"ANALYTICAL METHOD VALIDATION OF ASSAY OF TELMISARTAN IN TELMISARTAN TABLETS BY UV-SPECTROPHOTOMETER"

RESEARCH PROJECT SUBMITTED TO

SAVITRIBAI PHULE PUNE UNIVERSITY, PUNE

FOR THE DEGREE OF

MASTER OF SCIENCE

IN

ORGANIC CHEMISTRY

UNDER THE FACULTY OF SCIENCE

BY

Miss. Khandode Aarti Sunil

UNDER THE GUIDANCE OF

Miss. A. M. Rayate

DEPARTMENT OF CHEMISTRY

G.M.D. ARTS, B.W. COMMERCE AND SCIENCE COLLEGE, SINNAR 422103

MAR/APR 2024-2025

Maratha Vidya Prasarak Samaj's

G.M.D. ARTS, B.W. COMMERCE AND SCIENCE COLLEGE,
SINNAR, DIST- NASHIK

DEPARTMENT OF CHEMISTRY

This is to certify that the work incorporated in the project entitled

Topic name: "Analytical Method Validation of Assay of Telmisartan in Telmisartan Tablets By UV-Spectrophotometer"

Was satisfactorily carried out by **Miss. Khandode Aarti Sunil** of **M.Sc. Organic Chemistry**. He has completed this project under my supervision and guidance during **Academic Year 2024 -2025**. This project work submitted by his original and the scientific information obtain from other sources have been acknowledged.

Miss. A. M. Rayate

(Project Guide)

Maratha Vidya Prasarak Samaj's

G.M.D. ARTS, B.W. COMMERCE AND SCIENCE COLLEGE, SINNAR, DIST- NASHIK

DEPARTMENT OF CHEMISTRY

CERTIFICATE

This is to certify that PG dissertation entitled synthesis **"Analytical Method Validation of Telmisartan in Telmisartan Tablets by UV Spectrophotometer"**. submitted by **Miss. Khandode Aarti Sunil** and it was carried out by the candidate under the supervision of **Miss. A. M. Rayate** He has successfully completed the project work in Organic Chemistry **(CHO681)** during the Sem-IV of academic year 2024-2025.

Date:

Place: Sinnar

Miss. A. M. Rayate	**Prof.(Dr).M.R.Gaware**	**Dr.N.U.Patil**
(Project Guide)	**(HOD)**	**(Principal)**

Internal Examiner	**External Examiner**	**External Examiner**

DECLARATION

I hereby declare that the presented Research Project on **"Analytical Method Validation of Assay of Telmisartan in Telmisartan Tablets by UV Spectrophotometer**". at (Arni Analytical Training center Nashik) under the guidance of Miss. A. M. Rayate.

Place: Sinnar Sign- _____

Date: Name - Khandode Aarti Sunil

ACKNOWLEDEMENT

- I would like to thank M.V.P. Samaj's G.M.D. Arts B.W. Commerce and Science College Sinnar for providing me the necessary resources, infrastructural, and facilities to carry out this project.

- I would like to thank our College Principal Prof.Dr.N.U.Patil sir for constant support and providing infrastructural facility for this project work.

- I would like to thank, HOD Prof. Dr.M.R. Gaware for his constructive help during project.

- I would like to thank. Miss. A. M. Rayate (Project Guide), for their constant Encouragement, insightful constant Encouragement guidance that helped me to navigate through the various challenges of this project.
- I would like to thank all the faculty members of the Department of Chemistry, for Imparting me with the theoretical and practical knowledge necessary to complete this project
- I would like to thank my classmate, for their feedback suggestion and stimulating discussions that enriched my understanding of the subject matter.

Sign-

Name- Khandode Aarti Sunil

ANALYTICAL METHOD VALIDATION OF ASSAY

OF

TELMISARTAN

IN

TELMISARTAN TABLETS

BY

UV-SPECTROPHOTOMETER

TABLE OF CONTENTS

1. PURPOSE:

Perform the analysis of the marketed formulation by pharmacopoeia method using the instruments like HPLC, UV-Spectrophotometer, Analytical Balance, pH-Meter & Sonicator.

2. SCOPE:

The detailed study report and general information about the Project molecule is documented. Instrumentation method is used for determination of the content of Assay, Drug Release from the formulation & determination of the λmax for Telmisartan in Telmisartan Tablet 40mg. The methods used from the pharmacopoeia and the results are based on approved protocol with predetermined acceptance criteria.

3. REQUIREMENTS :

Following is the list of Reagents/Standards/Equipments required during project analysis.

LIST OF REAGENTS AND STANDARDS

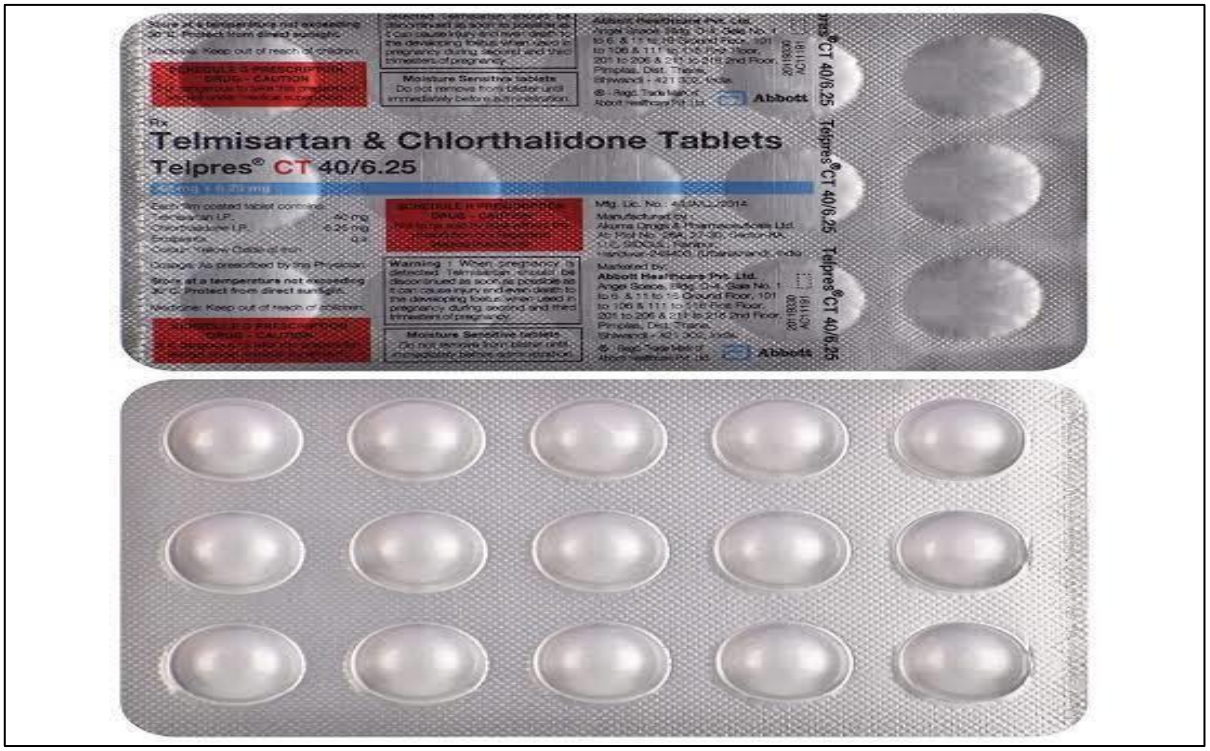
SR.NO.	REAGENTS & STANDARDS	GRADE	MAKE
1	Telmisartan Tablet	IHS	
2.	Potassium diHydrogen Phosphate	AR	
3.	Water	HPLC	
4.	Acetonitrile	HPLC	

4. LIST OF INSTRUMENTS / EQUIPMENTS :

Sr.No.	Instruments / Equipments
1.	UV-Spectrophotometer
2.	Sonicator
5.	Analytical Balance

