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Research Article

Comparative quality control study of different brands of telmisartan tablets marketed in Andhra Pradesh, India by *in-vitro* testing

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Disintegration, drug quality, drug release, friability, hardness, thickness, telmisartan tablets.

Abstract

Telmisartan is indicated for treating patients with high blood pressure (Hypertension). This study attempted to investigate the *In-vitro* quality control testing of six prominent pharmaceutical brands of telmisartan tablets marketed in Andhra Pradesh, India. Six different brands of tablets used in the study, named brand A (Telismart 40 mg), brand B (Telmisafe TM-40 mg), brand C (Teltan-40 mg), brand D (Telkonol-40 mg), brand E (telmiwock-40 mg), and brand F (Telmikind-40), were evaluated for weight variation, content uniformity, thickness, disintegration, hardness, friability, and assay. The study utilised standardised testing methods to ensure consistency and reliability across all assessments. The results revealed that all the brands of telmisartan tablets complied with the official specifications for hardness, friability, disintegration, and assay. All the selected brands of telmisartan tablets demonstrated robust mechanical strength, minimal friability, and prompt disintegration of active pharmaceutical ingredients.

1. Introduction

Hypertension is a major cause of premature death worldwide. Hypertension, also known as high blood pressure, is a long-term medical condition in which the blood pressure in the arteries is persistently elevated. High blood pressure usually does not cause symptoms itself. It is, however, a major risk factor for stroke, coronary artery disease, heart failure, atrial fibrillation, peripheral arterial disease, vision loss, chronic kidney disease, and dementia. Telmisartan is indicated for the treatment of hypertension [1]. Telmisartan is an angiotensin II receptor blocker that shows a high affinity for the angiotensin II receptor type 1 (AT1), with a binding affinity 3000 times greater for AT1 than AT2. In addition to blocking the renin-angiotensin system, telmisartan acts as a selective modulator of peroxisome proliferator-activated receptor gamma (PPAR-γ), a central regulator of insulin and glucose metabolism. The US

Table 1. Different brands of telmisartan

Sl. No.	Brand Name	Manufactured by	Batch No.	License No.	Mfg. Dt:	Exp. Dt:
1.	Telismart 40 mg	Windlass Biotech Ltd.	TEG24004	34/UA/2013	4/2024	3/2026
2.	Telmisafe TM-40 mg	Scott-Edill Pharmacia Ltd.	2315239T001	MNB/17/991	3/2023	2/2025
3.	Teltan-40 mg	Ajanta Pharma Ltd.	MT2403184	MNB/14/874	3/2024	2/2026
4.	Telkonol-40 mg	VIP Pharmaceuticals (P) Ltd.	TLB23015	MNB/07/569 & MB/07/570	4/2023	3/2025
5.	Telmiwock-40 mg	Innova Cap Tab Ltd.	WIG23069	MNB/16/970	11/2023	10/2025
6.	Telmikind-40	Mankind Pharma Ltd.	B55X009	M/743/2016	02/2024	01/2026

FDA approved this drug in 1998. The available dosages of telmisartan are 20 mg, 40 mg, and 80 mg. The IUPAC name of telmisartan (Fig. 1) is 4'-[(1,4'-dimethyl-2'-propyl [2,6'-bi-1H-benzimidazol]-1'-yl) methyl]-[1,1'-biphenyl]-2-carboxylic acid.

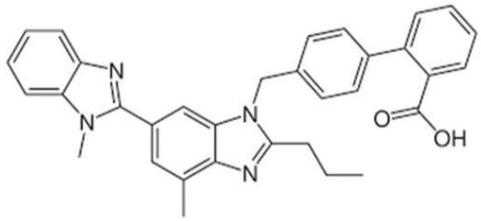

Figure 1. Chemical structure of telmisartan

Its empirical formula is $C_{33}H_{30}N_4O_2$, and its molecular weight is 514.63 g/mol. Telmisartan is a white to slightly yellowish solid [2]. It is practically insoluble in water and has a pH range of 3 to 9, sparingly soluble in strong acids, dichloromethane (except insoluble in hydrochloric acid) and soluble in strong bases. The warnings and precautions are fetal/neonatal morbidity and mortality, hypotension, hyperkalemia, impaired hepatic function, impaired renal function, and dual blockade of the renin-angiotensin-aldosterone system. The most common adverse events (≥1%) reported in hypertension trials are back pain, sinusitis, and diarrhoea. Cardiovascular risk reduction: The serious adverse events (≥1%) reported in cardiovascular risk reduction trials were intermittent coughing and skin ulcers [3].

