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STABILITY-INDICATING RP-UHPLC METHOD FOR DETERMINATION OF TELMISARTAN IN DRUG SUBSTANCE AND MARKETED FORMULATION

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Key words:

Telmisartan, RP-Ultra High Performance Liquid Chromatography Degradation, Method validation

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ABSTRACT: A simple, rapid and precise stability-indicating ultra high performance liquid chromatography (UHPLC) has been developed and validated for the estimation of telmisartan in drug substance and pharmaceutical dosage form. The chromatographic separation was achieved with a Poroshell 120EC-C18 column (4.6 x 50mm, 2.7µm) by using mobile phase acetonitrile: 50mM ammonium acetate buffer in the ratio of (45: 55 v/v), pH adjusted to 4.5 with acetic acid. The instrumental settings were flow rate of 0.5ml min⁻¹, column temperature at 25 0C and detector wavelength of 290 nm using a photodiode array detector. Telmisartan was exposed to thermolytic, photolytic, acid, base, hydrolytic and oxidative stress conditions and the stressed samples were analyzed by the proposed method. The developed method shows excellent linearity over a range of 100-300 µg ml⁻¹ for telmisartan. The recovery of telmisartan was above 96%. The proposed method was found to be suitable and accurate for quantitative determination and stability study of telmisartan pharmaceutical preparations.

INTRODUCTION: Telmisartan, chemically described as 2-(4-{[4-methyl-6-(1-methyl-1H-1, 3-benzimidazol - 2 - yl) - 2-propyl-1H-1, 3-benzimidazole-1-yl] methyl} phenyl) benzoic acid. Molecular formula C₃₃ H₃₀ N₄ O₂ Molecular weight 514.62¹. Telmisartan is an angiotensin II receptor antagonist which helps to lower blood pressure by blocking rennin-angiotensin-aldosterone system. Telmisartan is orally active and due to their specificity of action provide good conditions for patient compliance as well as high effectiveness². It is available as tablets for oral administration containing 40 mg of telmisartan.

Literature survey revealed that several RP-HPLC methods³⁻¹⁸, HPTLC method¹⁹⁻²³, UV spectroscopy method²⁴⁻²⁵ and several bioanalytical methods²⁶⁻³⁰, were reported for estimation of telmisartan. The objective of this work is to develop a simple accurate stability indicating isocratic reverse phase UHPLC method for estimation of telmisartan in drug substance and tablet dosage form.

MATERIAL AND METHODS:

Telmisartan standard drug was obtained as a gift sample from Micro lab, Bengaluru, India, ammonium acetate from Merck, India, acetic acid from Spectrochem, sodium dihydrogen orthophosphate dehydrate from Fisher Scientific, hydrochloric acid, sodium hydroxide, hydrogen peroxide, (AR grade) from Sd fine-chem. limited, acetonitrile (HPLC grade) was obtained from Spectrochem and methanol (HPLC grade) was obtained from Finar, India. Mill Q HPLC water was used for all purposes. Telmisartan tablet label

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claim 40 mg from Telvas tablet (40mg) Aristo Pharmaceuticals Pvt. Ltd. India was purchased from the market.

Instrumentation and chromatographic conditions:

UHPLC system (Agilent 1260 UHPLC System) consists of 1260 quaternary pump, standard auto sampler, poroshell 120EC-C₁₈ column (4.6 x 50mm, 2.7µm), Diode array detector with chemstation Software, Shimadzu AUX220 Weighing Balance, Elico India LI 127 pH meter and Grant Sub-aqua 12 Water bath were used in the analysis. Mobile phase was a mixture of acetonitrile and buffer in the ratio of (45: 55 v/v). The buffer used in the mobile phase contains 50mM ammonium acetate in Mill Q water and pH was adjusted to 6 with acetic acid filtered through a 0.45µm nylon filter and degassed in an ultrasonic bath prior to use. The flow rate was kept at 0.5ml/minute and Column temperature was maintained at 25⁰ C, the injection volume was 10µl and the detection was monitored at a wavelength of 290nm.

Preparation of Standard stock solutions:

Standard Solution was prepared by dissolving the drug in methanol and diluting it to the desired concentration.

Telmisartan:

A 25mg of standard telmisartan (99.26%) was accurately weighed, transferred in to 25ml volumetric flask and dissolved with methanol (1000 µg/ml).