5. BATCH NO. USED FOR ANALYSIS:

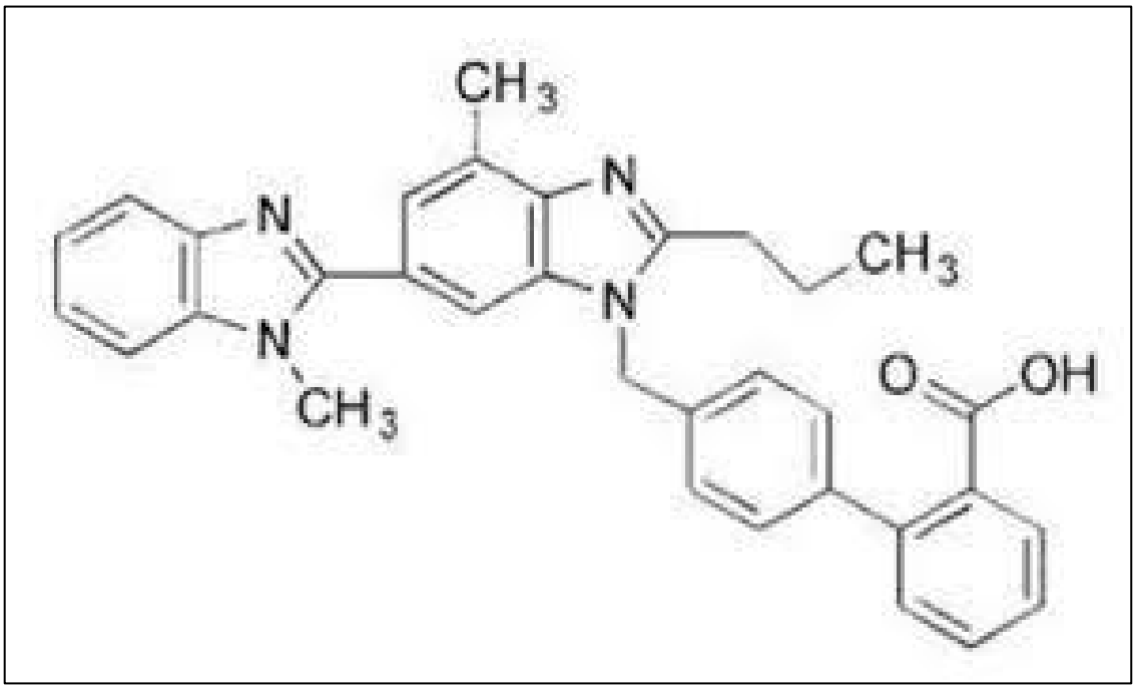
GENERIC NAME OF PRODUCT	**:**	**TELMISARTAN TABLET 40MG**
BRAND NAME	**:**	**TELMIKIND-40**
NAME OF MANUFACTURER	**:**	**MANKIND PHARMA LTD.**
MFG. DATE	**:**	**04/2024**
EXP. DATE	**:**	**03/2026**


Telmisartan & Chlorthalidone Tablets
Telpres® CT 40/6.25
Abbott


Telmisartan Tablets I.P. 40 mg
Telma® 40
टेल्मा ४०
5 STRIPS OF 30 TABLETS EACH
Glenmark

TELMISARTAN TABLET:

CHEMICAL STRUCTURE :



MOLECULAR FORMULA :- $C_{33}H_{30}N_4O_2$

MOLECULAR WEIGHT :- 514.6 g/mol

CHEMICAL NAME :- 2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1-yl]methyl]phenyl]benzoic acid

SIDE PRODUCTS (IMPURITIES):

1.

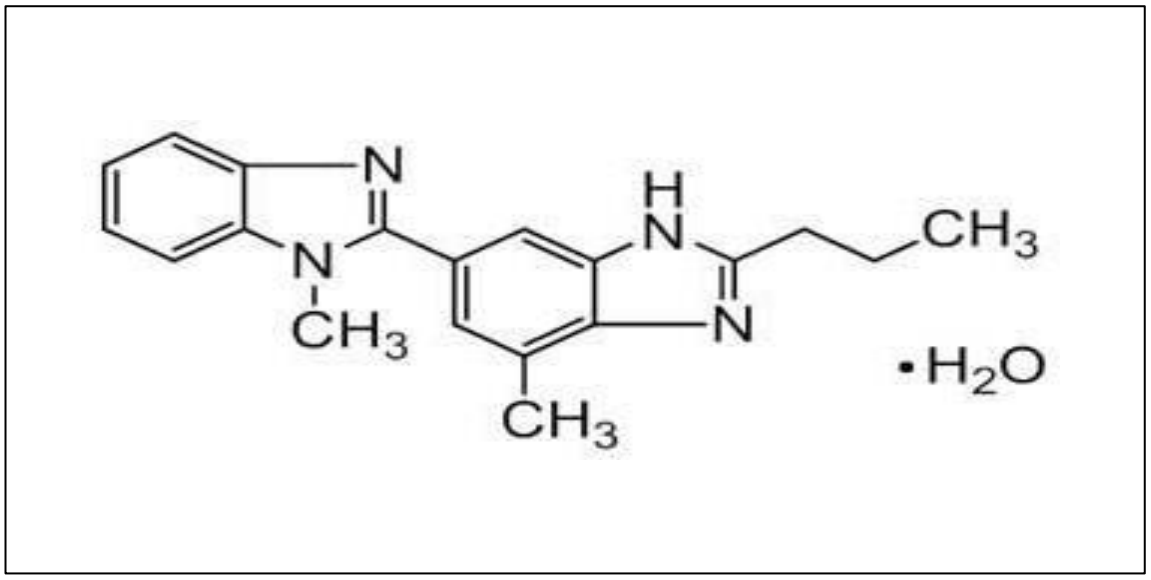
Chemical name: - 4-Methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2-propyl-1H-benzimidazole Hydrate

CAS Number**:-** 1282554-35-1

Molecular form:- $C_{19}H_{22}N_4O$

Appearance:- NA

Mol. Weight:- 322.40 g/mol



2.

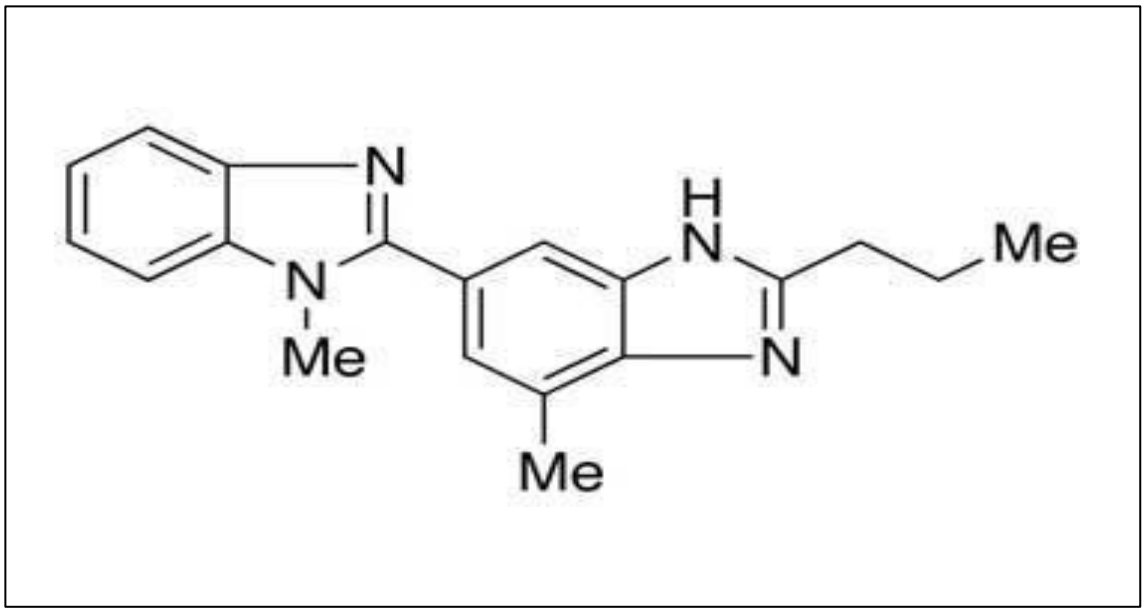
Chemical name: - 4-Methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2-propyl-1H-benzimidazole

CAS Number:- 152628-02-9

Molecular form:- $C_{19}H_{20}N_4$

Appearance:- Off-White to Pale Yellow Solid

Mol. Weight:- 304.39 g/mol



3.