The literature survey revealed that some authors have formulated and conducted quality control tests of different tablets of telmisartan reported to date [4-10]. This study aimed to evaluate quality control considerations for commercial telmisartan tablets marketed in Andhra Pradesh. The different brands of telmisartan 40 mg tablets were obtained from local pharmacy stores. Six brands of telmisartan tablets were used in this study.

2. Materials and methods

2.1. Chemicals, reagents and equipment

Different brands of 40 mg telmisartan tablets were bought from various pharmacy retail outlets in Andhra Pradesh. All the brands used were within their shelf life at the time of the study,it was conducted in September, 2024. The detailed descriptions of these products are presented in Table 1. The following chemicals were used for the experiment: Telmisartan, methanol (Thermo Fisher Scientific India Pvt. Ltd.) Di sodium hydrogen phosphate and potassium dihydrogen phosphate (Thermo Fisher Scientific India Pvt. Ltd.) and equipment were used for the experiment: UV-visible spectrophotometer (Double Beam Spectrophotometer, LAB INDIA, 3200+), analytical balance (Essae, Vibra AJ-220E), Monsanto hardness tester (Sisco's), friability tester (Roche Friability test), disintegration test apparatus (Veego), the digital vernier callipers from Perfect Sales India and the pH meter (Systronics-802) were used to provide accurate measurements.

2.2. Telmisartan UV-spectroscopy analysis

2.2.1. Preparation of phosphate buffer(pH 6.8)

A 28.80 g of disodium hydrogen phosphate and 11.45 g of potassium dihydrogen phosphate were dissolved with water and the volume was made up to 1000 mL [11].

2.2.2. Preparation of hydrochloric acid (0.1N)

Diluted 9 mL of hydrochloric acid in 100 mL of distilled water to give HCl (0.1N) [12].

2.2.3. Preparation of standard stock solution

The primary stock solution of telmisartan was prepared by dissolving 10 mg of the drug (accurately

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weighed) and transferred into a two clean and dry 100 mL volumetric flask and dissolved in 10 mL of methanol in each flask and made the volume up to the mark using phosphate buffer (pH 6.8) and HCl (0.1N) as a diluent to get 100 µg/mL drug solution. The standard stock solution is 100 µg/mL [13].

2.2.4. Selection of detection wavelength for estimation of telmisartan

The prepared solution of telmisartan (100 µg/mL) was scanned in the ultraviolet wavelength region (200-400 nm) to determine the wavelength of maximum absorption (λmax). It was observed that the drug showed maximum absorbance at 296 nm. It was chosen as the absorption maxima for further study of telmisartan.

2.2.5. Construction of standard calibration curve of telmisartan

Appropriate aliquots (0.2, 0.4, 0.6, 0.8, 1.0 and 1.2 mL) of prepared standard stock solution were transferred into a series of 10 mL volumetric flasks and diluted and made up to the mark with phosphate buffer (pH 6.8) and HCl (0.1N) to obtain a final concentration of 2-12 µg/mL. The above solutions were scanned over the range of 200 nm to 400 nm against a reagent blank and overlay spectra of telmisartan in both mediums. The absorbances of each solution were measured at 296 nm against phosphate buffer (pH 6.8) and HCl (0.1N) as a blank. The measured absorbances were plotted graph with concentration on the x-axis and absorbances on the y-axis to get a calibration curve. The results of the calibration curve are shown in Figs. 2 and 3.

2.3. Evaluation tests for the branded telmisartan tablets

Different analytical and test methods are necessary for pharmaceutical formulations. The evaluation of selected brands of telmisartan tablets were conducted by official test methods, including weight variation test, content uniformity test, disintegration test and non-official tests including friability, hardness and thickness tests.

2.3.1. Weight variation test

The dosage uniformity of telmisartan tablets was evaluated by weight variation, where twenty tablets from each of the six brands were selected by chance and weighed individually with an analytical balance. The average weights for each brand as well as the percentage deviation from the mean value were calculated [14].

