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DEVELOPMENT OF VALIDATED STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF IRBESARTAN IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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Keywords:

Irbesartan, RP- HPLC, ICH, Validation, Degradation

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ABSTRACT: A stability indicating RP-HPLC method was developed and validated for the determination of Irbesartan in bulk and dosage forms using Telmisartan (10 µg/ml) as the internal standard. An Inert ODS C-18, 5µm column having 250 x 4.6mm internal diameter in isocratic mode with mobile phase containing methanol: water (90:10) and the pH was adjusted to 3 with 1 % GAA. The flow rate was 1 ml/min and effluents were monitored at the wavelength of 246 nm. The retention time for Irbesartan was 2.3 min. The method was validated as per ICH guidelines for linearity, accuracy, precision, specificity, limit of detection, limit of quantification and robustness. Limit of detection (LOD) and limit of quantification (LOQ) were found 6.51µg/ml and 1.973µg/ml respectively and recovery of Irbesartan from bulk and dosage forms was found from 99.94% to 99.97%. As the separation of the degradants using this mobile phase is quite good, isolation of the degradants with preparative techniques can also be achieved using this mobile phase. The drug was prone to degrade more in acidic, alkaline, oxidative and thermal conditions. Further LC MS-MS analysis will help to deduce the structures of the degradants which can help to establish the possible degradation pathway of this drug. So this method can be economically very useful in both research and industrial aspect.

INTRODUCTION: Angiotensin antagonists are the first major innovation in essential hypertension management as a first-line treatment. Angiotensin II receptor antagonists have been developed to specifically and selectively block the AT1 receptor of the rennin angiotensin system by displacing angiotensin II from it. Losartan potassium, Telmisartan and Irbesartan are highly selective, non-peptide angiotensin-II receptor antagonists (ARA-II).

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Irbesartan is a synthetic, nonpeptide antagonist of angiotensin-II with chemical name 2-butyl-3-({4-[2- (2H-1, 2, 3, 4-tetrazol-5-yl) phenyl] phenyl} methyl)-1, 3 - diazaspiro[4.4] non –1–en -4 - one. Irbesartan is used mainly for the treatment of hypertension. Irbesartan pronounced is an angiotensin II receptor antagonist[1-7]. IAPUC name of Irbesartan is 2-butyl-3-({4-[2-(2H-1, 2, 3, 4 - tetrazol-5-yl) phenyl] phenyl} methyl) - 1, 3 - diazaspironon-1-en-4-one and molecular formula $C_{25}H_{28}N_6O$ [8-13]. Literature survey revealed that numerous methods have been reported for estimation of Irbesartan in pharmaceutical formulations has been reported.

Present study involves development of RP-HPLC method using simple mobile phase which is sensitive and rapid for quantification of Irbesartan

in bulk and tablet dosage forms as well as subsequent validation of developed method according to ICH guide lines.

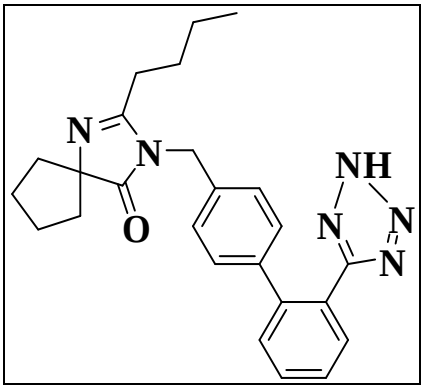

FIG. 1: CHEMICAL STRUCTURE OF IRBESARTAN

MATERIALS AND METHODS:

RP-HPLC Analysis of Irbesartan by Using Telmisartan as I.S:

Chemicals: The gift samples of Irbesartan and Telmisartan (pure drug) were procured from Glenmark Pharmaceutical Company, Mumbai. The required solvents like HPLC grade methanol, water were purchased from Sigma Aldrich Pvt. Ltd. HPLC grade water was prepared using Millipore System (Millipore, Molesheim France, Model Elix-10). All other reagents were of AR grade.