Standard solution:

A standard solution was prepared by pipetting out 2 ml of telmisartan from stock solution (1000 µg/ml), transferred to 10ml volumetric flask and the volume was made up to 10ml by using methanol. This solution contained 200µg/ml of telmisartan.

Calibration curve solution:

The calibration curve solutions of concentration contain 100 to 300 µg ml⁻¹ for telmisartan.

Preparation of Sample solution:

20 tablets of telmisartan (40 mg) were weighed accurately. A quantity of the powder equivalent to one tablet containing 40 mg of telmisartan was transferred in to a 100 volumetric flask. To this flask, 50 ml of methanol was added and solution was sonicated for 30 minutes. The solution was cooled to ambient temperature. Then the volume was made up with methanol, filtered through whatman filter paper. Pipetting out 5 ml from the above prepared solution (400 µg/ml), transferred to 10ml volumetric flask and the volume was made up to 10ml by using methanol. This solution contained 200 µg/ml of telmisartan. Prior injecting the solution in chromatographic system, it was filtered through 0.45 µm HPLC syringe filter. Sample analysis was performed for three replicates at 290nm.

Procedure for forced degradation studies of Drug substance:

Forced degradation of drug substance and drug product was carried out under thermolytic, photolytic, acid, base hydrolytic water hydrolysis and oxidative stress conditions.

Acid degradation:

Pipetting out 2 ml of telmisartan standard solution from the stock solution (1000 µg ml⁻¹) and transferring the solution in to a 10ml volumetric flask add 2ml of 1N HCl and diluted up to 10ml with methanol. The solution was kept at 60⁰C for 4 hours. The solution was allowed to attend ambient temperature. Repeated the same with 0.1N HCl.

Alkali degradation:

Pipetting out 2 ml of telmisartan standard solution from the stock solution (1000 µg ml⁻¹) and transferring the solution in to a 10ml volumetric flask add 2ml of 1N NaOH and diluted up to 10ml with methanol. The solution was kept at 60⁰C for 4 hours. The solution was allowed to attend ambient temperature. Repeated the same with 0.1N NaOH.

Degradation under neutral hydrolytic condition:

Pipetting out 2 ml of telmisartan standard solution from the stock solution (1000 µg ml⁻¹) and transferring the solution in to a 10ml volumetric flask, add 2ml of distilled water and diluted up to 10ml with methanol. The solution was kept at 60⁰C for 8 hours.

Degradation under oxidative condition:

Pipetting out 2 ml of telmisartan standard solution from the stock solution ($1000 \mu\text{g ml}^{-1}$) and transferring the solution in to a 10ml volumetric flask, add 2ml of 30% v/v H_2O_2 and diluted up to 10ml with methanol. The solution was kept at 60°C for 1 hour.

Degradation under dry Heat:

Dry heat study was performed by keeping drug sample in an oven at 80°C for 24 hours. Samples were withdrawn, allowed to attend ambient temperature and dissolved in methanol to prepare sample solution to get concentrations of 1000 mcg/ml. Pipetting out 2 ml of telmisartan sample solution and transferring the solution in to a 10ml volumetric flask and diluted up to 10ml with methanol.

Sunlight degradation studies:

Sunlight study was performed by exposing the drug sample directly to sunlight for 8 hours. Samples were withdrawn, dissolved in methanol to prepare sample solution to get concentrations of 1000 mcg/ml. Pipetting out 2 ml of telmisartan sample solution and transferring the solution in to a 10ml volumetric flask and diluted up to 10ml with methanol.

Photo degradation studies:

Photolytic studies were carried out by exposing the drugs to UV short 254nm and UV long light 366nm for 24 hours. Samples were withdrawn, dissolved in methanol to prepare sample solutions to get concentrations of 1000 mcg/ml. Pipetting out 2 ml of telmisartan sample solution and transferring these solutions in to a 10ml volumetric flask and diluted up to 10ml with methanol.

Procedure for forced degradation studies of Drug products:

A forced degradation study of drug products in acidic, basic, water hydrolysis, oxidative conditions was carried out using filtered solution (as described in sample preparation) to achieve $200\mu\text{g/ml}$ of telmisartan. For thermolytic and photolytic degradation, a quantity of powder equivalent to one tablet containing 40 mg of telmisartan was

exposed. Then the solutions were prepared as described in preparation of sample.