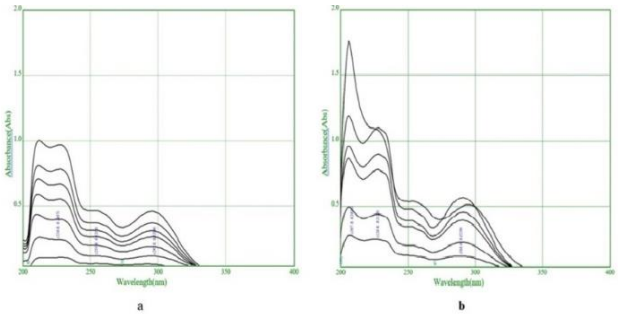

Figure 2. Overlay spectra of telmisartan (**a**). phosphate buffer (**b**) HCl

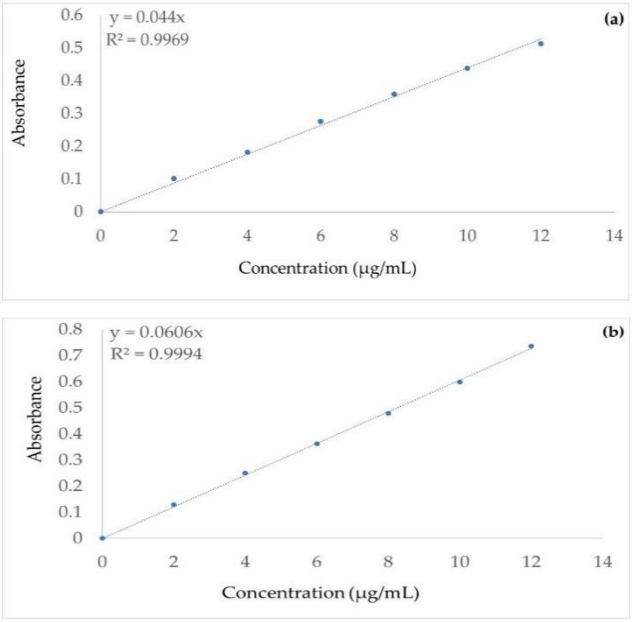

Figure 3. Calibration curve of telmisartan (**a**). phosphate buffer (pH 6.8); (**b**). HCl

2.3.2. Disintegration test

The disintegration test apparatus (Electolab ED-2L) was used to determine the disintegration time of the selected tablets. Six tablets were placed in a disintegration tester filled with distilled water at 37±0.5°C. The tablets were considered completely disintegrated when all the particles were passed through the wire mesh and time was recorded [15].

2.3.3. Drug content

The drug content of telmisartan in the formulated tablets was measured by randomly picking 20 tablets from each brand was crushed separately and finely powdered by using a mortar and pestle. An accurately weighed portion of the powder was transferred,

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Table 2. Weight variation test results of telmisartan tablets

Sl. No.	Weight variation (mg)					
	Telismart	Telmisafe	Teltan	Telkonol	Telmiwock	Telmikind
1	0.250	0.137	0.245	0.210	0.182	0.201
2	0.253	0.137	0.243	0.215	0.180	0.201
3	0.253	0.137	0.235	0.208	0.184	0.195
4	0.248	0.137	0.246	0.212	0.183	0.197
5	0.255	0.138	0.242	0.205	0.182	0.197
6	0.252	0.133	0.238	0.211	0.183	0.200
7	0.251	0.131	0.245	0.212	0.186	0.210
8	0.249	0.135	0.241	0.212	0.181	0.197
9	0.250	0.137	0.241	0.212	0.183	0.199
10	0.249	0.134	0.244	0.208	0.184	0.199
11	0.254	0.139	0.245	0.212	0.181	0.195
12	0.250	0.134	0.241	0.214	0.184	0.195
13	0.252	0.136	0.241	0.208	0.180	0.201
14	0.254	0.137	0.237	0.213	0.180	0.193
15	0.253	0.136	0.243	0.211	0.176	0.193
16	0.246	0.136	0.242	0.209	0.176	0.199
17	0.251	0.134	0.241	0.210	0.182	0.201
18	0.250	0.135	0.241	0.210	0.182	0.195
19	0.252	0.138	0.240	0.213	0.183	0.195
20	0.250	0.134	0.240	0.212	0.181	0.197
Avg. wt. (g)	5.022	2.719	4.826	4.853	3.654	3.964
Deviation (%)	0.04213	0.03523	0.05743	0.09832	0.1098	0.04121

equivalent to about 40 mg of telmisartan into 100 mL volumetric flasks and made up the volume to the mark using phosphate buffer (pH 6.8) and HCl (0.1N) as a diluent. The active pharmaceutical ingredient contents of sample solutions were determined by measuring their absorbance against the reagent blank at 296 nm using an ultraviolet-visible spectrophotometer. The contents of the drug in the tablet were found using the calibration curve [13].