Instrument: HPLC was performed on Shimadzu HPLC with LC- 20AT pumps besides SPD- 20A UV-Visible detector. Shimadzu spincrom-CFR software was used along with Phenomenex ODS C-18(250×4.6 mm, packed with 5 micron) for the separation.

Selection of Mobile phase: Irbesartan and Telmisartan were injected to the column with different with different mobile phases of different ratios with different flow rates till sharp peaks, without any interference peaks containing spectra were obtained. Different mobile phases were containing one or the combinations of two or three of the following: Methanol, Distilled water and Glacial acetic acid (all reagents were of HPLC grade).

Chromatographic Conditions: A reverse phase C-18 column was equilibrated with the mobile phase. Mobile phase flow rate was maintained at 1ml/min and eluents were monitored at 246 nm. The samples were injected using 20 µl fixed loop. All determinations were performed at ambient temperature for a run time of 6 min.

Preparation of Mobile phase: Mobile phase was prepared by mixing 900 ml of methanol along with 100 ml of water to get the proportion of 90:10 v/v and finally the pH was adjusted to 3 with glacial acetic acid. The mobile phase was sonicated for 10 minutes and filtered through 0.45µ membrane filter.

Preparation of Irbesartan Stock Solution (1000 µg/ml): About 50 mg of Irbesartan was weighed accurately and was taken in a 50 ml volumetric flask. It was dissolved in the mobile phase.

Preparation of Irbesartan Working Stock Solution (100µg/ml): From the above prepared stock solution of Irbesartan 5 ml was pipette out in to a 50 ml volumetric flask and the volume was made to up to the mark with mobile phase.

Preparation of Telmisartan Stock Solution (1000 µg/ml): About 50 mg of Telmisartan was weighed accurately and was taken in a 50 ml volumetric flask. It was dissolved in the mobile phase.

Preparation of Telmisartan Working Stock Solution (100µg/ml): From the above prepared stock solution of Telmisartan 5 ml was pipette out in to a 50 ml volumetric flask and the volume was made to up to the mark with mobile phase.

Calibration Curve: From Irbesartan standard solution stock solution (100µg/ml), working solution 1 ml, 2 ml, 3ml….to 9 ml were taken in nine separate 10 ml volumetric flask and 1 ml of Telmisartan working solution (100µg/ml) was added to each volumetric flask to produce solutions of concentration range 10µg/ml to 90µg/ml of Irbesartan keeping the concentration of Telmisartan constant at 10 µg/ml. Then each prepared solution was filtered and sonicated.

Validation: Validation of the method was performed using parameters like Accuracy, Precision, Linearity and Range, Robustness, Ruggedness, LOD, LOQ, Specificity and System suitability.

Forced degradation studies: The specificity of the method can be demonstrated through force

degradation studies conducted on the sample using acid, alkaline, oxidative, thermal, photolytic and UV degradations. The sample was exposed to these conditions and the API peak was studied for the peak purity, which will indicate the method effectively separated from the degradation products.

Degradation in Neutral Condition: About 10 mg of pure drugs were accurately weighed and taken into three sets of three different 10 ml volumetric flasks and dissolved in minimum volume of methanol. Then the volumes were made up to the mark with water and refluxed in round bottom flasks for 1 hr, 2 hr and 6 hr. From these samples, different solutions were prepared and 20 µl of the sample solutions were injected into the HPLC system.

Degradation in Acidic Condition: About 10 mg of pure drugs were accurately weighed and taken into three sets of three different 10 ml volumetric flasks and dissolved in minimum volume of methanol. Then the volumes were made up to the mark with 0.1N, 0.5N and 01 N HCl and refluxed in round bottom flasks for 1 hr, 2 hr and 6 hr. From these samples, different solutions were prepared and 20 µl of the sample solutions were injected into the HPLC system.