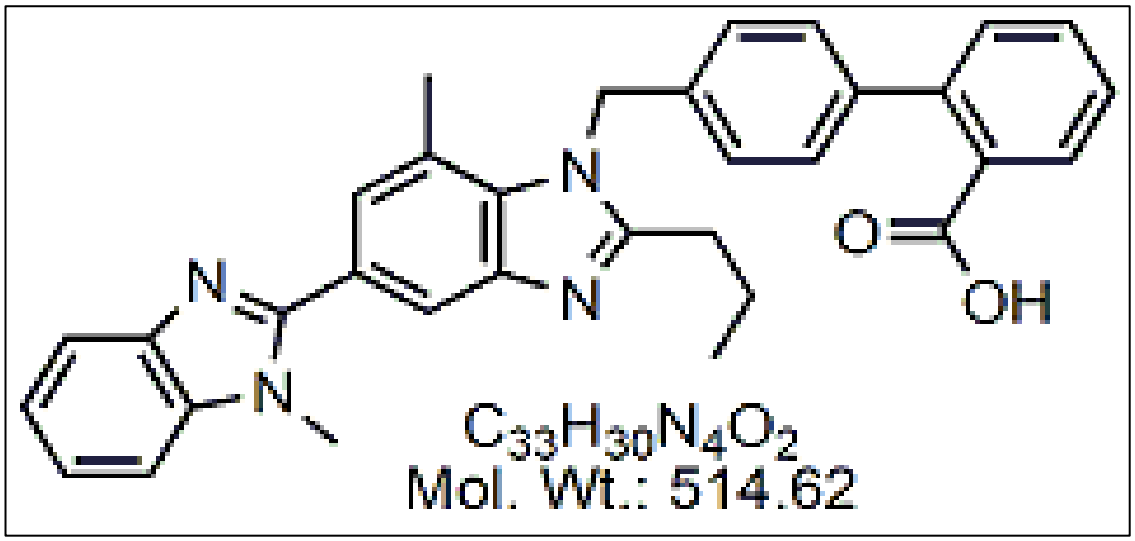
Chemical name:- Telmisartan Isomer

CAS Number:- 1026353-20-7

Molecular form:- $C_{33}H_{30}N_4O_2$

Appearance:- NA

Mol. Weight:- 514.62 g/mol



4.

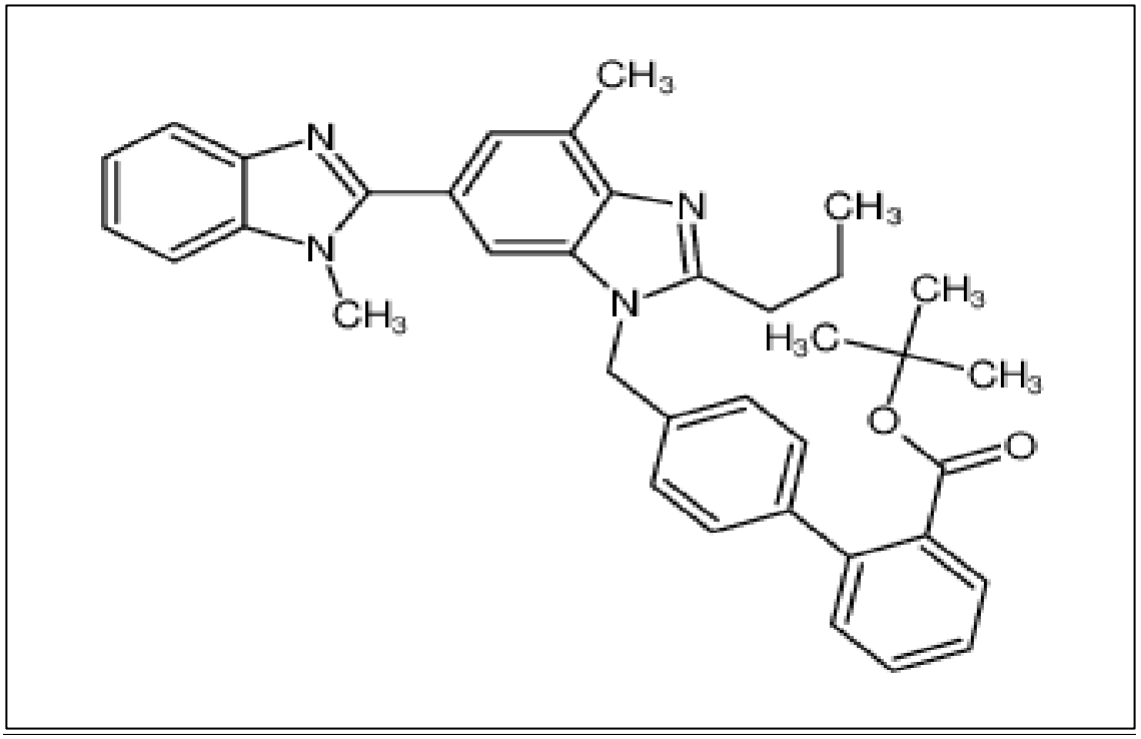
Chemical name:- 1,1-Dimethylethyl 4'-[[4-methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2-propyl-1H-benzimidazol1-yl]methyl]biphenyl-2-carboxylate

CAS Number:- 144702-26-1

Molecular form:- $C_{37}H_{38}N_4O_2$

Appearance:- Off-White Solid

Mol. Weight:- 570.72 g/mol



5.

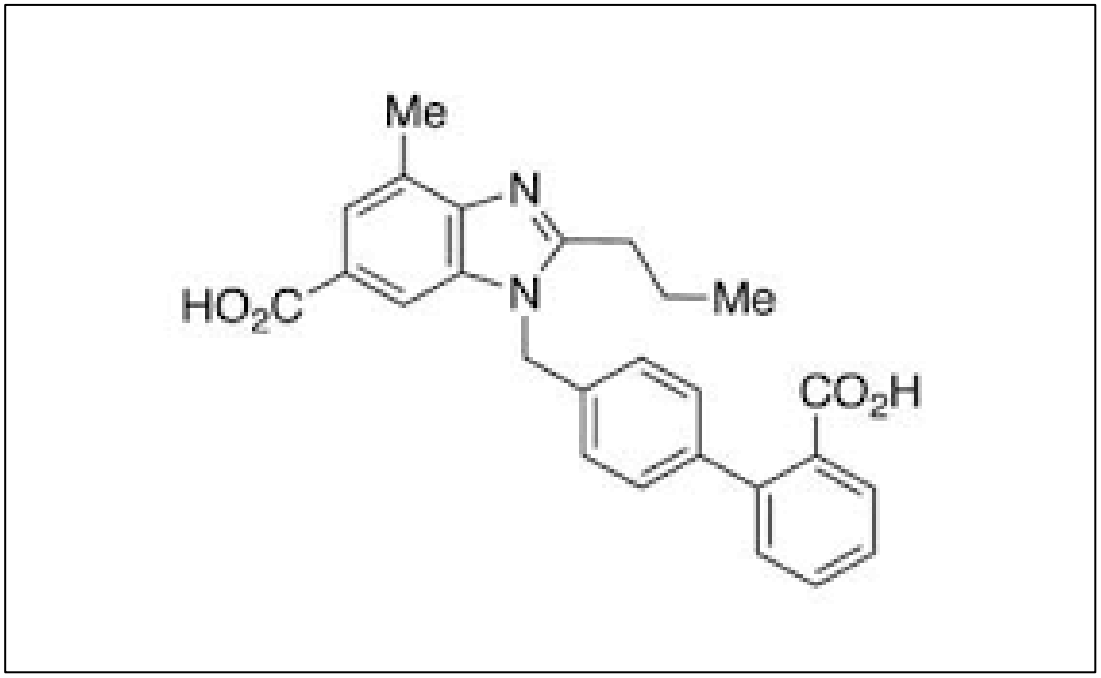
Chemical name:- 6-Des(1-methyl-2-benzimidazolyl)-6-carboxy Telmisartan

CAS Number:- 884330-12-5

Molecular form:- $C_{26}H_{24}N_2O_4$

Appearance:- White Solid

Mol. Weight:- 428.48 g/mol



6.

