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Comparative Study of Generic and Branded Products

Prof. Sarda. R. R, Shinde Khanderao

Assistant Prof, Student,
Pharmaceutics
Dayanand College of Pharmacy, Latur, India

Abstract : Most of the Standard products of pharmaceutical companies are the patented drugs, when a pharmaceutical company innovates or discovers new drug they file a patent for the same and only they have the rights to manufacture the drug for around 20 years. After 20 Years when the patent is expired other companies can also manufacture that particular product, which is termed as branded generics. This means generics are the copy of branded drugs manufactured by different companies. In India there are lots of myths about quality of generic products because of different types of packaging and labelling of products. Many people consider generics as lower quality products because of lack of knowledge and not very well known manufacturers. So in this article we did comparative study of generic and branded products to understand whether generics maintain good quality and have same efficacy as that of standard drugs.

***IndexTerms* - : Branded Products, Generic Products, Electrolab Disintegration Apparatus (ED2L) Electrolab Dissolution Apparatus, Roche Friability Apparatus, Spectrophotometer Shimadzu (1900)**

I. INTRODUCTION

India today is known as world's pharmacy due to the giant production facilities in the country. It approximately caters 20% of global generic drug supply. Indian pharmaceutical sector may grow to US $100 billion in near future. Pharmaceuticals export from India stood at US $16.3 billion in FY20. As of November 2020, India exported pharmaceuticals worth US $15.86 billion in FY21. Pharmaceutical exports from India stood at US $16.28 billion in FY20.
There are two general terms used to describe medicinal products.

1. Innovator/Branded Product- A product which is developed for the first time by researcher and approved by regulatory agency.
2. Generic product- These are marketed once the patent expires for the innovator product. But, they may or may not hold specific brand name.

Why Generic Product

- **a.** The generic and branded products contain same API.
- **b.** Generics are sold at low cost as compared to innovator product.
- **c.** These are used for same therapeutic indication as that of innovator product.
- **d.** Excipient which are used in generic medicine are acceptable.
- **e.** The manufacturing of generic products follows same standard as the branded products.
- **f.** Generics are bioequivalent to the innovator products and hence it has good efficacy.

However, many patients in India still do not have enough knowledge about the concepts of generic medicines and hence in spite of having all possible advantages some patients deny using these medicines. Present study aims at comparing generic and branded products in terms of quality and efficacy by evaluating them as per formulation standards mentioned in IP.

Sr No	Generic Product	Price/tab (MRP)	Branded Product	Price/tab (MRP)
01	Aceclofenac and Paracetamol (100+325)	9.00/10	Acecloplus	76/15
02	Teneligliptin tab 20 mg	50/10	Tagon 20	186/15
03	Gliclazide tab IP 40 mg	14/10	Euclide 40	51.5/10
04	Bisacodyl tab IP 5 mg	6/10	Dulclox 5	10.19/10

Table 1- Some examples of generic and branded drug with their price

Pharmacologically Paracetamol is the mild analgesic and antipyretic drug which is used to treat mild pain, headache and fever. The Ibuprofen is the most potent antipyretic & analgesic drug which is effective for treatment of acute and chronic pain osteoarthritis, rheumatoid arthritis and related conditions.

The Ibuprofen & paracetamol are slightly soluble in water. Paracetamol tablet and Ibuprofen tablet contain not less than 95.0 % and not more than 105.0 % of the stated amount of drug. The paracetamol & Ibuprofen are frequently prescribed together to patient hence a combination tablet usually increase the patient compliance.

II. Apparatus and Equipment

Contech Analytical Balance, Electrolab Disintegration Apparatus (ED2L), Electrolab Dissolution Apparatus, Roche Friability Apparatus, Spectrophotometer Shimadzu (1900).

III. Sample Collection

Tablet Code	Manufacturing Date	Expiry Date
A	Sep.2018	Aug.2020
B	Sep.2018	Aug.2021
C	Feb.2018	Jun.2021
D	Feb.2018	Jan.2021
E	May.2018	Apr.2020

Table 2- Tablet samples with their manufacturing and expiry dates

To perform the study of paracetamol and ibuprofen combination tablet of five different brands of multinational and local companies were collected from the medical shop within the Maharashtra state and coded as A, B, C, D and E respectively. The entire paracetamol ibuprofen brands were labeled to contain 400 mg paracetamol and 325 mg ibuprofen per tablet. The commercial brands selected were of different companies.