Degradation in Basic Condition: About 10 mg of pure drugs were accurately weighed and taken into three sets of three different 10 ml volumetric flasks and dissolved in minimum volume of methanol. Then the volumes were made up to the mark with 0.1N, 0.5N and 01 N NaOH and refluxed in round bottom flasks for 1 hr, 2 hr and 6 hr. From these samples, different solutions were prepared and 20 µl of the sample solutions were injected into the HPLC system.

Oxidation Degradation: About 10 mg of pure drugs were accurately weighed and taken into three sets of three different 10 ml volumetric flasks and dissolved in minimum volume of methanol. Then the volumes were made up to the mark with 1 % w/v H_2O_2, 3 % H_2O_2 and 6 % w/v H_2O_2 and refluxed in round bottom flasks for 1 hr, 2 hr and 6 hr. From these samples, different solutions were prepared and 20 µl of the sample solutions were injected into the HPLC system.

Photolytic Degradation: About 100 mg of API was taken in a clean petridish and exposed to day light. Sampling was done at an interval 12 hr, 24 hr and 72 hr. From these samples, different solutions were prepared and 20 µl of the sample solutions were injected into the HPLC.

UV-Degradation: About 100 mg of API was taken in a clean petridish and subjected to UV illumination of 1.2×10^6 lux hours. Sampling 12 hr, 24 hr and 72 hr and from these samples, different solutions were injected into the HPLC system.

Thermal Degradation: About 100 mg of API was taken in three separate clean petridishes and subjected to dry heat at 70^0C. Sampling was done at intervals of 10 days, 20 days and 30 days. Solutions of the pure drug were prepared and 20 µl of the samples were injected into HPLC system.

RESULTS AND DISCUSSION: The objective of the present work was to develop and validate a stability indicating RP-HPLC method for the determination of Irbesartan in bulk and dosage forms. The method was found to be simple and the accuracy, precision, intra-day precision, inter-day precision, repeatability and assay was performed and the results was tabulated below. The retention time for Irbesartan was 2.3 min.

The method was validated for linearity, accuracy, precision, specificity, limit of detection, limit of quantification and robustness. Limit of detection and limit of quantification were found 6.51µg/ml and 1.973µg/ml respectively and recovery of Irbesartan from bulk and dosage forms was found 100.61%. With this study the degradation pattern were also studied and results are shown in the corresponding **Tables** and the **Figures** are also given.

RP-HPLC Analysis of Irbesartan Using Telmisartan as I.S: The various concentrations of Irbesartan (10-90µg/ml) along with Telmisartan (10µg/ml) used as internal standard were subjected for HPLC analysis and the resultant chromatogram as given below.