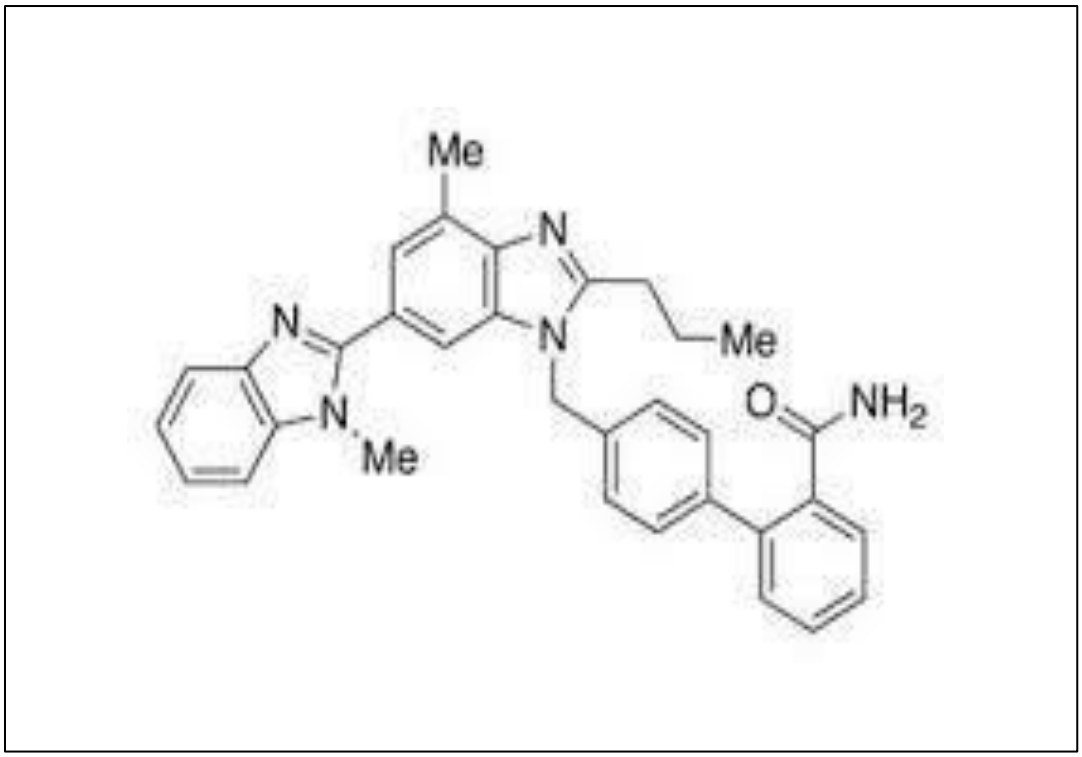
Chemical name:- 2-(4-{[4-Methyl-6-(1-methyl-1H-1,3-benzodiazol-2-yl)-2-propyl-1H-1,3-benzodiazol-1-yl] methyl}phenyl)benzamide

CAS Number:- 915124-86-6

Molecular form:- $C_{33}H_{31}N_5O$

Appearance:- Off-White Solid

Mol. Weight:- 513.63 g/mol



7.

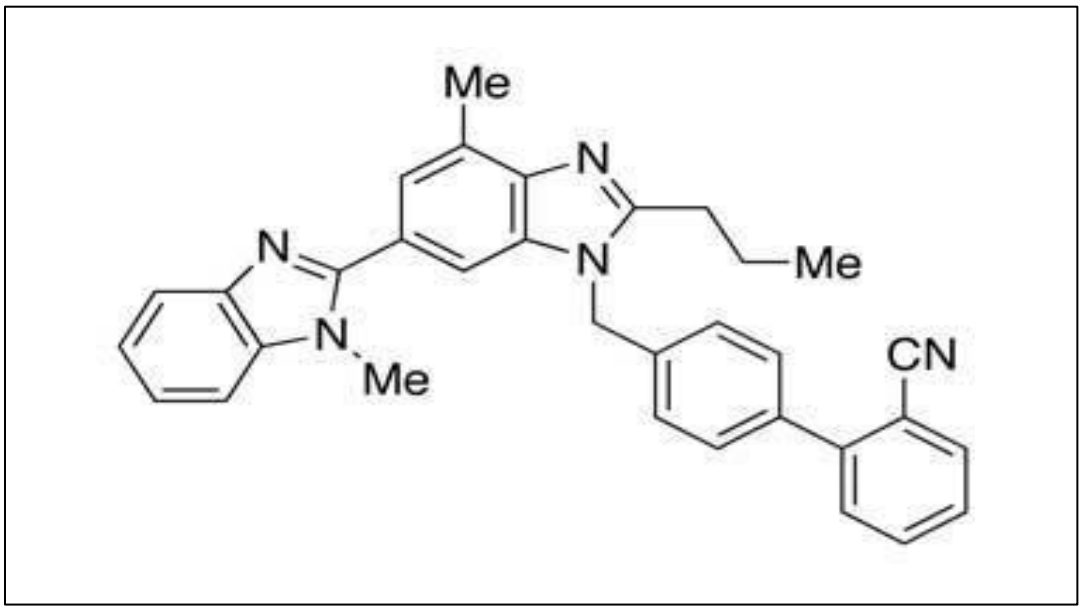
Chemical name . 4'-[(1,4'-Dimethyl-2'-propyl[2,6'-bi-1H-benzimidazol]-1'-yl)methyl]-[1,1'-biphenyl]-2-carbonitrile

CAS Number:- 144702-27-2

Molecular form:- $C_{33}H_{29}N_5$

Appearance:- White Solid

Mol. Weight:- 495.62 g/mol



8.

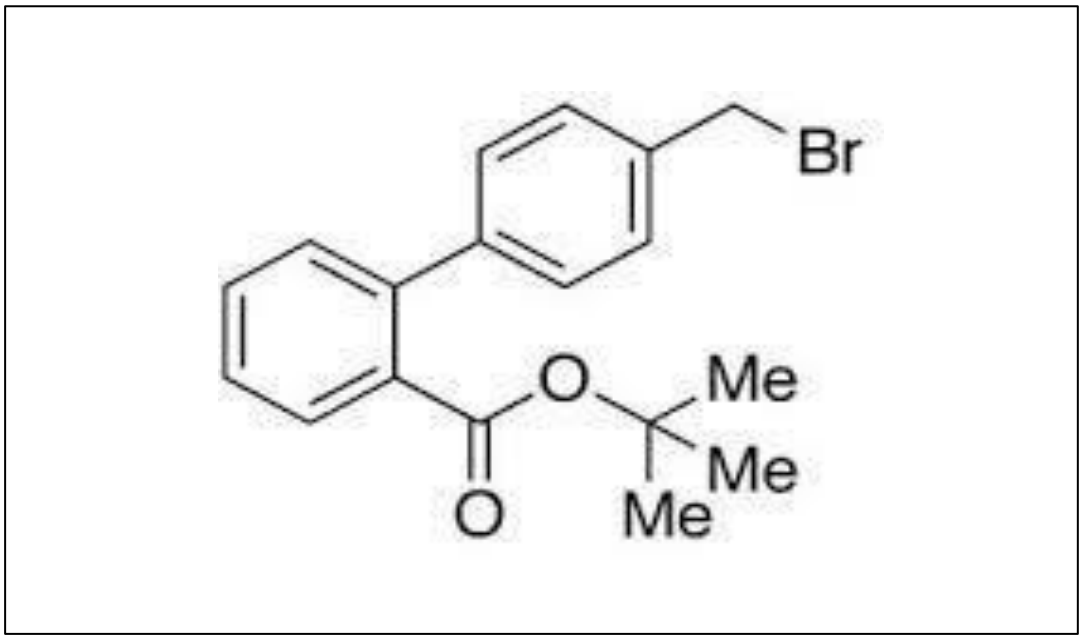
Chemical name:- 4'-(Bromomethyl)biphenyl-2-carboxylic Acid tert-Butyl Ester

CAS Number:- 114772-40-6

Molecular form:- $C_{18}H_{19}BrO_2$

Appearance:- White to Off-White Solid

Mol. Weight:- 347.25 g/mol



9.