RESULTS:**Optimization of the Chromatographic Conditions:**

UHPLC procedure was optimized with a view to develop a stability-indicating method. Depending on the nature of the sample (ionic or neutral molecule), its molecular weight and solubility; chromatographic method is to be selected. Our drug is polar in nature and so reverse phase chromatographic technique was selected for the present study. To develop stability indicating method different stationary phases like C_{18} C_8 , different mobile phases containing buffers like ammonium acetate, phosphate etc were used. The main objective of the chromatographic method development was to achieve a peak tailing factor less than 2, retention time in between 1 to 5 minutes due to short column length. The chromatographic separation was achieved using poroshell 120EC- C_{18} column ($4.6 \times 50\text{mm}$, $2.7\mu\text{m}$) by changing the composition of mobile phase, wavelength, chromatographic method was optimized.

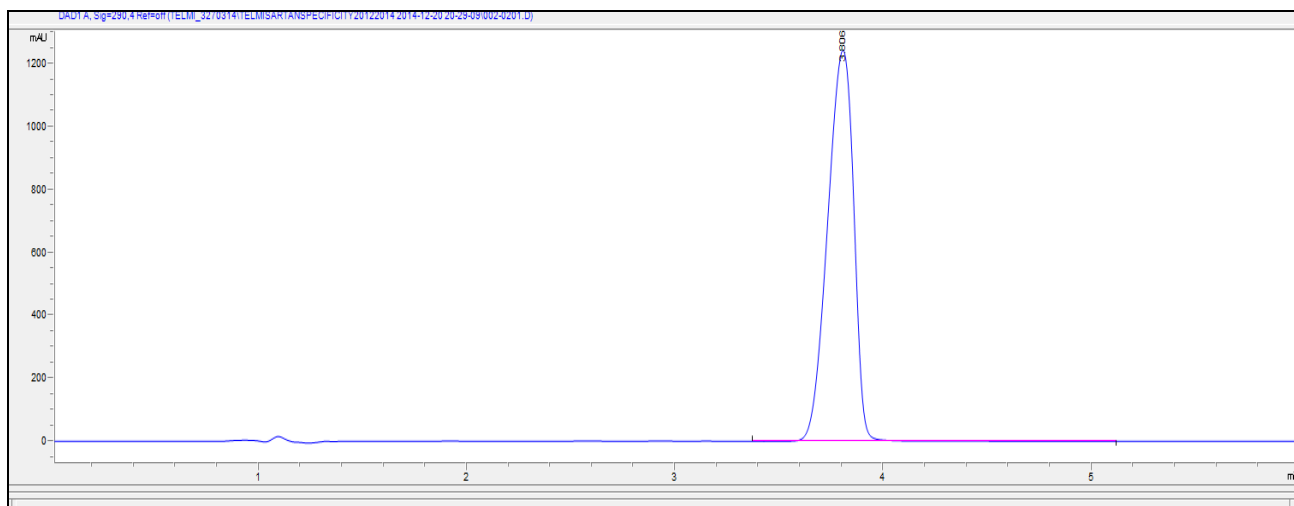
During development studies, mobile phase containing 50mM ammonium acetate in water, pH adjusted to 4.5 with acetic acid and acetonitrile in the ratio of 55:45 (v/v) with flow rate of 0.5 ml min^{-1} and a column temperature of 25°C was selected. In these selected optimized conditions, the drug telmisartan (in **Fig. 1** and **2**) had adequate retention, peak shape with less tailing and the chromatographic analysis was less than 5 minutes, which also separates the degradants from telmisartan.

Degradation observed:

