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COMPARATIVE STUDY ON COMMERCIALLY AVAILABLE OF GENERIC AND BRAND NAME TABLETS CONTAINING PARACETAMOL AS API

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ABSTRACT

Now a day we are doing the work for developing the awareness about generic medicines. In this research article, we are focused on the exact fact about generic and brand name drugs regarding their quality, strength and purity. In laboratory we tested commercially available tablets of generic and brand name in which PARACETAMOL as Active Pharmaceutical Ingredient (API). Paracetamol is one, which has antipyretic & analgesic activity. Comparative study was made using various apparatus and instruments. A comparison was made between the claimed value of the different brand and generics according to their observed value. The results of comparative study of various samples are discussed in respect to their evaluation test i.e. Friability, Disintegration, Weight variation, UV Spectroscopy and Hardness test. As per practical results we expect excellent class of generic medicines than already available in market for better therapeutic activity.

INTRODUCTION

"The decision to choose a brand name or a generic is one that involves you and your health care team." A brand name drug is a medicine that's discovered, developed and marketed by a pharmaceutical company. Once a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drug. At this point the drug has two names: a generic name that's the drug's common scientific name and a brand name to make it stand out in the marketplace. This is true of prescription drugs as well as over-the-counter drugs. An example is the pain reliever Tylenol®. The brand name is Tylenol® and the generic name is acetaminophen.

Generic drugs have the same active ingredients as brand name drugs already approved by the Food and Drug Administration (FDA). Generics only become available after the patent expires on a brand name drug. Patent periods may last up to 20 years on some drugs. The same company that makes the brand name drug may also produce the generic version. Or, a different company might produce it. Generic medicines are those where patent protection has expired, and which may be produced by manufacturers other than the innovator company. Use of generic medicines has been increasing in recent years, primarily as a cost saving measure in healthcare provision. Generic medicines are typically 20 to 90% cheaper than originator equivalents. Our objective is to provide a high-level description of what generic medicines are and how they differ, at a regulatory and legislative level, from originator medicines. The same company that makes the brand name drug may also produce the generic version. Or, a different company might produce it.

PARACETAMOL

Paracetamol (acetaminophen, C8H9O2N) is one of the most frequently prescribed anti-inflammatory, antipyretic, and analgesic drugs [8].It is a common analgesic & antipyretic drug that is used for the relief of fever, headache, & other minor aches & pains [6]. An Antipyretic is a drug that is responsible for lowering the temperature of a feverish organism to normal but has no effect on normal temperature states. The words ace amino Phenol & Paracetamol both come from the chemical name for the compound N-Acetyl Para- Amino phenol & Para acetyl amino phenol. Paracetamol has a characteristic of both antipyretic as well as analgesic [9]. Its effectiveness as an antipyretic agent has been attributed to its effect on the hypothalamic heat center, while its analgesic efficacy is due to its ability to raise the pain threshold [7].

MATERIAL AND METHODS:

Easily available Brand Name and Generic tablet samples in the market containing paracetamol as API.

Description: White crystalline powder or white crystal.

Samples taken for the Evaluation study & analysis of Paracetamol Tablet

Experimental:

Evaluation of Different Paracetamol Tablet:

1. **Friability Test**

   Procedure:

   Weigh 20 tablets and place it in a friabilator, run the friabilator for 4 minutes at 25 rotations/minute or 100 rotations, again weigh the tablets and calculate the percentage loss in weight.

2. **Disintegration Test**

   Procedure:

   Place 6 tablets into each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified time. The tablets pass the test if all of them have disintegrated.

   Limit: Maximum limit is 15 minutes.

3. **Hardness Test**

   Place the tablets between the jaws of Monsanto hardness tester and slowly go on rotating the screw until the tablet breaks. Note down the reading in terms of Kg/cm2 and make the recording of 5 tablets.

   Limit: The hardness should be more than 4 Kg/cm2.

4. **Weight Variation Test**

   Weigh 20 tablets selected at random and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the following table and none deviates by more than twice the percentage.

Sr. NO.	Average weight of tablets	Percentage of deviation
1.	80 mg or less	10
2.	More than 80 mg but less than 250 mg	7.5
3.	250 mg or more	5

QUALITATIVE ANALYSIS:

Melting Point:

Instrument Used: - Melting Point Apparatus, Capillary tubes

Procedure

The tablets were crushed to a very fine powder and were introduced into a capillary glass tube in sufficient quantity to form a compact column of 4 to 5 mm high. The bath was heated until the temperature was about 100^0C below the expected melting temperature. The heating was continued and the temperature was noted at which the column of the sample collapsed against the side of the tube at any point, when melting may be considered to have begun as seen by the formation of a definite meniscus.