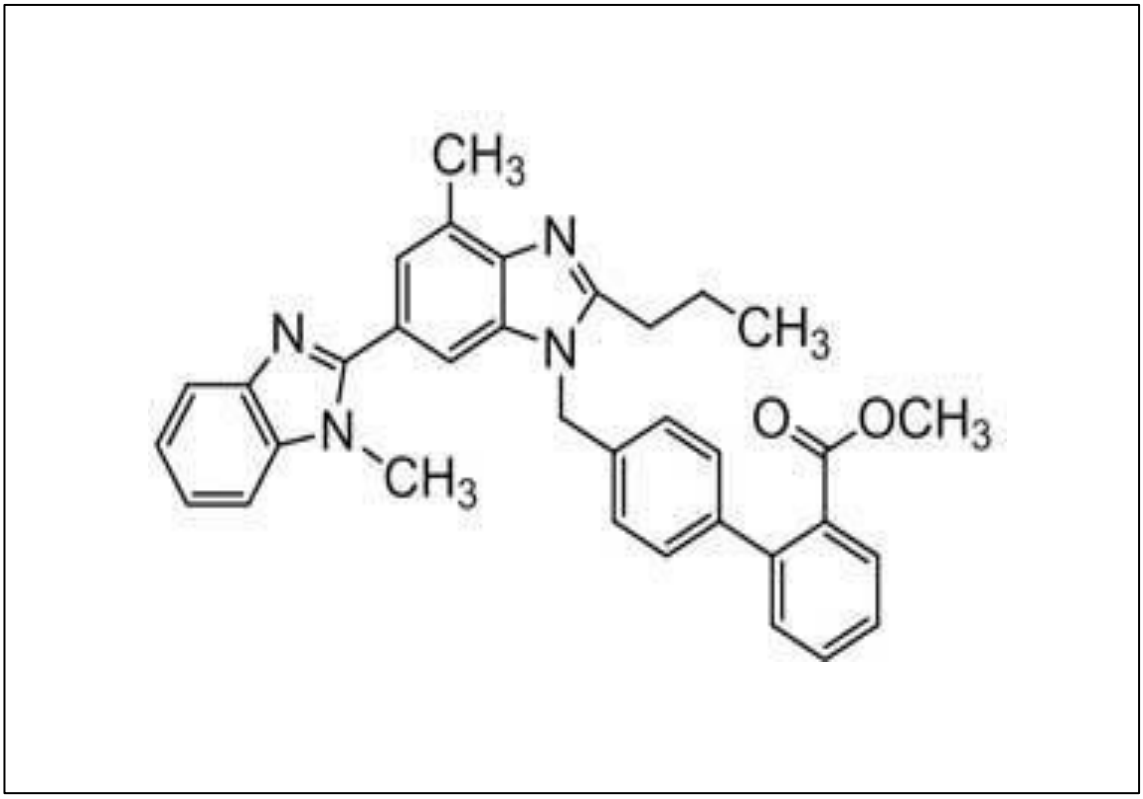
Chemical name: Telmisartan Methyl Ester

CAS Number:- 528560-93-2

Molecular form:- $C_{34}H_{32}N_4O_2$

Appearance:- White to Pale Yellow Solid

Mol. Weight:- 528.64 g/mol



6. CLINICAL TRIAL:

Telmisartan used as a monotherapeutic agent or as a part of combination therapy was successful and effective in reducing blood pressure and achieving the blood pressure target. Irrespective of the patient's age, duration, and stages of hypertension, the study resulted in a good to excellent scale in efficacy and tolerability in the Indian patients having hypertension.

Methods

Study design and ethical approval

This study was a retrospective, multicentre, observational, and real-world study conducted at 331 sites across Indian healthcare centers. Patients having medical records with diagnosed hypertension, and who were receiving telmisartan as monotherapy and/or combination therapy for hypertension were included. The study was approved by the Independent Ethics Committee (IEC), Clinicom, Bangalore. The study procedure was in accordance with the principles of the Declaration of Helsinki,the International Conference on Harmonization Good Clinical Practices (ICH GCPs), and the applicable legislation on noninterventional studies.

Study population:

Patients of either sex, aged above 18 years, diagnosed with hypertension as per the American College of Cardiology (ACC) or American Heart Association (AHA) criteria (ACC/AHA guidelines 2017), and receiving treatment for hypertension with telmisartan monotherapy and/or combination therapy, were included in this study. According to the ACC/AHA criteria, normal BP is defined as <120/<80 mmHg, elevated BP as 120-129/<80 mmHg, hypertension stage 1 as 130-139/80-89 mmHg,and hypertension stage 2 as ≥140/≥90 mmHg. Investigators' discretion and the decision were considered for excluding the patients having incomplete data or any specific unsuitable conditions.

Statistical analysis:

Data were analyzed using Statistical Package for The Social Sciences (SPSS) software (version 23.0). Demographic characteristics included median and interquartile range (IQR) for the continuous variables and frequency and percentages for the categorical variables. A comparison of qualitative variables between the

groups was done using the chi-square test, and the Mann-Whitney U test was used for the quantitative variables. A paired sample t-test was used for comparing the pre-and posttreatment systolic BP (SBP) and diastolic BP (DBP). A P-value less than 0.05 were considered statistically significant.

Result

A total of 8607 patients with hypertension were enrolled. The median age of the patients was 51.0 years. The number of male patients (64.3%) was higher than the number of female patients (35.7%). The majority of the patients (51.7%) were from urban locations. A total of 64.4% of the patients were diagnosed with stage II hypertension, and the remaining patients (35.6%) having stage I hypertension. The median systolic blood pressure (SBP) and diastolic blood pressure (DBP) were 155.0 mmHg and 94.0 mmHg, respectively

Conclusion

Telmisartan has been extensively studied and shown to be effective in reducing blood pressure and improving cardiovascular and renal outcomes across various patient populations. Its favorable safety profile makes it a valuable option in hypertension management and related conditions. Analysis of 8607 hypertension patients suggested that telmisartan is efficacious and tolerable for BP control when used as part of monotherapy and in combination therapy for Indian patients. This is effective irrespective of age, duration, and stages of hypertension; the therapies were tolerable by the study population with few minor adverse events.

7. PHARMACOKINETIC PROPERTY:

Telmisartan is an angiotensin II receptor antagonist used primarily for managing hypertension. It features a bioavailability of about 50% and reaches peak plasma concentrations within 0.5 to 1 hour after oral administration. With a large volume of distribution (approximately 500 L) and over 99.5% protein binding, it extensively distributes into body tissues. Telmisartan undergoes minimal metabolism and has an elimination half-life of around 24 hours, allowing for once-daily dosing. Most of the drug is excreted unchanged in feces, making it suitable for patients with mild to moderate renal impairment.

Pharmacokinetics:

1. Absorption:

Bioavailability: Telmisartan has an oral bioavailability of about 50%. This means that roughly half of the drug reaches systemic circulation after administration.

Peak Plasma Concentrations: The time to reach peak plasma concentration (Tmax) is typically between 0.5 to 1 hour after ingestion.

Food Effects: The absorption of telmisartan is minimally affected by food. However, taking it with a high-fat meal may slightly reduce peak concentration and delay Tmax, though this does not significantly impact overall bioavailability.

2. Distribution:

Volume of Distribution: Telmisartan has a large volume of distribution (approximately 500 liters), indicating that it extensively distributes into body tissues.

Protein Binding: The drug is highly bound to plasma proteins, with about 99.5% binding to serum albumin and alpha-1 acid glycoprotein. This high degree of binding suggests a low free fraction in circulation, which is important for its pharmacological activity.

3. Metabolism:

Metabolic Pathways: Telmisartan undergoes minimal hepatic metabolism, with the primary metabolic pathway being glucuronidation. It does not have significant active metabolites, which contributes to its pharmacokinetic profile.

4. Elimination:

Half-Life: The elimination half-life of telmisartan is approximately 24 hours, allowing for once-daily dosing. This extended half-life supports consistent antihypertensive effects over a 24-hour period.

Excretion: Around 90% of telmisartan is excreted unchanged in the feces, with only a small fraction (about 10%) eliminated in urine. This highlights its enterohepatic circulation and minimal renal excretion.

5. Steady State:

Time to Steady State: Steady-state plasma concentrations are typically achieved within 3 to 5 days of regular dosing, which is important for establishing effective blood pressure control.

6. Special Populations:

Renal Impairment: While telmisartan is primarily excreted via the feces, caution is advised in patients with severe renal impairment. Dosage adjustments may be necessary, although data suggest that moderate renal impairment does not significantly affect pharmacokinetics.

Hepatic Impairment: In patients with mild to moderate hepatic impairment, careful monitoring is recommended, though specific adjustments may not be required.

Age and Gender: There are minor pharmacokinetic differences in elderly patients and between genders, but these generally do not warrant routine dosage adjustments.

7. Clinical Implications:

Dosing Considerations: The pharmacokinetics of telmisartan support its use as a once-daily medication. Its extensive tissue binding and half-life make it effective for maintaining steady blood pressure control.

Drug Interactions: Due to its minimal hepatic metabolism, telmisartan is less likely to interact with other drugs that are substrates for cytochrome P450 enzymes, making it a favorable option in polypharmacy scenarios.

8. PATIENT INFORMATION:

Adult dosage (ages 18 years and older)

- The typical starting dose is 40 mg, taken by mouth, once per day.
- The maintenance dose is 20–80 mg, taken by mouth, once per day.

Child dosage (ages 0–17 years)

This medication hasn't been studied in children and should not be used in children under the age of 18 years.

Senior dosage (ages 65 years and older)

There are no specific recommendations for senior dosing. Older adults may process drugs more slowly. A normal adult dose may cause levels of this drug to be higher than normal in your body. If you're a senior, you may need a lower dose or a different schedule.

For pregnant women:

Studies show a risk of serious negative effects to the fetus when a mother takes this drug, especially during the second and third trimesters. Telmisartan may harm or end your pregnancy. However, in certain cases, the benefits of taking the drug during pregnancy may outweigh the potential risks.