IV. Study Design

It is the comparative in-vitro study of evaluation parameter between the collected branded and generic pharmaceutical brands. The standards and specifications followed were as per IP.

V. Methodology

All evaluation tests were conducted as per Indian pharmacopeia

Identification Test for Paracetamol

Extract a quantity of the powdered tablet containing 0.5 g of paracetamol with 20 ml of acetone, filtered; evaporate the filtrate to dryness and dry at105^0. The residue complies with the following tests.

A. Determine by infrared absorption spectrometry compare a spectrum with that obtained with paracetamol RS or reference spectrum of paracetamol.
B. Boil 0.1 g in 1ml of hydrochloric acid for 3 minutes, Add 10 ml of water and cool no precipitate is produced. Add 0.05 ml of 0.0167 M potassium dichromate a violet colour develops which does not turn red.

Identification Test for Ibuprofen

Extract a quantity of the powdered tablets containing 0.5 g of Ibuprofen with 20 ml of acetone, filter and evaporate the filtrate to dryness in a current of air without heating. The residue complies with the following tests.

A. Determine by infrared absorption spectroscopy compare the spectrum with that obtained with Ibuprofen RS or with the reference spectrum of Ibuprofen

B. The residue obtained in test A, after recrystallisation from light petroleum (40^0–60^0) melts at about $75^{0.}$

Weight Variation Test

Tablet of each brand were weighted individually using a digital analytical balance. Calculate the average weight using 20 tablets. Calculate percentage deviation of the individual tablet from the mean weight. Deviations were calculated as per IP standards.

Hardness Test

A tablet was placed vertically on the Monsanto Hardness tester. The load was then applied along the radial axis of the tablet. The weight or load required for breaking the tablet was noted down. Similarly it was done for 10 tablets

Friability.

Friability was performed using Roche Friabilator. 10 tablets were weighted and placed in apparatus. The apparatus was rotated at speed of 25 rpm for 4 minutes. The tablets were then weighed and the weight was compared with the initial weights. The percentage friability was calculated using the formula.

Tablet Disintegration

It was performed using Electro Lab disintegration apparatus (ED2L). Six tablets were placed in disintegration tests apparatus. It was maintained at $37^0 \pm 0.2^0$ containing simulated gastric fluid (0.1N HCL). Note down the time taken for tablet to disintegrate.

Dissolution Test

For this test USP Type-1 (Paddle) 6 Paddle Apparatus (ELECTROLAB Model no TDT-08L) was used. The tablet formed were immersed into 900 ml of dissolution medium, simulated gastric fluid (0.1N HC1).The temperature of the dissolution medium was maintained at 37 ± 0.2^0The basket was rotated at a speed of 150rpm.After an interval of every 10 minutes,2ml.of the medium was pipette out and replaced with fresh medium (0.1 N HC1).This was continued all along for one hour. pipette out samples were then diluted to 10ml.with fresh dissolution medium and were then filtered. The absorbance of the filtered samples were determined using U.V.Spectroscopy at max 222 nm. According to USP (10) specifications not less than 80% (Q)of the labeled amount of acetaminophen is dissolved within 30 minutes.

Assay

The dilution was obtained to the concentration of 10 µg/ml for both paracetamol and ibuprofen solution. Both the solution was scanned in UV range (200-400) in 10mm cell against solvent blank. Calculate the concentration of drug by using simultaneous equation method.

VI. Results

The results obtained for all the tests performed are summarized below-

Tablet Code	Weight Variation (%)	Friability (%)	Hardness (kg/cm^2)	Disintegration time (sec)
A	0.15	0.65	7	121
B	0.5	0.217	6.5	115
C	0.5	0.76	7.5	163
D	0.4	0.63	7.9	128
E	0.6	1.17	5	90

Table 3- Results of various evaluation tests carried out.