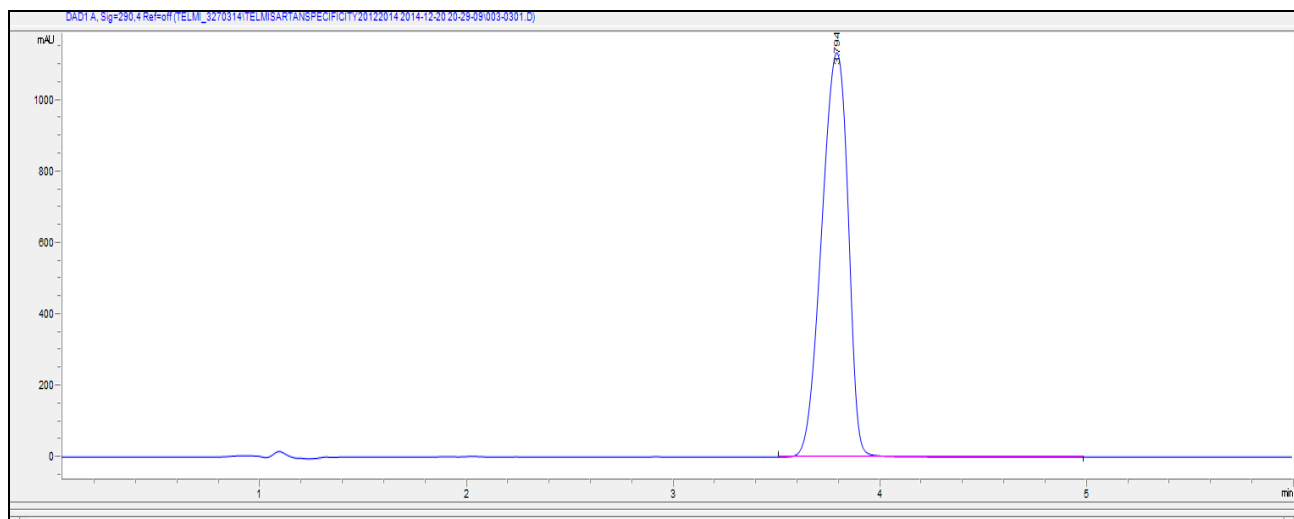
Blessy and Ruchi³¹, in their article on stress testing suggested a target degradation of 5-20% has been accepted as reasonable for validation of chromatography assay. Similarly Singh and Bakshi³², in their article on stress testing suggested a target degradation of 20-80% for establishing stability-indicating studies, and also intermediate degradation products should not interfere with any stage of drug analysis. Though conditions used for forced degradation were attenuated to achieve

degradation in the range of 5-80% but this could not achieve in case of water hydrolysis, thermal and photolytic degradation even exposure for prolonged duration. Extensive degradation of telmisartan was observed on acidic, alkali

hydrolysis and oxidative condition (in **Fig. 3a to 3c**). **Table 1** showed the extent of degradation of telmisartan under various stress condition.



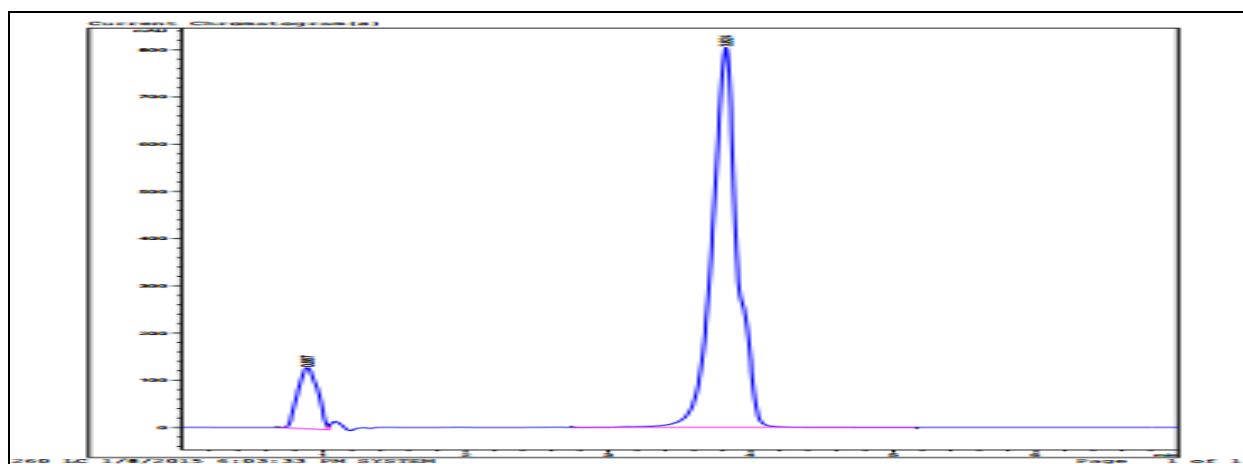
CHROMATOGRAM OF TELMISARTAN STANDARD (RT: 3.909 MIN)