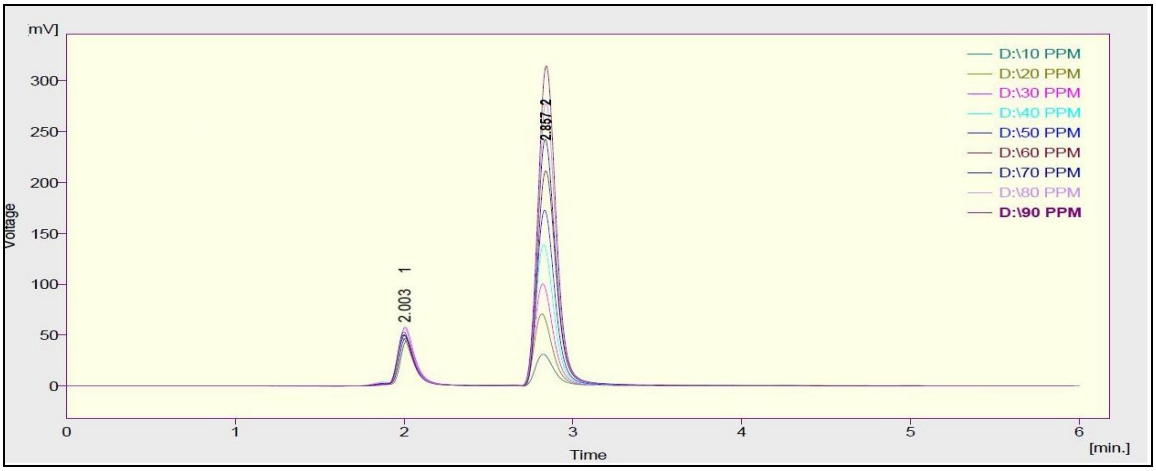

FIG. 2: OVERLAY CHROMATOGRAM OF IRBESARTAN USING TELMISARTAN AS I.S.

TABLE 1: CALIBRATION TABLE OF IRBESARTAN USING TELMISARTAN AS I.S.

Conc. (µg/ml)	Peak Area Ratio	Statistical Analysis
10	0.935	
20	1.753	
30	2.671	
40	3.504	
50	4.322	
60	5.139	Slope= 0.084
70	6.005	Intercept= 0.111
80	6.798	SD=0.007
90	7.675	% RSD=0.291

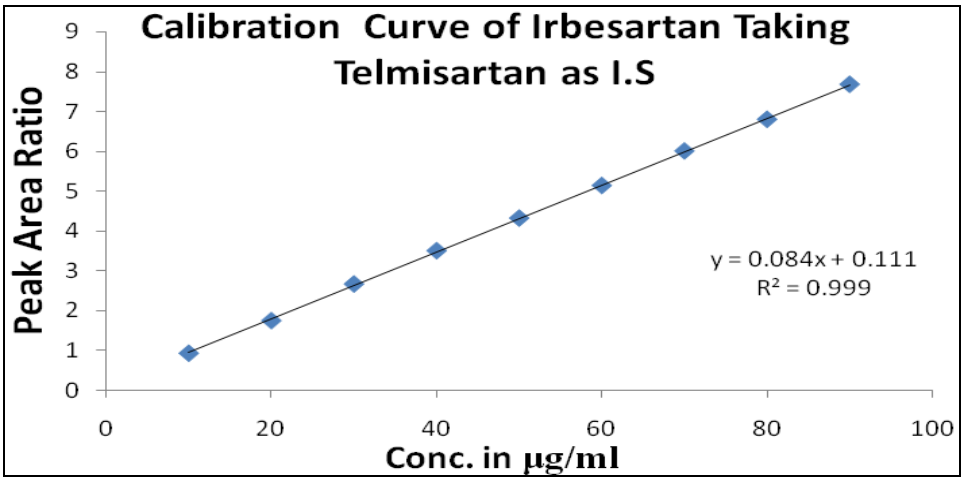

FIG. 3: CALIBRATION CURVE OF IRBESARTAN USING TELMISARTAN AS I.S

Validation Parameters:

Accuracy: The accuracy of the method was determined by calculating recoveries of drug by method of standard drug. Known amounts of standard drug corresponding to 80%, 100% and 120% of the label claim was added to pre quantified sample solution and the amounts of drug were estimated by measuring the peak areas and by fitting these values to the straight line equation of calibration curve.

Precision: The intraday and inter-day precision studies of the drugs were carried out by estimating the corresponding responses on the same day and consecutive three days respectively. The results were reported in terms of standard deviation and %RSD.

Ruggedness: Ruggedness is the degree of reproducibility of the results obtained under a variety of conditions, expressed as %RSD. These conditions include different laboratory conditions and different analysts.