RESULTS:

1. **Friability Test**

   For Generic Drugs:

   Weight of 20 tablets, X: = 12.02gm

   Weight of tablets after test, Y: = 11.72gm

   Loss in weight, X-Y: =0.3 gm

   Percentage loss in weight :=(X-Y/X) x 100

   =**2.49%**

   For Brand-Name Drugs:

   Weight of 20 tablets, X: =12.73gm

   Weight of tablets after test, Y: =12.62 gm

   Loss in weight, X-Y: =0.11gm

   Percentage loss in weight:=(X-Y/X) x 100

   =**0.86%**

   Limit: It should be less than 1%w/w.

   Result:

The Brand-Name tablets **‘’PASS’ ’**the friability test.

2. **Disintegration Test:**

Limit: Maximum limit is 15 minutes.

Result:

The disintegration time for **Brand-Name** tablets is **1min 20sec**.

The disintegration time for **Generic** tablets is **30 sec.**

3. **Hardness Test**

No. of Tablets	**Hardness in Kg/cm2**				
	1	2	3	4	5
For Generic Drugs	**3.1**	**3**	**3**	**3.2**	**3**
For Brand-Name Drugs	**5**	**5**	**5**	**5**	**5.1**

Result:

The tablet **‘’PASS’’** the Hardness test for brand-name drugs.

4. **Weight Variation Test**

For Generic drugs:

Tablet No.	1	2	3	4	5	6	7	8	9	10
Weight in gm.	0.58	0.57	0.56	0.56	0.57	0.57	0.57	0.54	0.55	0.57
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Tablet No.	11	12	13	14	15	16	17	18	19	20
Weight in gm.	0.59	0.57	0.57	0.56	0.57	0.55	0.56	0.57	0.55	0.56
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

$$\text{Average weight} = \frac{\text{Weight of 20 tablets}}{20}$$

= 12.02/20

= **0.601 mg**

For Brand-name Drugs:

Tablet No.	1	2	3	4	5	6	7	8	9	10
Weight in gm.	0.63	0.63	0.63	0.65	0.65	0.65	0.64	0.63	0.64	0.63
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Tablet No.	11	12	13	14	15	16	17	18	19	20
Weight in gm.	0.63	0.63	0.63	0.62	0.65	0.63	0.62	0.64	0.63	0.64
Pass/Fail	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Average weight= $\frac{\text{Weight of 20 tablets}}{20}$

= 12.73/20

= **0.6365 mg**

Result:

The given tablets **‘’PASS’’** the test for uniformity of weight.

QUALITATIVE ANALYSIS:

5. Melting Point:

Range;- Melts between 169^{o} C and 172 ^{o} C

Sr. No.	**Brand Name**	**Generic**
	M.P. (169-172˚ C)	
1	170^{0}C	173˚ C
2	169˚ C	171˚ C
3	169˚ C	174˚ C
Average	**169.33˚ C**	**172.66^{0}C**

Result:

The given Brand Name tablets **‘’PASS’’** the test for Melting Point

DISCUSSION

The present investigation on different samples which contain paracetamol was carried out to study comparative evaluation test. The comparative results for the different evaluation test were shown as 1. Friability Test for generic tablet does not pass while brand name tablet pass the test. Percentage loss in weight was found 2.49% and it was above limit. So it indicates tablets get breached during transportation and handling. 2. The disintegration time for Brand-Name tablets is 1 min 20 sec. while the disintegration time for Generic tablets is 30 sec. it's due to the Compression force, improper granulation, conc. of binder. 3. The tablet ''PASS'' the Hardness test for brand-name drugs while hardness of generic tablet was below 4 Kg/cm^2 so it indicates generic tablet having less binding agent, Compression force and improper granulation. 4. Weight of uniformity test passes by both the tablet; the weight observed by us is acceptable. 5. Melting point of the all samples of brand name tablet were under range while for generic is above its M. P. Range. It may be due to the presence of excipients.

CONCLUSION

Evaluation tests were carried out for comparative study on commercially available of generic and brand name tablets containing paracetamol as API. We concluded from the different evaluation parameters that generic medicines having some variations in respect to hardness test, disintegration test and Friability test. The total amount of API, which present in the both the tablet has sufficient quantity but differ in their evaluation test results so there is need to increase the quality and standard of generics. Also there is need to perform the other test like FTIR, SEM, DSC, XRD and dissolution test for prediction of exact results.

As per our initial lab experimental study, we found various loops in generic medicines such as Low quality of excipients, poor appearance and poor packaging may be responsible factors for the low price of generic medicines.

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