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EVALUATION OF VARIOUS BRANDS OF TELMISARTAN IP FOR ITS QUALITY CONTROL TEST

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Abstract: **Telmisartan is a Cardiovascular drug used to treat high blood pressure, heart failure, and diabetic kidney disease and belongs to the Angiotensin II receptor blocker. The drug absorption varies in different patients from the gut. Selected brands of Telmisartan IP 40 mg were procured from the market with the same label claim amount of drug for quality control test. Various quality control tests such as weight variation, friability, disintegration, dissolution and uniformity content were performed as per Indian Pharmacopeia. The quality control tests were done for five different brands of Telmisartan IP marketed Products. The result proved that the Telmisartan IP 40 mg, varies with disintegration, dissolution, uniformity content tests but within the limit. Further studies are needed to support the variation in the quality control test with human volunteers.**

Keywords: **Telmisartan, Angiotensin II receptor, Drug absorption, Quality control tests.**

1. INTRODUCTION

Telmisartan is a Cardiovascular drug. It is widely used to treat high blood pressure, heart failure, and diabetic kidney disease and belongs to the Angiotensin II receptor blocker. It works by blocking the renin-angiotensin system (ACE Inhibitors). It usually binds with the angiotensin II type 1 (AT1) receptors which have a high affinity, causing the inhibition of the action of the angiotensin II on vascular smooth muscle, which leads to the decrease in the arterial blood pressure[1]. Usually, the drug absorption varies with different patients from the gut. In the higher dose, it may lead to a fast heartbeat, severe dizziness, and fainting. The objective of the present experiment was to evaluate the quality control tests of various brands of commercially available Telmisartan IP 40mg tablets. Various quality control tests such as weight variation, friability, disintegration, uniformity content, and dissolution were performed as per Indian Pharmacopeia.

2. QUALITY CONTROL TEST

I. Weight Variation:

The weight of the tablet is usually determined by the quantity of powder fill in the die of a tablet press. The volume of fill is adjusted with the first few tablets to yield the desired weight and content[2]. If there is any improper flow of powder to the die, it forms the uneven tablets which contain the low dose or high dose of the drug. The percentage of deviation allowed as per IP is 10% for 80mg or less, 7.5 % for 80mg to 250mg, 5% for more than 250mg. For Telmisartan tablets it is 10%.

II. Friability:

Friability is a tablet's durability or the ability of the tablets to withstand the mechanical shocks during manufacturing, packing, handling, and shipping. It is intended to determine the physical strength of the tablet. It is one of the in-process quality control tests for tablets. The maximum loss of percentage allowed as per IP is 1%. For Telmisartan tablets of various brands, the average is found to be 0.8%.

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III. Disintegration:

Disintegration is the mechanical break up of a compressed tablet into small granules upon ingestion and therefore it is characterized by the breakdown of the inter particulate bonds, which were forged during the compaction of the tablet. It is the state in which no residue of the unit under the test remains on the screen of the disintegrating Apparatus[3]. For uncoated tablets, the time needs to disintegrate is 15 minutes as per IP. For Telmisartan IP 40mg tablets it varies in the brand but they are within the limit

IV. Uniformity Content:

An assay or uniformity content is an analytical procedure for quantitatively measuring the amount of active ingredient present in the tablet. It gives an accurate and exact numeric quantitative measure of the amount of a substance present in a tablet.

V. Dissolution:

Dissolution is the amount of drug that goes into the solution per unit time. It demonstrates that the drug will be readily available for absorption after oral administration *(Ousama Rachid et al.,)*. During dissolution, the drug molecules in the surface layer dissolve, which leads to a saturated solution around the particles to form the diffusion layer. Dissolved drug molecules then pass through out the dissolving fluid to contact absorbing mucosaand are absorbed. Figure 1 explains the dissolution process in detail. It is usually performed to maintain the batch to batch consistency of tablets in the pharmaceutical industry.