For people with severe heart failure:

Telmisartan may reduce the amount of urine you produce or increase your risk for kidney injury.

For people with kidney problems:

Telmisartan may reduce the amount of urine you produce or increase your risk for kidney injury.

9. MODE OF ACTION:

Telmisartan is used alone or together with other medicines to treat high blood pressure (hypertension). High blood pressure adds to the workload of the heart and arteries. If it continues for a long time, the heart and arteries may not function properly. This can damage the blood vessels of the brain, heart, and kidneys, resulting in a stroke, heart failure, or kidney failure. Lowering blood pressure can reduce the risk of strokes and heart attacks.

Telmisartan is also used to lower the risk of heart attacks or stroke in patients 55 years of age and older who have diabetes or heart problems.

Telmisartan is an angiotensin II receptor blocker (ARB). It works by blocking a substance in the body that causes blood vessels to tighten. As a result, telmisartan relaxes the blood vessels. This lowers blood pressure and increases the supply of blood and oxygen to the heart.

10. STORAGE AND HANDLING:

Storage Conditions:

- **Temperature**: Store at room temperature, typically between 20°C to 25°C (68°F to 77°F).
- **Humidity**: Keep in a dry place, away from excessive moisture.
- **Light**: Protect from light and store in the original container to prevent degradation.

Handling:

- **Dispensing**: Ensure that the medication is dispensed in its original packaging with the label intact.
- **Expiration Date**: Check the expiration date before use; do not use past this date.
- **Disposal**: Dispose of unused or expired medication properly, following local regulations. Do not flush down the toilet unless specifically instructed.

General Precautions:

- Keep out of reach of children and pets.
- If a dose is missed, take it as soon as remembered, but skip if it's almost time for the next dose; do not double up.

ANALYTICAL METHOD VALIDATION

FOR

ASSAY OF

TELMISARTAN

IN

TELMISARTAN TABLET BY

UV-SPECTROPHOTOMETER

1. Objective:
This method validation report applies to the method for determining the Telmisartan in Telmisartan Tablets 40mg

2. Scope:
This report is to outline method validation parameters, set acceptance criteria and complete method validation report in compliance with USP and ICH guidelines. Analytical parameters such as Specificity/Selectivity, Precision, Ruggedness, Accuracy/Recovery, Linearity/Range to be evaluated to complete the method validation.

3. Methodology:
Specification of Telmisartan Tablets 40mg
(Quantitative Determination of Telmisartan):
Telmisartan content in Syrup should be within limits NLT 90.0% of the labeled amount.

Preparation of Samples:

- **Preparation of Standard :**
  Weigh accurately 40 mg of Telmisartan working standard and transfer in 100 ml volumetric flask, add 50 ml Methanol and sonicate for 5 minutes to dissolve, cool the flask at room temperature and dilute to the volume with Methanol solution upto the mark and mix.
  Transfer 5 ml of obtained solution in a 50 ml volumetric flask, dilute the solution to volume up to the mark and mix.

- **Preparation of Sample:**
  Grind 5 tablets contents into fine powder with mortar and pestle and transfer the powder accurately weighed average weigh (Equivalent to 40 mg of Telmisartan in 100 ml volumetric flask of Methanol and sonicate for 45 minutes with intermittent shaking, cool the flask at room temperature and dilute to volume with Methanol upto the mark. Filter through whatman filter paper no.1 discarding first few ml (about 3-4 ml) of filtrate.
  Transfer 5 ml of above filtrate to 50 ml volumetric flask and dilute to volume with mobile phase upto the mark.

PROCEDURE:
.

Measure the absorbance at 296nm against Methanol as blank.

4) Specificity & Selectivity

The specificity of the method was ascertained by analyzing standard drugs and sample. The retention time (RT) of Baricitinib was confirmed by comparing the RT with that of the standard. The use of the standard Baricitinib and interference was observed in the chromatogram of blank.

Table No-1

Sample ID	Telmisartan	Remarks
Blank	-0.0004	----------
Standard	0.629	No interference
Sample	0.627	No interference

- Acceptance Criteria:

Blank should not interfere in the absorbance of the Telmisartan .

- Conclusion:

There is no interference in the absorbance of Blank preparation of the Telmisartan .

Photometric Analysis Report

Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180005		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	3	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	-0.0004		Measured	
2	Standard	0.629		Measured	
3	Sample	0.627		Measured	

5). Precision:

Precision is a measurement of degree of Reproducibility of analytical method and it will be expressed in terms of % relative standard for the area and retention time of Solution prepared. 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

Table No-2 (for Sample Preparation)

No of sample	UV Reading		% Assay
			Telmisartan
1	Standard	0.627	99.68%
2	Sample	0.625	

- **Acceptance Criteria:**

Telmisartan content should be within limits NLT 90.0% of the labeled amount.

- **Conclusion:**

% Assay is 99.68% for Telmisartan which is well acceptable limit, hence the method is Precise.

Photometric Analysis Report

Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180006		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	3	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	0.0009		Measured	
2	Standard	0.627		Measured	
3	Sample	0.625		Measured	

6) Accuracy / Recovery:

The accuracy of an analytical method is defined as the closeness between the observed values with actual or true value for a specific concentration. Accuracy - closeness to the true value, measured by % recovery of sample spikes or % error in the analysis of a reference sample

Table No-4 (for Telmisartan)

Level	Added Conc. (mg)	Telmisartan Absorbance	Qty. Recovered (mg)	% Recovery (Assay)
80%	32.0	0.5048	31.8	99.53
100%	40.0	0.631	39.8	99.53
120%	48.0	0.7572	47.8	99.53
			Average	**99.53**

➢ **Acceptance Criteria:**

%RSD for %Recovery should not be more than 2.0 %.
%Recovery should be between 98.0% to 102.0% for individual and for all level

➢ **Conclusion:**

%Recovery for Telmisartan is 99.53% for 80%, 99.53% for 100%, 99.53% for 120%, and 99.53% for all level, which is well acceptable limit, hence the method is accurate

Photometric Analysis Report

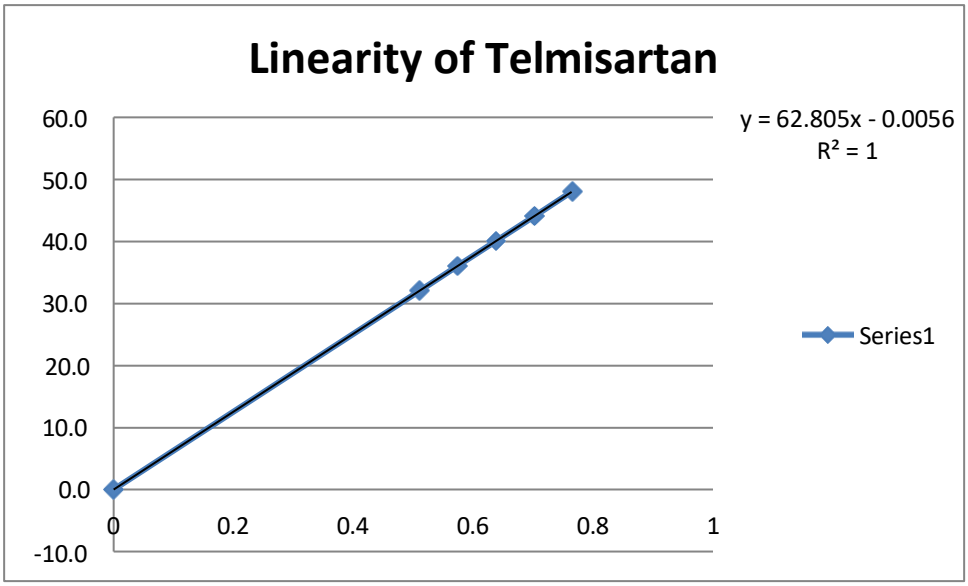
Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180013		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	4	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	0.0001		Measured	
2	80%	0.5048		Measured	
3	100%	0.631		Measured	
4	120%	0.7572		Measured	

7) Linearity and Range:

No of Injection	Concentration (ppm)	Titrant (ml) Consume
1	32.0	0.510
2	36.0	0.573
3	40.0	0.637
4	44.0	0.701
5	48.0	0.764
Coefficient Correlation =		1.0000
Y-Intercept =		**0.0001**
Slope =		**0.0159**



➢ **Acceptance Criteria:**

Correlation coefficient should not be less than 0.99

➢ **Conclusion:**

Correlation coefficient is 0.9997 and method is linear between 12.80 ppm to 19.20 ppm in concentration. Which is well acceptable limit hence the method is linear for Telmisartan .