TABLE 2: ACCURACY DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Samples	Concentration (µg/ml)		% Recovery	Statistical Analysis
	Amount present in Formulation	Amount of drug added		
S1: 80%	30	24	99.87	Mean=99.97
S2: 80%	30	24	99.98	SD=0.193
S3: 80%	30	24	100.07	% RSD=0.193
S4: 100%	30	30	99.99	Mean=99.98
S5: 100%	30	30	99.95	SD=0.416
S6: 100%	30	30	100.01	% RSD=0.415
S7: 120%	30	36	99.91	Mean=99.94
S8: 120%	30	36	99.88	SD=0.335
S9: 120%	30	36	100.03	% RSD=0.334

TABLE 3: PRECISION DATA SHOWING REPEATABILITY OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Sl. no.	Concentration (µg/ml)	Peak Area Ratio	Calc. Amt. (µg/ml)	Statistical Analysis
1	30	2.637	30.07	
2	30	2.643	30.14	Mean= 30.07
3	30	2.639	30.09	SD=0.115
4	30	2.633	30.02	% RSD=0.384
5	30	2.641	30.11	
6	30	2.634	30.03	

TABLE 4: INTRADAY PRECISION DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Sl. No.	Concentration (µg/ml)	Peak Area Ratio	Calc. Amt. (µg/ml)	Statistical Analysis
1	30	2.629	29.97	
2	30	2.628	29.96	Mean=29.98
3	30	2.633	30.02	SD=0.196
4	30	2.630	29.98	% RSD=0.655
5	30	2.635	30.04	
6	30	2.626	29.94	

TABLE 5: INTERDAY PRECISION DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Sl. No.	Concentration (µg/ml)	Day 1	Day 2	Day 3	Statistical Analysis
1	30	2.619	2.628	2.637	
2	30	2.627	2.631	2.645	
3	30	2.634	2.639	2.644	
4	30	2.630	2.643	2.645	
5	30	2.625	2.638	2.648	Mean=30.05
6	30	2.632	2.642	2.651	SD=0.168
Mean Peak Area Ratio		2.627	2.636	2.645	% RSD=0.560
Calc.Amt. (µg/ml)		29.95	30.05	30.16	

TABLE 6: RUGGEDNESS DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Analyst-1				Analyst-2			
Conc. (µg/ml)	Peak Area Ratio	Calc. Amt. (µg/ml)	Statistical Analysis	Conc. (µg/ml)	Peak Area Ratio	Calc. Amt. (µg/ml)	Statistical Analysis
30	2.651	30.23		30	2.655	30.28	
30	2.644	30.15	Mean=30.17	30	2.653	30.26	Mean=30.24
30	2.647	30.19	SD=0.143	30	2.649	30.21	SD=0.181
30	2.642	30.13	% RSD=	30	2.652	30.25	% RSD=
30	2.642	30.13	0.476	30	2.644	30.15	0.597
30	2.649	30.21		30	2.656	30.29	

TABLE 7: ROBUSTNESS DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

pH 2.8				pH 3.2			
Conc. (µg/ml)	**Peak Area Ratio**	**Calc. Amt. (µg/ml)**	**Statistical Analysis**	**Conc. (µg/ml)**	**Peak Area Ratio**	**Calc. Amt. (µg/ml)**	**Statistical Analysis**
30	2.661	30.35	Mean=30.33 SD=0.148 % RSD= 0.490	30	2.639	30.09	Mean=30.14 SD=0.136 % RSD=0.452
30	2.658	30.32		30	2.648	30.20	
30	2.660	30.34		30	2.636	30.05	
30	2.652	30.25		30	2.644	30.15	
30	2.665	30.40		30	2.643	30.14	
30	2.658	30.32		30	2.652	30.25	