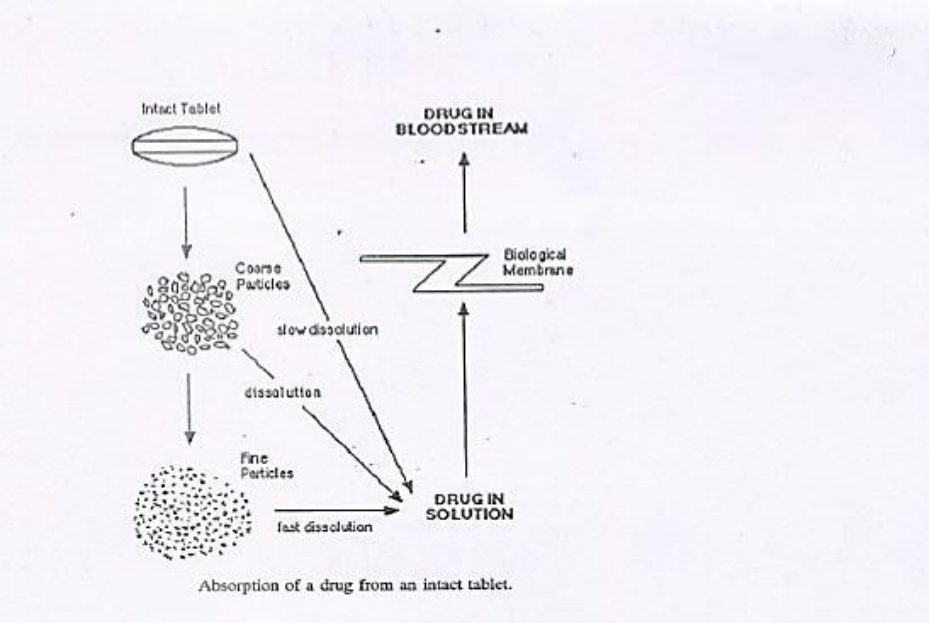

Fig no.1 Dissolution process

3. METHODOLOGY

Materials and methods:

Various marketed brands of Telmisartan tablets, were chosen for the experiment.

1. Telmikind-40
2. Telma-40
3. Targit-40
4. Tazloc-40
5. Telmisartan tablet IP 40 mg (Jan aushadhi).

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I. Weight Variation:

Weigh individually 20 units of selected telmisartan tablets at random, and calculate its average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage which stated in the IP and none deviates by more than twice that percentage.

Instruments Used: Calibrated Electronic Digital Weighing Balance.

II. Friability:

Take the telmisartan tablets and dedust the tablets carefully, weigh them accurately to 6.5 g, then the weighed tablets are placed in the drum and rotate the drum in 100 times rotation or set the RPM to 25 for 4 minutes. At the end of operation remove all the tablets and ensures that the tablets are free from the dust and weigh them accurately, determine the percentage loss.

Instrument used: "Roche's Friabilator"

III. Disintegration Test:

Introduce the telmisartan tablets into each tube and suspend the assembly in a beaker containing 900 ml of 0.01 M HCL and operate the apparatus for the specific time for the temperature of $37^0 \pm 2^0$ C with the frequency of 32 cycles per minute. At the end of the test remove the assembly from the liquid.

Instruments used: **"**Disintegration tester"

IV. Uniformity Content:

1. Preparation of sample solution:

Accurately weigh the 20 tablets and crush the tablets using mortar and pestle. Take the equivalent weight of 20 mg of the telmisartan drug powder and transfer into the 100 ml volumetric flask and dissolve it using freshly prepared 20 ml of 0.1 N NaOH under sonification and make up the volume to 100 ml using distilled water, and then filter with what man filter paper No. 41, from that, take 5 ml and then transfer to 100 ml volumetric flask and makeup to the volume with distilled water. The absorbance is to be measured at 234 nm[4] against the blank solution.

2. Preparation of Blank solution:

Take freshly prepared 20ml of NaOH and transfer it into a 100 ml volumetric flask and makeup to the volume of 100 ml. From this solution, take 5ml and transfer to the 100 ml volumetric flask and makeup to the volume of 100 ml.

3. Preparation of 0.1 N NaOH:

Dissolve the 3.9 g of NaOH pellets in 1000ml of distilled water.

Instrument used: "Digital weighing balance, UV-Visible Spectrophotometer"

V. In-Vitro Dissolution Test:

(PARAMETERS)

Apparatus No:	*1 (IP Paddle apparatus).*
Medium:	*900 ml of Phosphate buffer pH 7.5.*
Speed and time:	*75 Rpm and 30 min.*
Temperature:	*37℃ (for both medium and water bath).*

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1. Preparation of medium:

900 ml of Phosphate buffer pH 7.5 is prepared by dissolving the 13.61 g of Potassium dihydrogen Phosphate in 800 ml of distilled water, adjusted to pH 7.5 M with 2 M sodium hydroxide, dilute with water to 1000 ml.