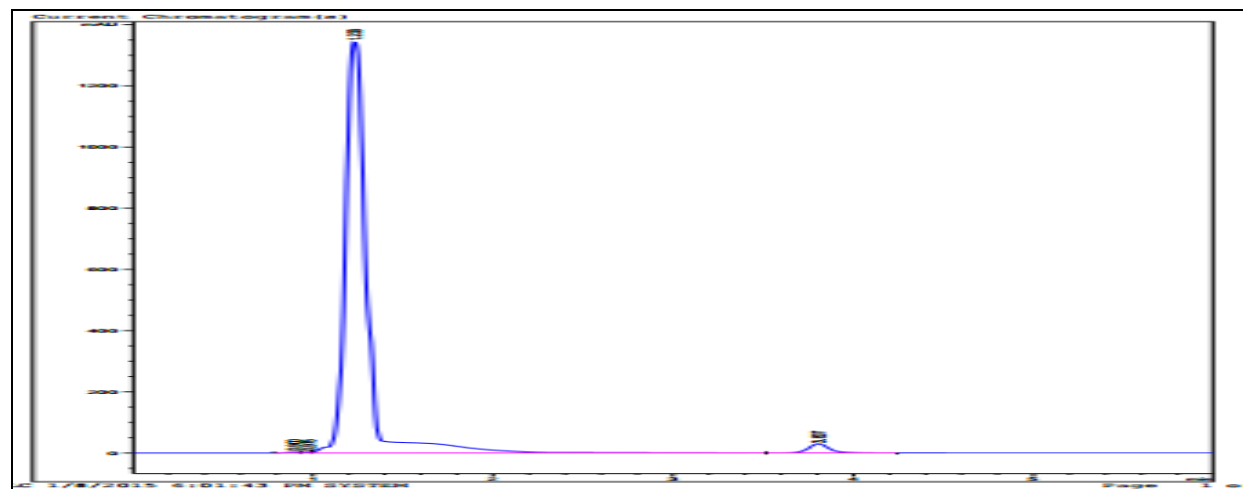
CHROMATOGRAM OF TELMISARTAN IN TELVAS TABLET (RT: 3.909 MIN)

RESULTS OF ANALYSIS OF FORCED DEGRADATION STUDY SAMPLES

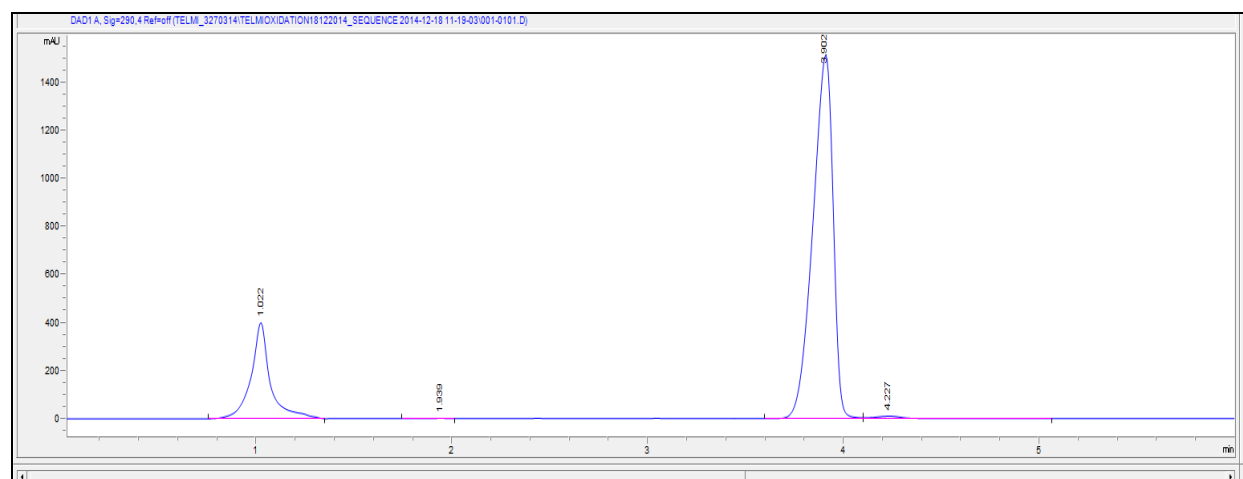
Conditions(Stress induced)	Peak Purity (P)	% Telmisartan degradation
Acidic	999.857	1.6 (0.1N HCl) 12.6 (1N HCl)
Alkali	999.456	11.8 (0.1N NaOH) 71.9 (1N NaOH))
Water	999.984	No degradation
Oxidative	999.676	26.4
Thermal	999.915	0.7
UV light (254 nm for 24 hours)	999.903	0.5
UV light (326nm for 24 hours)	999.915	0.7
Sun light for 8 hours	999.967	No degradation



1N HCL Time in(minutes)



1N NaOH Time in(minutes)



Oxidation Time in(minutes)

Chromatograms of forced degradation of acid & alkali hydrolysis, oxidative degradation for telmisartan.