TABLE 8: ROBUSTNESS DATA OF THE METHOD FOR IRBESARTAN USING TELMISARTAN AS I.S

Flow Rate 0.8				Flow Rate 1.2			
Conc. (µg/ml)	**Peak Area Ratio**	**Calc. Amt. (µg/ml)**	**Statistical Analysis**	**Conc. (µg/ml)**	**Peak Area Ratio**	**Calc. Amt. (µg/ml)**	**Statistical Analysis**
30	2.618	29.84	Mean= 29.87 SD=0.108 % RSD= 0.362	30	2.620	29.86	Mean=29.96 SD=0.171 % RSD=0.573
30	2.615	29.80		30	2.617	29.83	
30	2.624	29.91		30	2.629	29.97	
30	2.622	29.89		30	2.633	30.02	
30	2.619	29.85		30	2.634	30.03	
30	2.628	29.96		30	2.637	30.07	

Forced Degradation Studies of Irbesartan:

Hydrolytic Degradation of Irbesartan Condition in Neutral Condition: Samples were withdrawn according to protocol. From the drawn samples 100 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 11.89% degradation after 6 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

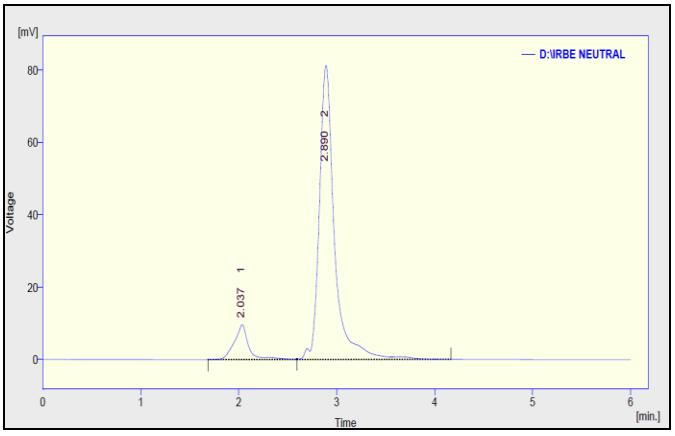

FIG 4: REPRESENTATIVE CHROMATOGRAM OF HYDROLYTIC DEGRADATION OF IRBESARTAN

Hydrolytic Degradation of Irbesartan in Acidic Condition: Samples were withdrawn according to protocol. From the drawn samples 100µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 25.86% degradation after 6 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

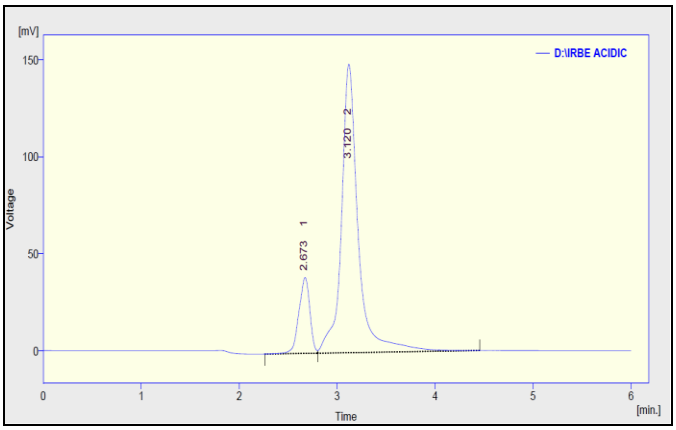

FIG. 5: REPRESENTATIVE CHROMATOGRAM OF ACIDIC DEGRADATION OF IRBESARTAN

Hydrolytic Degradation of Irbesartan in Basic Condition: Samples were withdrawn according to protocol. From the drawn samples 100 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 26.96% degradation after 6 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants.