2. Preparation of 2M Sodium Hydroxide:

Dissolve 78 g of Sodium Hydroxide in 1000 ml of distilled water.

3. Procedure:

900 ml of Phosphate Buffer having pH 7.5 is placed in the vessel of the dissolution test apparatus and the medium is equilibrated to the temperature of 37± 5℃. To each basket, one tablet of the same brand was placed and the dissolution apparatus is operated for 30 minutes. At end of 30 minutes of operation with drawn the10ml of fluid with a pipette (cotton edge) from the dissolution apparatus, transfer it into the 50 ml volumetric flask and make up the volume

with distilled water so that the concentration of the solution become $8.8\mu g/ml$. The absorbance is to be measured at 234 nm against the blank solution.The same procedure is repeated for the subsequent brands.

4. Preparation of Blank solution:

Take freshly prepared 10 ml of Phosphate Buffer having pH 7.5 and transfer it into a 50 ml volumetric flask and makeup to the volume of 50 ml with distilled water.

Instruments Used: "Dissolution test apparatus, UV-Visible Spectrophotometer"

4. RESULT

The result of the evaluation of various brands of telmisartan tablets under different quality control test was given and discussed.

I. Weight variation test:

- The weight variation test of various brands of telmisartan tablets are shown in Table.1

Table.1

S.No	Brand	Label claim	Average Weight of 20 tablets	Percentage Difference
1.	Telmikind 40	40 mg	3.107	0.15
2.	Telma 40	40 mg	8.207	0.41
3.	Tazloc 40	40 mg	2.24	0.11
4.	Targit 40	40 mg	13.33	0.66
5.	Telmisartan Tablets (Jan aushadhi)	40 mg	8.23	0.41

II. Friability test:

- The Friability test of various brands of telmisartan tablets are shown in Table.2

Table.2

S.No	Brand	Initial Weight	Final Weight	Friability
1.	Telmikind 40	4.095	4.074	0.512820513
2.	Telma 40	3.726	3.706	0.536768653
3.	Tazloc 40	5.432	5.384	0.88365243
4.	Targit 40	6.502	6.467	0.538295909
5.	Telmisartan Tablets(Jan aushadhi)	3.985	3.953	0.803011292

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III. Disintegration test:

- The Disintegration test of various brands of telmisartan tablets are shown in Table.3

Table.3

S.No	Brand	Average Time is taken to disintegrate (in minutes)	Inference
1.	Telmikind 40	13.55	Passes the IP Limit
2.	Telma 40	12.5	Passes the IP Limit
3.	Tazloc 40	11.31	Passes the IP Limit
4.	Targit 40	9.45	Passes the IP Limit
5.	Telmisartan Tablets(Jan aushadhi)	14.16	Passes the IP Limit

IV. Uniformity Content Test:

- The Uniformity Content Test of various brands of telmisartan tablets are shown in Table.4 and Figure.2 shows the comparison of various brands.

Table. 4

S.No	Brand Name	Weight of 20 Tab	Average weight	Eq.wt	Abs	A ($1^{\%}_{1cm}$)	After Dilution	Drug present in Average weight content	Purity
1	Telmikind 40	3.982	0.1991	0.0995	0.889	912.02	0.01949	0.038990031	97.4
2	Telma 40	2.544	0.1272	0.0636	0.882	912.02	0.01934	0.038683023	96.7
3	Tazloc 40	5.192	0.2596	0.1298	0.879	912.02	0.01927	0.038551448	96.3
4	Targit 40	4.834	0.2417	0.1208	0.896	912.02	0.01964	0.039297039	98.2
5	Telmisartan Tablets (Jan aushadhi)	3.967	0.1983	0.0991	0.875	912.02	0.01918	0.038376015	95.9