Method Validation:

The method was validated according to the ICH guideline³³. The following validation parameters were considered for the newly developed method

such as system suitability, linearity, precision/reproducibility, accuracy, specificity, robustness, stability of analytical solution.

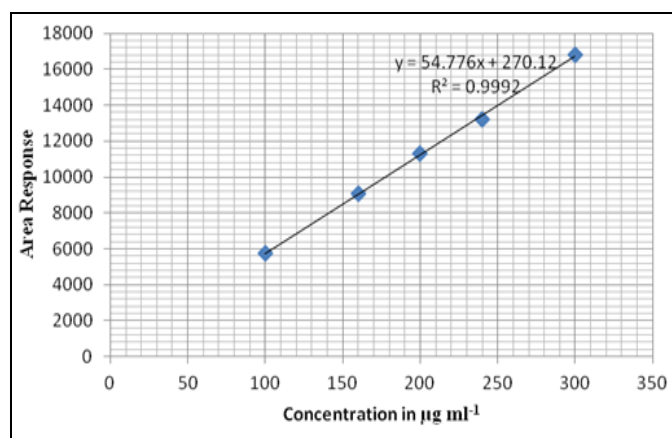
System suitability:

The system suitability of the method was tested by Injected blank (1 injection), standard preparation

200 $\mu\text{g ml}^{-1}$ (5 injection) and then system suitability parameters like theoretical plates, tailing factor, % RSD were studied and found that all the system suitability parameters are within acceptance criteria.

Calibration & Linearity:

Linearity of the method was tested by preparing five standard solutions from 50% to 150% of telmisartan and injected in triplicate. The standard solutions contain the concentration range from 100 to 300 $\mu\text{g ml}^{-1}$ of telmisartan. The calibration graph was obtained by plotting peak area against the concentration of the drug (Fig.4). The equation of the calibration curve for telmisartan obtained was $y = 54.776x + 270.12$. The calibration graph was found to be linear with regression coefficient and correlation coefficients were found to be 0.9992 and 0.9996.



LINEARITY RANGE OF TELMISARTAN

Precision (Repeatability):

The precision of the analytical method is determined by using telmisartan standard preparation to ensure that the analytical system is working properly. The retention time and area of six determinations of standard solution of concentration 200 $\mu\text{g ml}^{-1}$ was measured and % RSD was calculated. Similarly intermediate precision of the method was determined by analyzing the telmisartan standard solution of concentration 200 $\mu\text{g ml}^{-1}$ for six times on different days, by different analysts. The precision of analytical method was usually expressed as standard deviation or relative standard deviation of series of measurements. The results of the precision study indicate that the method is precise. (RSD % <2)

Accuracy (Recovery Test):

Accuracy of the method was studied by recovery experiments. The accuracy of an analytical method was performed in three different levels, with each level in triplicate for telmisartan standard drug (nine determinations). Spiked known quantity of telmisartan standard drugs at 50%, 100% and 150% levels in to the telmisartan tablet sample solutions containing 40 $\mu\text{g ml}^{-1}$ of telmisartan. The prepared solutions were then analyzed and percentage recoveries were calculated. The recovery value of telmisartan ranges from 99.4 to 100.4 %. The average recovery of three levels (9 determinations) for telmisartan was 99.7%.

Specificity:

Photodiode array detection was used as an evidence of the specificity of the method and to evaluate the homogeneity of the drug peak. The peak purity values are more than 997 for drug substance as well as drug product at 290 nm which shows that the peaks of analyte were pure and also the formulation excipients and degradants were not interfering with the analyte peaks.