The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

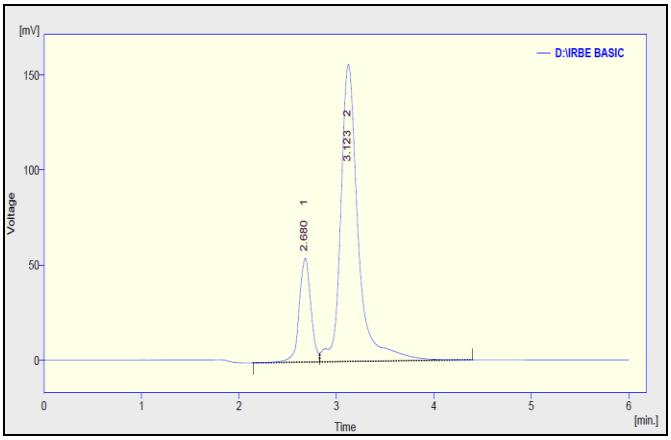

FIG. 6: REPRESENTATIVE CHROMATOGRAM OF BASIC DEGRADATION OF IRBESARTAN

Oxidative Degradation of Irbesartan: Samples were withdrawn according to protocol. From the drawn samples 60 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 17.89% degradation after 6 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

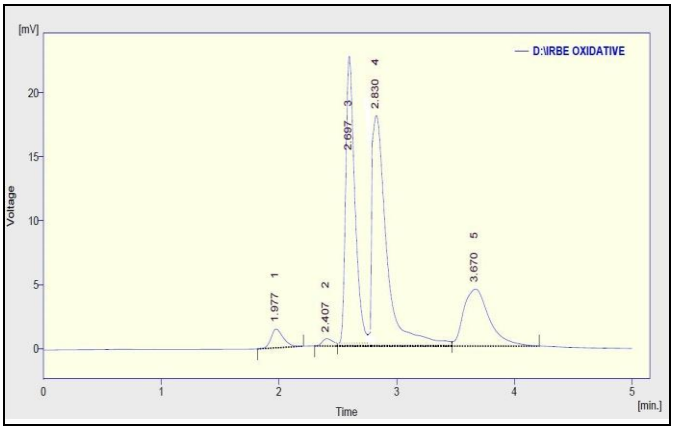

FIG 7: REPRESENTATIVE CHROMATOGRAM OF OXIDATIVE DEGRADATION OF IRBESARTAN

Photolytic Degradation of Irbesartan: Samples were withdrawn according to protocol. From the drawn samples 100 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 4.88% degradation after 72 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

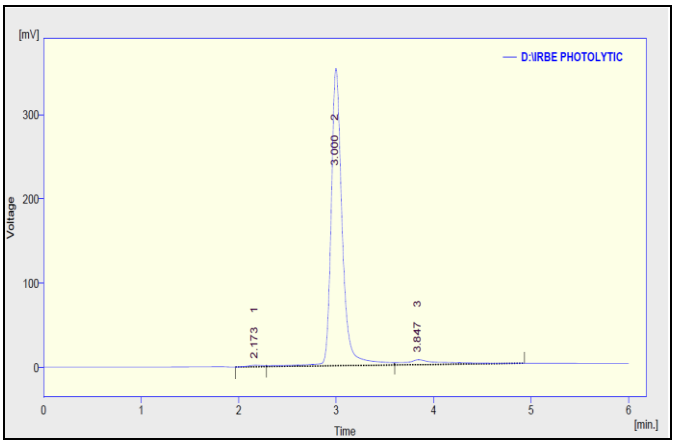

FIG. 8: REPRESENTATIVE CHROMATOGRAM OF PHOTOLYTIC DEGRADATION OF IRBESARTAN

UV- Degradation of Irbesartan: Samples were withdrawn according to protocol. From the drawn samples 100 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 5.77% degradation after 72 hr. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak width of the drug and degradants are given in tabulated form below.