Time interval in minutes	% release of paracetamol and ibuprofen tablet				
	A	**B**	**C**	**D**	**E**
0	0	0	0	0	0
10	28.21	30.11	28.15	27.40	31.50
20	42.50	43.12	41.27	40.80	42.17
30	62.70	61.45	62.40	63.10	64.18
40	76.20	75.12	74.20	74.80	79.50
50	87.10	82.17	85.40	86.20	81.14
60	92.20	89.13	92.20	94.40	85.30

Table 4- Comparative dissolution study of tablets

Tablet code	Paracetamol (ug/ml)	% Content (paracetamol)	Ibuprofen (ug/ml)	% Content (Ibuprofen)
A	6.15	94.61	7.97	99.62
B	6.23	95.84	7.86	98.25
C	6.27	96.46	7.65	95.62
D	6.47	99.53	7.83	97.87
E	5.98	92	7.1	88.75

Table 5- Percent content of drugs in tablet sample

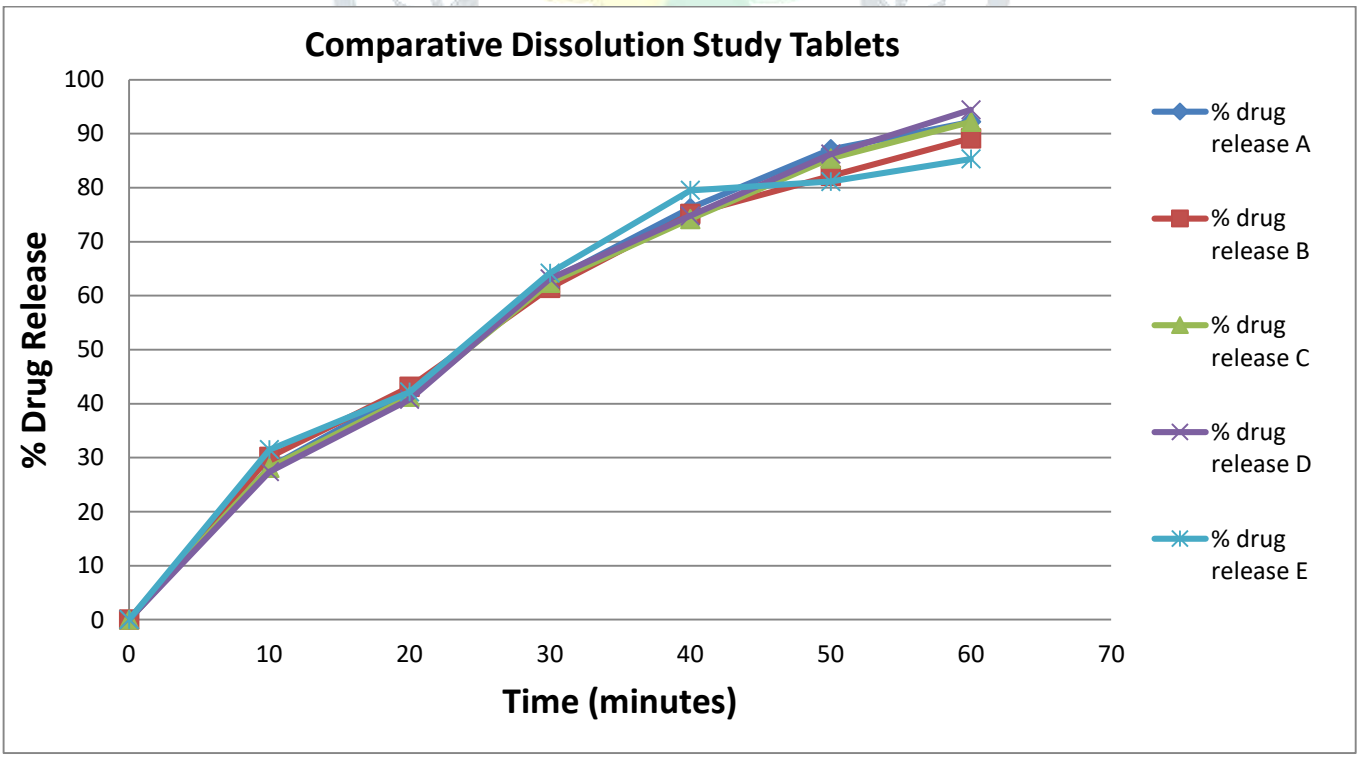

Figure 1- Comparative dissolution study of tablet samples

VII. Conclusion

All the samples including generic and branded products were evaluated as per tests and standards mentioned in IP. The results indicated that most of the generic products are having comparable quality with the branded products. All the samples except

sample E passed the evaluation criteria. It may be concluded that use of generic products should be encouraged to make affordable medicines available to all. At the same time substantial regulatory and quality checks must be implemented to ensure good generic products in market.

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