Photometric Analysis Report

Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180014		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	6	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	0		Measured	
2	80%	0.51		Measured	
3	90%	0.573		Measured	
4	100%	0.637		Measured	
5	110%	0.701		Measured	
6	120%	0.764		Measured	

8) Ruggedness:

Intermediate Precision under analysis repeatability conditions i.e. conditions where independent test results were obtained with the same method on identical test items in the same laboratory by the same operator using the same equipment within short intervals of time.

(For Test Preparation)

No of sample	UV Reading		% Assay
			Telmisartan
1	Standard	0.627	99.52%
2	Sample	0.624	

➢ **Conclusion:** % Assay is 99.41%

	% Assay	Difference
Precision %Assay	99.68	
Intermediate Precision %Assay	99.52	0.16

(Difference = Intermediate Precision % Assay –Precision %Assay)

➢ **Acceptance: Criteria:**
Difference of average assay between Precision %Assay & Intermediate Precision % Assay should not be more than 2.0

➢ **Conclusion:**
Difference of average Assay is 0.16 between Precision %Assay & Intermediate Precision % Assay

Photometric Analysis Report

Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180008		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	3	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	-0.0002		Measured	
2	Standard	0.627		Measured	
3	Sample	0.624		Measured	

9) Solution Stability:

The solution stability of Telmisartan in the assay method was carried out by leaving the working standard in tightly capped volumetric flasks at room temperature for 24 hrs. The assay sample is also prepared and kept for stability up to 24 hours.

(for Telmisartan)

Time (Hrs)	Absorbance	% Assay	Difference
Standard	0.621		
Initial	0.620	99.84	---
1 Hrs	0.618	99.52	0.32

- **Acceptance Criteria:**

%Assay difference should not be more than 2.0 %

- **Conclusion:**

% Assay difference for Telmisartan is 0.32 up to 1 hours which is well acceptable limit;

.

Photometric Analysis Report

Company	Telmisartan		
Operator	admin		
Document No.	Pht2503180004_1		
WaveLength	296nm	K1	0.99
Unit		K0	0
Calculate the Conc.	No	K2	0
Number of samples	4	K3	0
Remark			

Detail

No.	Name	Abs.	Conc.	Status	Remark
1	Blank	-0.0006		Measured	
2	Standard	0.621		Measured	
3	Initial Sample	0.62		Measured	
4	1 Hr Sample	0.618		Measured	

9. Summary: for Summary Result

Parameter	Limit	Observation
Specificity/ Selectivity	Placebo should not interfere in the absorbance of the Telmisartan	There is no interference in the abosorbance of Placebo preparation of the Telmisartan .
Precision	➢ Telmisartan content in TABLET should be within limits NLT 90.0% of the labeled amount.	➢ % Assay is 99.68% for Telmisartan
Accuracy /Recovery	➢ % Recovery should be between 98.0% to 102.0% for individual and for all level.	➢ %Recovery for Telmisartan is 99.53% for 80%, 99.53% for 100%, 99.53% for 120%, and 99.53% for all level, which is well acceptable limit, hence the method is accurate
Linearity and Range	➢ Correlation coefficient should not be less than 0.999.	➢ Correlation coefficient is 0.9997 and method is linear Which is well acceptable limit hence the method is linear for Telmisartan .
Ruggedness	➢ %RSD should not be more than 2.0 % for individual and for two analysts for assay. ➢ % Assay should be between 90.0% and 110.0% ➢ Difference of average assay between two analyst should not be more than 2.0	➢ % Assay for Analyst-1 & Analyst-2 for individual analysis for Telmisartan is 99.68% and 99.52% respectively ➢ Difference of average Assay is 0.16 between two analyst for Telmisartan which is well acceptable limit, hence the method is precise
Solution Stability	% Assay difference should not be more than 2.0 %.	% Assay difference for Telmisartan is 0.32 up to 1 hours, which is well acceptable limit;

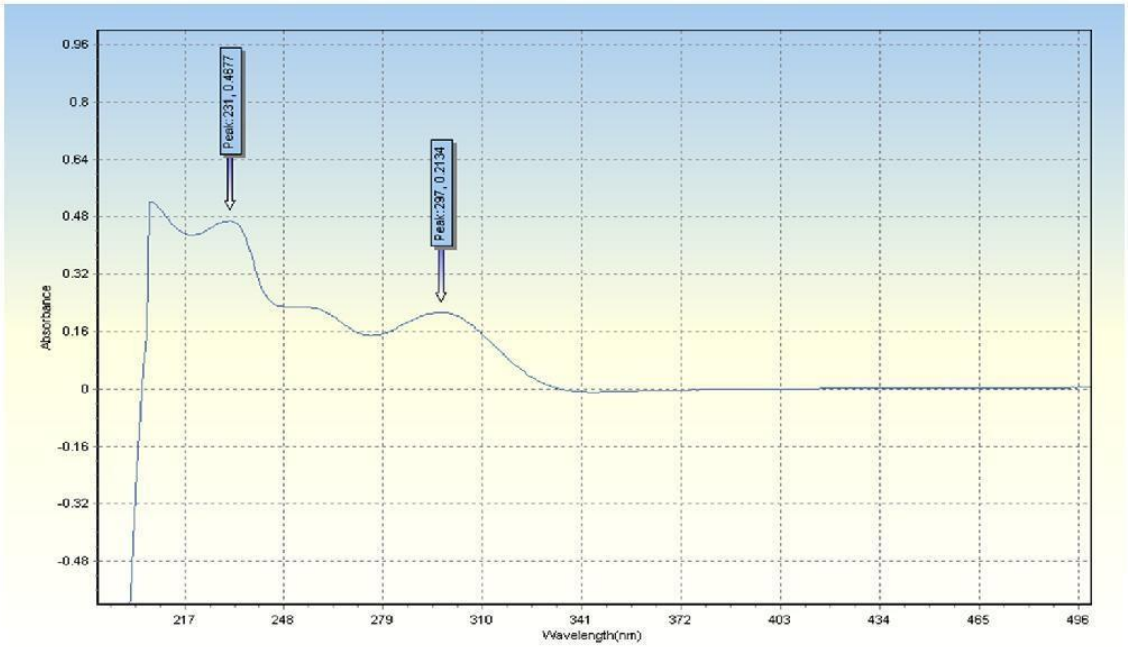
10. Conclusion:

All the above parameters are completed, result are tabulated and compared against the acceptance criteria of each parameter. From the above data and results it was concluded that the above-validated method was suitable for Telmisartan in NAME OF TABLET for regular analysis.

UV-SPECTROPHOTOMETER REFERENCE DATA

Wavelength Scan Report

Company	Telmisartan		
Operator	admin		
Document No.	WLS2306190011_1		
Start wavelength	500nm	Number of data	311
End wavelength	190nm	K1	0.99
Unit	mg/ml	K0	0
Interval	1nm	K2	0
Calculate the Conc.	Yes	K3	0



Scan Data

No.	Wavelength	Abs	Peak/Valley	Visible	Remark
1	500	0.0039	0	0	
2	499	0.0042	0	0	
3	498	0.0042	0	0	
4	497	0.0041	0	0	
5	496	0.004	0	0	
6	495	0.0037	0	0	
7	494	0.0039	0	0	
8	493	0.0038	0	0	
9	492	0.0037	0	0	
10	491	0.0038	0	0	
11	490	0.0035	0	0	
12	489	0.0037	0	0	
13	488	0.0036	0	0	
14	487	0.0034	0	0	
15	486	0.0032	0	0	
16	485	0.0032	0	0	
17	484	0.0033	0	0	
18	483	0.0036	0	0	
19	482	0.0034	0	0	
20	481	0.0033	0	0	
21	480	0.0033	0	0	
22	479	0.0032	0	0	
23	478	0.0032	0	0	
24	477	0.003	0	0	
25	476	0.0031	0	0	
26	475	0.0033	0	0	
27	474	0.003	0	0	
28	473	0.0026	0	0	
29	472	0.003	0	0	
30	471	0.0032	0	0	
31	470	0.0024	0	0	
32	469	0.0026	0	0	
33	468	0.0028	0	0	
34	467	0.0028	0	0	