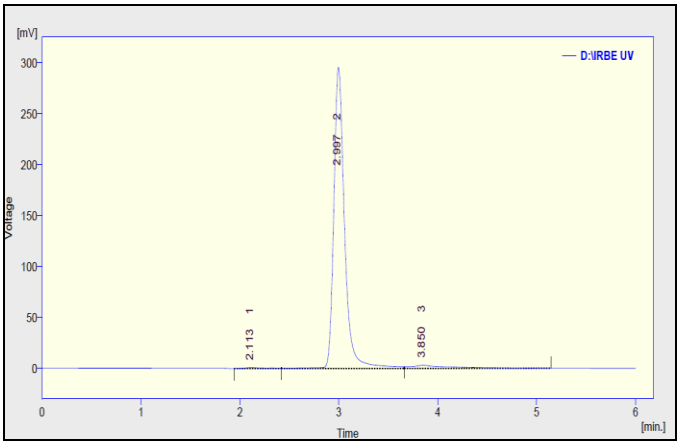

FIG. 9: REPRESENTATIVE CHROMATOGRAM UV-DEGRADATION OF IRBESARTAN

Thermal Degradation of Irbesartan: Samples were withdrawn according to protocol. From the drawn samples 100 µg/ml solution were prepared and subjected for analysis. The representative chromatogram indicates 15.86% degradation after 1 month. The chromatogram also reveals that the drug can be analysed in the presence of degradants. The retention time, peak area, peak height, peak

width of the drug and degradants are given in tabulated form below.

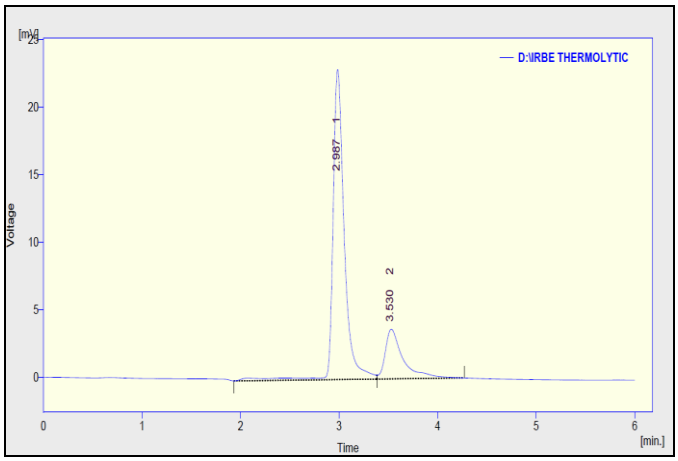

FIG. 10: REPRESENTATIVE CHROMATOGRAM THERMAL DEGRADATION OF IRBESARTAN

TABLE 9: OVERALL SUMMARY OF DEGRADATION STUDY

Stress Condition	Stressing Agents	Time	Degradation
Neutral	Water	6 Hours	11.89%
Acidic	0.1 N	6 Hours	Stable
	0.5 N	6 Hours	Stable
	1 N	6 Hours	25.86%
Basic	0.1 N	6 Hours	Stable
	0.5 N	6 Hours	Stable
	1 N	6 Hours	26.96%
Oxidation	1% H_2O_2	6 Hours	Stable
	2% H_2O_2	6 Hours	Stable
	3% H_2O_2	6 Hours	17.89%
Light	Sun Light	12 Hours	Stable
		24 Hours	Stable
		72 Hours	4.88%
Thermal	70°C Heat	10 Days	Stable
		20 Days	Stable
		30 Days	15.86%
UV Radiation	1.2×10^6 Lux Hours (UV Illumination At 256 Nm)	12 Hours	Stable
		24 Hours	Stable
		72 Hours	5.77%

CONCLUSION: The developed RP-HPLC stability indicating assay method was found suitable for the analysis of drug in their pure form in presence of their respective degradants since the resolution between the drug with their corresponding degradants was better. The drug was prone to degrade more in acidic, alkaline, oxidative and thermal conditions. The method was found to be fast, simple, reliable, sensitive, economical, accurate and precise. The sensitivity and accuracy of the method were also ascertained by using internal standards. The results of stability studies of Irbesartan suggest that the drug is stable to photolytic and UV radiation degradations. Therefore, the proposed method can be used for routine analysis of estimation of Irbesartan in its bulk and dosage formulations.

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