2.3.4. Hardness test

The tablet hardness tester function is based on the principle that it yields a definite extent of force to break down a tablet. The hardness of each tablet was determined by selecting six tablets randomly using a hardness tester. Each tablet was placed between two anvils and force was applied to the anvils, and the crushing strength that causes the tablet to break was recorded. The crushing strength of an average of six tablets was recorded [16].

2.3.5. Friability test

The friability test was completed by using the Roche friabilator. Twenty tablets were selected randomly from each brand and weighed, then placed together in the friabilator device. All tablets were subjected to the combined effect of abrasion and shocks and it was rotated at 25 revolutions per minute (rpm) for four minutes (100 times). Then, tablets were weighed and compared with their initial weights and percentage friability was calculated [17].

2.3.6. Thickness measurement

The measurement of the diameter and the thickness was done for selected telmisartan 20 tablets was taken from different brands, and the diameter and thickness of the tablets were measured using micrometres to determine the average thickness and diameter. The mean, percentage deviation from the mean and Standard Deviation (SD) were calculated [18].

3. Results and discussion

3.1. Weight variation test

All results for the weight variation test of the six marketed products from different companies are documented in Table 2. The weight variation test of the tablet is used to confirm that the prepared tablet has the accurate amount of active drug in which no more than two tablets are outside the percentage limit. The results indicate a weight uniformity in the selected tablets and all tablets within the usual range,

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and no one exceeds the allowed percentage specified in the Indian Pharmacopoeia (IP).

3.2. Disintegration test

The mean disintegration times of the different brands of telmisartan tablets are shown in Table 3.

Table 3. Disintegration test results of telmisartan tablets

S.No.	Brand	Disintegration #	Acceptance criteria
1	Telismart	6 mins 32 secs	Pass
2	Telmisafe	6 mins 14 secs	Pass
3	Teltan	11 mins 45 secs	Pass
4	Telkonol	27 mins 13 secs	Pass
5	Telmiwock	25 mins 40 secs	Pass
6	Telmikind	8 mins 46 secs	Pass

 # Six tablets of each brand

The results showed that all the brands passed the disintegration test according to USP in 2007, which specifies 15 minutes for uncoated and 30 minutes for film-coated tablets. Tablet disintegration is a prerequisite to dissolution and subsequent absorption of a drug from the dosage form. A drug incorporated in a tablet is released rapidly as the tablet disintegrates because the rate of disintegration affects the dissolution and subsequently the therapeutic efficacy of the medicine. Different formulation factors are known to affect the results of the disintegration test. The type and number/amount of excipients used in tablet formulation as well as the manufacturing process are all known to affect both the disintegration and dissolution parameters.

3.3. Drug content

Percentages of content uniformity tests for selected brands of telmisartan tablets were shown in Table 4. The percentage range for all selected marketed tablets were found to be between 99.48% to 99.92% for phosphate buffer (pH 6.8) and 99.88% to 100% for HCl (0.1N). In content uniformity testing for selected tablets, each content was within the limits range of the average content; therefore, all the selected tablets passed the uniformity of content test.

3.4. Hardness test

Sufficient tablet hardness is essential to ensure destruction resistance to endure mechanical shocks during production, packaging, and transportation. In addition, tablets should be able to tolerate reasonable mishandling by the consumer. The mean hardness values of telmisartan tablets are tabulated in Table 5.

Table 4. Drug content results of telmisartan tablets

Sl.No.	Brand	In Buffer (pH 6.8)		In HCl (0.1N)	
		Drug content (mg/tab) #	Recovery (%)	Drug content (mg/tab)	Recovery (%)
1	Telismart	39.96	99.92	39.968	99.92
2	Telmisafe	39.55	99.92	39.96	99.92
3	Teltan	39.55	99.00	39.95	99.87
4	Telkonol	39.79	99.48	39.79	99.48
5	Telmiwock	39.05	99.625	39.85	100
6	Telmikind	39.20	98.00	39.48	100.2

 # Twenty tablets of each brand

Table 5. Hardness test results of telmisartan tablets

Sl. No.	Hardness(kg/cm^2)					
	Telismart#	Telmisafe#	Teltan#	Telkonol#	Telmiwock#	Telmikind#
1	4.5	4	7.5	4.5	5.5	5
2	4.5	4	7.5	4.5	5.5	5
3	4.5	4	7.5	4.5	5.5	5
4	4.5	4	7.5	4.5	5.5	5
5	4.5	4	7.5	4.5	5.5	5
6	4.5	4	7.5	4.5	5.5	5

