm for irbesartan, losartan and atenolol, respectively. Under the indicated conditions, this method was linear over the concentration range of 40-240 µg/ml, 80-240 and 40-200 µg/ml for irbesartan, losartan and atenolol respectively. In method (II), 1, 2-Naphthoquinone-4-sulphonate sodium reacts with irbesartan, losartan and hydrochlorothiazide through nucleophilic substitution reaction producing orange colored product in alkaline medium showing maximum absorption at λmax 465 nm for irbesartan, losartan and hydrochlorothiazide where the method was linear over the concentration range of 1-6 µg/ml, 0.2-1 µg/ml and 0.25-1.25 µg/ml for irbesartan, losartan and hydrochlorothiazide, respectively. The methods were statistically applied for the determination of drugs in both bulk and tablet forms.

6. B. Raja[8] *et al.,* A simple, precise, accurate reverse phase high performance liquid chromatographic method has been developed and validated for the simultaneous estimation of Irbesartan and hydrochlorothiazide in combined dosage forms. The mobile phase used was a mixture of sodium acetate buffer: Acetonitrile (45:55). The elution was carried out at 260 nm. The method was validated in terms of solubility, precision, accuracy, linearity, ruggedness and robustness.

7. Ramesh Bhukya[9] *et al.,* A simple, precise, accurate and rapid reverse phase high performance liquid chromatographic method had been developed for simultaneous estimation of Irbesartan (IRBE) and Hydrochlorothiazide (HCTZ) in bulk and Pharmaceutical dosage form. A Phenomex Luna C-18 column having I'd of 150×4.6 mm and 5µm particle size was used. The method was carried out in gradient program using mobile phase, 0.02M Potassium dehydrogenate orthophosphate: Acetonitrile (60:40 v/v) adjusted to pH-3.4 using dilute ortho phosphoric acid. Flow rate was adjusted to 1.0ml/min and effluents were monitored at 224nm. The retention time obtained for Irbesartan and HCTZ was 2.59 & 8.13min respectively. The calibration curves were linear in the concentration range of 100-300µg/ml for Irbesartan and 50-150µg/ml for HCTZ. The developed method was validated in accordance to ICH guidelines.

8. Sahoo[10] *et al.,* A simple and rapid reversed phase-high performance liquid chromatographic method was developed for simultaneous determination of Irbesartan and Hydrochlorthiazide in Tablet Dosage form. The elution was done with a mobile phase of Methanol:0.05 % Orthophosphoric acid (90:10) on Intersil-BDS C18 column (250 × 4.6 mm, 5 µm particle size). The wavelength detector was set at 226 nm. Retention times for Irbesartan and Hydrochlorthiazide were around 2.869 min, 3.942 min respectively. The reliability and analytical performance of the proposed HPLC procedure were statistically validated according to the respect of linearity, ranges, precision, accuracy, repeatability, reproducibility, detection and quantification limits. Linear ranges were established between 36-216 µg/mL for Irbesartan and 3-18 µg/mL for Hydrochlorthiazide. The LOD and LOQ for Irbesartan were found to be 0.65, 1.97 and for Hydrochlorthiazide were found to be 0.513, 1.556 respectively.

9. Rishabh K. Dagariya[11] *et al.,* The present work describes a validated reverse phase high performance liquid chromatographic method for simultaneous estimation of Irbesartan chlorthalidone, and cilnidipine in tablet dosage form. The quantification was carried out using $_{C18}$ column (250 x 4.6mm, 5µm) and mobile phase comprised of Buffer, Acetonitrile and TEA in proportion of 80:20:0.1%v/v/v. The flow rate was 1.0 ml/min and the eluent was monitored at 222 nm. The selected chromatographic conditions were found to effectively separate Irbesartan Chlorthalidone and cilnidipine were 3.807 min, 4.667 min and 6.887 min respectively. Linearity were found to be in the range of 30-90 µg/ml, 1.25-3.75 µg/ml and 1-3 µg/ml for Irbesartan

Chlorthalidone and cilnidipine respectively.

10. Kalaiselvi P[12] *et al.,* A Simple precise and accurate method was developed and validated for the simultaneous analysis of chlorthalidone and irbesarton in tablet formulations. The method has been shown adequate separation of the two ingredients from each other. The chromatographic separation was achieved on a reverse phase column C18 (250 mm x 4.6 mm, 5µ), in a mobile phase consisting of 0.02 M ammonium phosphate buffer (adjusted to pH 5.5 with triethyl amine), acetonitrile and methanol in the ratio (40:40:20, v/v/v) at a flow rate of 1 ml/min with UV detection at 220 nm. This new method was validated, which include assay determination, accuracy, precision, selectivity, linearity and range, robustness and ruggedness. The current method demonstrates good linearity over range of 40-60% µg/ml of chlorthalidone with r2 =0.9991 and in the range of 480 - 720 % µg/ml of irbesarton with r2 = 0.9990. The average recovery of the method is 99.22 % µg/ml and 102.28 % µg/ml for chlorthalidone and irbesarton, respectively. The degree of reproducibility of the results obtained as a result of small deliberate variations in the method parameters and by changing analytical operator indicating that the method was found to be sufficiently robust and rugged. A simple, accurate, precise RP-HPLC method was developed and validated for the simultaneous determination of chlorthalidone and irbesarton in tablet formulation.

11. T. M. Kalyankar[13] *et al.,* A simple, precise, accurate, rapid and economical analytical method was developed and validated for simultaneous estimation of hydrochlorothiazide and irbesartan by RP-HPLC in Pharmaceutical Preparation. Analysis was performed on a C_{18} (250 mm x 4.6 mm, 5 µm) column with methanol: 0.05 M potassium dihydrogen ortho phosphate buffer pH 2.5 (60:40 v/v) as mobile phase, a flow rate 0.8 ml/min and column temperature 40ºC. Quantitation was achieved with UV detection at 226 nm. Both the drugs were well resolved on the stationary phase and the retention times were found to be 3.21 min for Hydrochlorothiazide and 10.19 min for irbesartan. The calibration curves were linear in the concentration range of 5-30 µg/ml for hydrochlorothiazide and 60-360 µg/ml for irbesartan. Intra-day and inter-day relative standard deviations for both the components were < 2.0%. The Percentage recovery for hydrochlorothiazide and irbesartan are ranged between 99.72–100.38 and 100.00–100.44 respectively.

12. R. Magesh[14] *et al.,* High performance thin layer chromatographic (HPTLC) method has been developed and validated for simultaneous investigation of Irbesartan and Hydrochlorothiazide in tablet formulation. Chromatographic separation was performed on aluminium plates precoated with silica gel 60F254, with methanol: ethyl acetate (7: 3 % v/v) as mobile phase. Detection was performed densitometrically at 254 nm. The Rf values of Irbesartan and Hydrochlorothiazide were 0.24 ± 0.10 and 0.42 ± 0.06, respectively. Linearity was found to be in the concentration range of 150-900 ng/spot for Irbesartan and 25- 150 ng/spot for Hydrochlorothiazide, accuracy (100.05 % for Irbesartan and 100.26 % for Hydrochlorothiazide) and specificity, in accordance with ICH guidelines. The method can be used for routine analysis of Irbesartan and Hydrochlorothiazide in tablet formulation.

CONCLUSION

Literature survey suggested that various HPLC, UV, and few HPTLC methods were developed and reported. The published methods were validated for various parameters as per ICH guidelines. Statistical analysis proved that the published methods were reproducible and selective. Thus it can be concluded that the reported and published methods can be successfully applied for the estimation of the Irbesartan in pure and pharmaceutical dosage form.

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