Robustness:

The robustness of an analytical method was measure of its capacity to remain unaffected by small but deliberate variations in method parameters. To determine robustness of the method, experimental conditions were purposely altered chromatogram of telmisartan was studied. The flow rate of the mobile phase was 0.5ml/minute; it was changes to ± 0.2 units from 0.5 to 0.3 ml/minute and 0.7 ml/minute. The column temperature was 25 $^{\circ}\text{C}$, changes to $\pm 5^{\circ}\text{C}$ from 25 $^{\circ}\text{C}$ to 20 $^{\circ}\text{C}$ and 30 $^{\circ}\text{C}$ while the other mobile phase components were held constant. Similarly change in mobile phase composition was studied at buffer: acetonitrile (57:43v/v) and 53:47 (v/v). At all conditions area % RSD was within acceptance criteria. Hence it is concluded that the method is robust.

Stability of analytical solution:

Stability of standard and sample solutions of telmisartan was evaluated injecting sample and standard at regular intervals up to 48 hours and calculated the area % difference. The area % difference value indicate that the solutions were stable for 48 hours at ambient temperature as there

is no formation of unknown peaks and solution remained stable.

TABLE 2: RESULTS OF METHOD VALIDATION FOR TELMISARTAN

Validation parameters		Observed Value	Acceptance criteria
System Suitability	Tailing factor	0.86%	RSD NMT 2.0%
	Theoretical Plate count	8305	RSD NLT 2000
	The % RSD for the areas of 5 replicate injections of telmisartan peak	0.1%	RSD NMT 2.0%
Linearity	Regression coefficient	0.9992	RSD NLT 0.998
	Correlation coefficient	0.9996	RSD NLT 0.998
	slope	54.776	----
	Intercept	270.12	-----
Precision	System precision	0.04%	RSD NMT 2.0%
	Method precision	0.05%	RSD NMT 2.0%
	Intermediate precision	0.06%	RSD NMT 2.0%
Accuracy	50%, 100% and 150% Level	99.7 %	Mean Recovery 95% and 105%.
Specificity	Peak purity	999.948	More than 997
Robustness	Change in column temperature $\pm 5^{\circ}$ C	0.06% (20 ⁰ C), 0.1% (30 ⁰ C)	RSD NMT 2.0%
	Change in flow rate ± 0.2 mL/min	0.93 (-0.2) 0.3(+0.2)	RSD NMT 2.0%
	Change in organic phase ratio $\pm 2\%$	0.34 (-2 %) 0.5 (+2 %)	RSD NMT 2.0%
Solution stability	Area % difference for telmisartan standard solution	0.1%	NMT 2.0%
	Area % difference for telmisartan sample solution	0.2%	

DISCUSSION: Telmisartan drug substance and drug product when it is treated with acid, alkali, neutral, hydrogen peroxide, dry heat, sunlight and UV light, showed well separated peak of pure telmisartan as well as some additional degradants. The peaks of the degraded products were well resolved from the telmisartan drug peak. The chromatogram of the 1 N acid degraded sample for telmisartan showed 01 additional peak of retention time 0.887 minute. The chromatogram of the 1 N NaOH degraded sample for telmisartan showed 01 additional peak of retention time 1.233 minutes. The chromatogram of the oxidation degraded sample for telmisartan showed 2 additional peaks of retention time 1.022 and 4.227 respectively. No additional peaks were developed in water, dry heat & UV light and sunlight degradation studies. Major degradation of telmisartan was observed under acidic, alkali, oxidation. No degradation was observed under hydrolytic, thermal and photolytic conditions.

The response for the drug was found to be linear in the concentration range 100-300 $\mu\text{g ml}^{-1}$ for telmisartan with respect to the peak area. The % RSD value for repeatability of standard application

for precision study was found to be less than 2% for telmisartan, this conform that the method is precision. The accuracy of the method was determined and the mean recovery of telmisartan was 99.7%. The specificity of the method was ascertained by peak purity profiling studies and the developed method was specific. The low values of % R.S.D obtained after introducing small deliberate changes in the developed UHPLC method indicated the robustness of the method.

CONCLUSION: The developed isocratic RP-UHPLC method for the analysis of telmisartan is precise, accurate and with a short run time for the estimation of telmisartan in bulk and pharmaceutical formulation. The method was fully validated, that shows satisfactory data for the validation parameters according to ICH guideline. As the developed method separates the drug from its degradation products, it can be employed as a stability indicating one. Hence this method can be used in quality control laboratories, research institutions for the analysis of telmisartan.

CONFLICT OF INTEREST STATEMENT: We declare that we have no conflict of interest.

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