 # Six tablets of each brand

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Table 6. Friability test results of telmisartan tablets

S.No.	Friability				
	Brand name	Initial weight (g) #	Final weight (g) #	Friability (%) #	Result#
1	Telismart	5.056	5.046	0.1977	Pass
2	Telmisafe	2.732	2.730	0.0732	Pass
3	Teltan	4.846	4.872	0.4127	Pass
4	Telkonol	4.876	4.872	0.0936	Pass
5	Telmiwock	3.654	3.642	0.3280	Pass
6	Telmikind	3.964	3.956	0.2018	Pass

 # Twenty tablets of each brand

Table 7. Thickness of selected brands of telmisartan tablets

Sl. No.	Thickness (mm)#					
	Telismart	Telmisafe	Teltan	Telkonol	Telmiwock	Telmikind
1	3.86	3.63	3.51	3.64	2.97	3.69
2	3.84	3.63	3.51	3.72	2.97	3.70
3	3.83	3.64	3.51	3.63	2.97	3.68
4	3.86	3.58	3.51	3.65	2.97	3.70
5	3.85	3.63	3.49	3.65	2.97	3.69
6	3.86	3.62	3.44	3.67	2.98	3.65
7	3.87	3.62	3.46	3.60	2.93	3.69
8	3.86	3.62	3.48	3.68	2.96	3.66
9	3.86	3.61	3.47	3.67	2.93	3.69
10	3.88	3.64	3.46	3.64	2.98	3.64
11	3.85	3.61	3.49	3.63	2.99	3.70
12	3.88	3.60	3.44	3.61	2.97	3.69
13	3.85	3.64	3.45	3.58	2.98	3.67
14	3.88	3.62	3.45	3.59	2.96	3.69
15	3.88	3.65	3.44	3.58	2.99	3.62
16	3.88	3.67	3.51	3.54	2.99	3.64
17	3.87	3.63	3.50	3.66	2.98	3.61
18	3.86	3.66	3.49	3.65	2.96	3.66
19	3.86	3.62	3.51	3.67	2.94	3.68
20	3.86	3.63	3.50	3.64	2.97	3.65
Average	3.862	3.6275	3.481	3.635	2.968	3.67
S.D	0.6246	0.3556	0.1082	0.0418	0.4437	0.5091

 # Twenty tablets of each brand

3.5. Friability test

Tablets must resist corrosion when subjected to tensions from collision and tablet slip towards one another and other solid bodies, which can result in removing small pieces from the tablet surface. It is usually measured by a friability tester. In the friability test, the friability values for telmisartan tablet brands ranged from 0.732 to 0.3280%. All Six brands of telmisartan have passed the friability test and met the IP specification, which specifies that any brand must not lose more than 1% of its initial weight presented in Table 6. The result may further suggest the resistance of the tablets to external forces from manufacturing, distributing, and shipping. At the same time, high tablet strength should not interfere with the disintegration than the dissolution of the drug in the stomach.

3.6. Thickness measurement

Results showed that the different brands examined thicknesses were within the range of 3.60-3.88 mm (Table 7) except telmiwock shows nearly 2.94 - 2.99 mm. All brands showed acceptable thickness as none of the selected brands deviated by up to ± 5.0% from the mean value as stipulated by the reference.

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4. Conclusions

The results of this study showed that all brands of telmisartan 40 mg (telismart, telmisafe, teltan, telkonol, telmiwock and telmikind) oral tablets conformed to the official specification of the standard pharmacopoeia. All tablets disintegrated within a time limit of less than 30 minutes. According to the outcomes of this study, there were no deviations from pharmacopeial standards. This study provides valuable insights into the manufacturing processes of these pharmaceutical brands, instilling confidence in the reliability and effectiveness of their tablet formulations. Further research may explore additional parameters or variations in manufacturing conditions to enhance our understanding of tablet quality across different production scenarios.

Authors' contributions

Conceived of the presented idea, M.M.E., P.S.K.; Methodology developed and assessed, G.R.S., P.V.N., D. A., M. N.H., C.S.K.; Supervised the calculations, M.M.E., P.S.B.; Wrote the manuscript, G.R.S., M.M.E.

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Availability of data and materials

All relevant data are within the paper and its supporting information files. Additional data will be made available on request according to the journal policy.

Conflicts of interest

The authors confirm that no conflict of interest is involved with any parties in this research study.

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