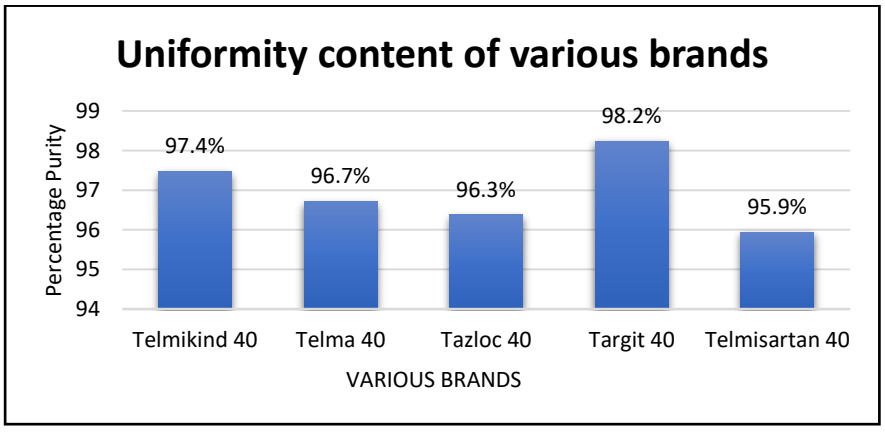

Fig no.2

V. Dissolution Test:

- The Dissolution Test of various brands of telmisartan tablets are shown in table 5 and figure 3 shows the differences in various brands.

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Table. 5

S.No	Brand Name	Label claim	Wavelength	$A^{1\%}_{1cm}$	Time (min)	Dilution Factor	% of drug Release
1	Telmikind 40	0.04	234 nm	912.028	30 min	45	86.65
2	Telma 40	0.04	234 nm	912.028	30 min	45	84.76
3	Tazloc 40	0.04	234 nm	912.028	30 min	45	82.43
4	Targit 40	0.04	234 nm	912.028	30 min	45	93.02
5	Telmisartan 40 (Jan aushadhi)	0.04	234 nm	912.028	30 min	45	77.13

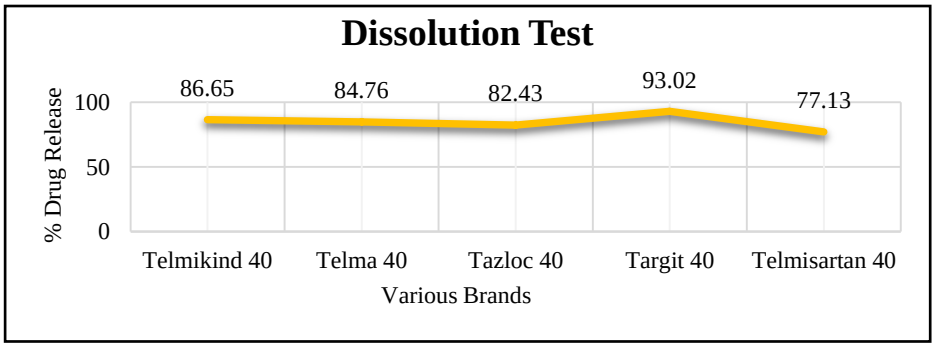

Figure 3

5. DISCUSSION

S.No	Brand Name	label claim	Weight Variation test (1)	Friability (2)	Disintegration (3)	Assay (4)	Dissolution (5)
1	Telmikind 40	40 mg	✓	✓	✓	✓	✓
2	Telma 40	40 mg	✓	✓	✓	✓	✓
3	Tazloc 40	40 mg	✓	✓	✓	✓	✓
4	Targit 40	40 mg	✓	✓	✓	✓	✓
5	Telmisartan 40 (Jan aushadhi)	40 mg	✓	✓	✓	✓	✓

✓ - Pass the IP Limit.

X - Fails the IP Limit.

Limitations of the study:

- As the evaluations are experimental, there might be errors related to instrumental constraints or technical problems. Here hardness test was not performed due to the non-availability of the instrument.

6. CONCLUSION

As a result of the evaluation study of different marketed brands of Telmisartan IP 40 mg, we have concluded that all the five brands which we have taken comply with the Indian Pharmacopeial standards. As quality control parameters are important for the desired pharmacological action of the drug, a high-quality tablet should meet all the standard quality control parameters for getting its desired therapeutic response. Here for telmisartan IP 40 mg drugs there might be quantitative variation often exists among drugs of different brands. However, despite the variation, most of the brands are

within the official limit (i.e. IP).The prescribing patterns of telmisartan should be changed depending upon the socio-economic status of the patients. In conclusion, these formulations of different brands of telmisartan IP 40 mg were passing the Indian Pharmacopeial limit and it will produce the desired pharmacological action to the patient.

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