35	466	0.0029	0	0
36	465	0.0029	0	0
37	464	0.0026	0	0
38	463	0.0024	0	0
39	462	0.0024	0	0
40	461	0.0024	0	0
41	460	0.0025	0	0
42	459	0.0027	0	0
43	458	0.0028	0	0
44	457	0.0026	0	0
45	456	0.0028	0	0
46	455	0.0029	0	0
47	454	0.003	0	0
48	453	0.0028	0	0
49	452	0.0024	0	0
50	451	0.0026	0	0
51	450	0.0026	0	0
52	449	0.003	0	0
53	448	0.0027	0	0
54	447	0.0025	0	0
55	446	0.0023	0	0
56	445	0.0027	0	0
57	444	0.0025	0	0
58	443	0.0023	0	0
59	442	0.0026	0	0
60	441	0.0029	0	0
61	440	0.002	0	0
62	439	0.002	0	0
63	438	0.0022	0	0
64	437	0.0022	0	0
65	436	0.0021	0	0
66	435	0.0022	0	0
67	434	0.002	0	0
68	433	0.0016	0	0
69	432	0.0021	0	0
70	431	0.002	0	0
71	430	0.0021	0	0
72	429	0.0019	0	0
73	428	0.0015	0	0
74	427	0.0015	0	0
75	426	0.0013	0	0
76	425	0.0008	0	0
77	424	0.0016	0	0
78	423	0.0015	0	0
79	422	0.0013	0	0
80	421	0.0015	0	0
81	420	0.0011	0	0
82	419	0.0012	0	0
83	418	0.0011	0	0
84	417	0.0009	0	0
85	416	0.0008	0	0
86	415	0.0005	0	0
87	414	0.0006	0	0
88	413	0.0003	0	0
89	412	0.0002	0	0
90	411	0.0006	0	0
91	410	0.0002	0	0
92	409	0.0005	0	0
93	408	0.0002	0	0
94	407	0	0	0
95	406	-0.0003	0	0
96	405	-0.0003	0	0
97	404	-0.0007	0	0
98	403	-0.0005	0	0
99	402	0	0	0
100	401	-0.0009	0	0
101	400	-0.0009	0	0
102	399	-0.0011	0	0
103	398	-0.001	0	0
104	397	-0.0007	0	0
105	396	-0.001	0	0
106	395	-0.0003	0	0
107	394	-0.0012	0	0
108	393	-0.0012	0	0
109	392	-0.001	0	0
110	391	-0.0008	0	0
111	390	-0.001	0	0

112	389	-0.0008	0	0
113	388	-0.001	0	0
114	387	-0.0005	0	0
115	386	-0.0009	0	0
116	385	-0.0013	0	0
117	384	-0.001	0	0
118	383	-0.0012	0	0
119	382	-0.0018	0	0
120	381	-0.0018	0	0
121	380	-0.0013	0	0
122	379	-0.0018	0	0
123	378	-0.0023	0	0
124	377	-0.0026	0	0
125	376	-0.0023	0	0
126	375	-0.0024	0	0
127	374	-0.0024	0	0
128	373	-0.0031	0	0
129	372	-0.003	0	0
130	371	-0.0024	0	0
131	370	-0.0026	0	0
132	369	-0.0031	0	0
133	368	-0.0038	0	0
134	367	-0.0039	0	0
135	366	-0.0043	0	0
136	365	-0.0047	0	0
137	364	-0.0045	0	0
138	363	-0.0048	0	0
139	362	-0.0051	0	0
140	361	-0.0051	0	0
141	360	-0.0053	0	0
142	359	-0.0052	0	0
143	358	-0.0056	0	0
144	357	-0.0055	0	0
145	356	-0.0062	0	0
146	355	-0.0063	0	0
147	354	-0.0065	0	0
148	353	-0.0069	0	0
149	352	-0.0066	0	0
150	351	-0.0066	0	0
151	350	-0.0066	0	0
152	349	-0.0076	0	0
153	348	-0.008	0	0
154	347	-0.0082	0	0
155	346	-0.0089	0	0
156	345	-0.0085	0	0
157	344	-0.0085	0	0
158	343	-0.0085	0	0
159	342	-0.0083	0	0
160	341	-0.008	0	0
161	340	-0.0076	0	0
162	339	-0.0065	0	0
163	338	-0.0056	0	0
164	337	-0.0049	0	0
165	336	-0.0035	0	0
166	335	-0.0016	0	0
167	334	0.0001	0	0
168	333	0.002	0	0
169	332	0.0052	0	0
170	331	0.0081	0	0
171	330	0.0112	0	0
172	329	0.0148	0	0
173	328	0.019	0	0
174	327	0.0239	0	0
175	326	0.0287	0	0
176	325	0.034	0	0
177	324	0.0403	0	0
178	323	0.0472	0	0
179	322	0.0533	0	0
180	321	0.0601	0	0
181	320	0.0678	0	0
182	319	0.0762	0	0
183	318	0.0835	0	0
184	317	0.0918	0	0
185	316	0.1002	0	0
186	315	0.1089	0	0
187	314	0.1172	0	0
188	313	0.1255	0	0

189	312	0.1342	0	0
190	311	0.1421	0	0
191	310	0.1499	0	0
192	309	0.1589	0	0
193	308	0.1674	0	0
194	307	0.1744	0	0
195	306	0.181	0	0
196	305	0.1875	0	0
197	304	0.1938	0	0
198	303	0.199	0	0
199	302	0.203	0	0
200	301	0.207	0	0
201	300	0.21	0	0
202	299	0.2117	0	0
203	298	0.2129	0	0
204	297	0.2134	1	1
205	296	0.2128	0	0
206	295	0.2119	0	0
207	294	0.2103	0	0
208	293	0.2081	0	0
209	292	0.2053	0	0
210	291	0.2022	0	0
211	290	0.1986	0	0
212	289	0.1948	0	0
213	288	0.191	0	0
214	287	0.1872	0	0
215	286	0.1826	0	0
216	285	0.178	0	0
217	284	0.1741	0	0
218	283	0.1688	0	0
219	282	0.1641	0	0
220	281	0.1595	0	0
221	280	0.1564	0	0
222	279	0.1538	0	0
223	278	0.152	0	0
224	277	0.1503	0	0
225	276	0.1492	0	0
226	275	0.1487	0	0
227	274	0.1498	0	0
228	273	0.1507	0	0
229	272	0.1531	0	0
230	271	0.1566	0	0
231	270	0.1613	0	0
232	269	0.1659	0	0
233	268	0.1716	0	0
234	267	0.1789	0	0
235	266	0.1861	0	0
236	265	0.1918	0	0
237	264	0.1986	0	0
238	263	0.2043	0	0
239	262	0.2094	0	0
240	261	0.2137	0	0
241	260	0.2175	0	0
242	259	0.2209	0	0
243	258	0.2236	0	0
244	257	0.2259	0	0
245	256	0.2275	0	0
246	255	0.2283	0	0
247	254	0.2286	0	0
248	253	0.2283	0	0
249	252	0.2278	0	0
250	251	0.2277	0	0
251	250	0.2283	0	0
252	249	0.2285	0	0
253	248	0.2292	0	0
254	247	0.2301	0	0
255	246	0.2319	0	0
256	245	0.2354	0	0
257	244	0.2417	0	0
258	243	0.2505	0	0
259	242	0.2643	0	0
260	241	0.283	0	0
261	240	0.3055	0	0
262	239	0.3336	0	0
263	238	0.3657	0	0
264	237	0.3958	0	0
265	236	0.4204	0	0

266	235	0.4401	0	0
267	234	0.4551	0	0
268	233	0.4638	0	0
269	232	0.467	0	0
270	231	0.4677	1	1
271	230	0.4671	0	0
272	229	0.4655	0	0
273	228	0.4625	0	0
274	227	0.4587	0	0
275	226	0.4536	0	0
276	225	0.4486	0	0
277	224	0.4432	0	0
278	223	0.4377	0	0
279	222	0.4332	0	0
280	221	0.4305	0	0
281	220	0.428	0	0
282	219	0.4272	0	0
283	218	0.4282	0	0
284	217	0.4316	0	0
285	216	0.4368	0	0
286	215	0.4434	0	0
287	214	0.4507	0	0
288	213	0.4601	0	0
289	212	0.4711	0	0
290	211	0.4805	0	0
291	210	0.4925	0	0
292	209	0.5041	0	0
293	208	0.5137	0	0
294	207	0.5203	0	0
295	206	0.5217	0	0
296	205	0.1469	0	0
297	204	0.059	0	0
298	203	-0.0659	0	0
299	202	-0.2268	0	0
300	201	-0.4305	0	0
301	200	-0.5798	0	0
302	199	-0.6571	0	0
303	198	-0.6905	0	0
304	197	-0.7021	0	0
305	196	-0.7127	0	0
306	195	-0.7128	0	0
307	194	-0.7172	0	0
308	193	-0.7198	0	0
309	192	-0.7235	0	0
310	191	-0.7304	0	0
311	190	-0.7376		

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