

A Brief Review Of The Research Comparing Branded Vs Generic Drug

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Abstract- The usage of branded and generic medications has generated a lot of global debate in recent years. Additionally, the government of several nations is adamantly encouraging the substitution of generic medications for branded ones. A generic medication has the same active component as its branded equivalent and has been demonstrated to have an equivalent therapeutic effect. Because generic drugs do not require the extensive and expensive preclinical or clinical trials that are required for branded drugs, their costs are significantly lower than those of branded drugs. This review sheds insight on the relative efficacy of generic and branded medications. Additionally, an effort is made to draw attention to the cost comparison of the two classes. Branded medication Generic medications are not subject to a patent that lasts for a specific amount of years. generic medication only need to fulfill the bioequivalency standards of their branded equivalents. Additionally, it takes a long time for branded drugs to be approved, whereas it takes significantly less time for generic drugs. Because it takes longer for a branded medication to be approved and because it costs more to create, branded medications end up being more expensive than generic medications on the market.

Keywords: Paracetamol, Calpol, Non-Steroidal, Non-Inflammatory, Assay, Organoleptic, Friability, Disintegration.

INTRODUCTION

Branded drugs:

The pharmaceutical company is the one who produced the initial product. For a limited time, it has the exclusive right to manufacture and distribute (patent). A brand-name drug is a tiny medication that a pharmaceutical company discovers, develops, and markets. When a new medication is discovered, the company applies for a patent to prevent other businesses from duplicating and selling the medication. To differentiate itself in the marketplace, which is the medication currently goes by two names: a brand name and a generic name.

Generic drugs:

"Dosage form strength, route of administration, quality and performance, characteristics, and intended use are drug product attributes that are comparable to branded products," said the US Food and Drug Administration. It's a replica of a branded medication whose patent has expired and which no longer has the exclusive right to manufacture and market pharmaceuticals. The chemical name of a drug.

1. A term referring to the chemical makeup of a drug rather than to the advertised brand
2. Name under which the drug may be sold A term referring to any drug marketed under its chemical name without

advertising

While meeting the same requirements for safety, purity, and efficacy as name-brand medications and being chemically identical to them, generic medications sold under non-brand names are typically less expensive than name-brand medications. In the US, generic medications can be produced lawfully if a patent has expired or if the medication has never been patented. The patent holder's monopoly on medicine sales licensing ends when the patent expires.

Similarity between generic and branded drugs:

- It must contain same active ingredients.
- It must have same dosage form.
- They have same quality and performance
- It must have same route of administration.
- Generic drugs are safe as branded drug.
- It has same bioavailability.

Difference between generic and branded drugs

- It must contain different inactive ingredients
- Generic drugs are cheaper than branded
- They look different due to difference in shape, size, color, marking, in generic and branded medicines.
- Branded drug has sole right (patent) to manufacture and distribution for a period of time, while generic drug has not any patent on its manufacturing and distribution.

Tablet

A tablet is a solid dosage form that has been compressed and contains medication, either with or without excipients. Pharmaceutical tablets are defined as solid, flat or biconvex dishes that are made by compressing a drug or combination of pharmaceuticals, with or without diluents. This is in accordance with the Indian Pharmacopoeia. Depending on the amount of medication and the planned manner of administration, they differ significantly in size, weight, and form. It is the most often used dose form, and 70% of all medications are given out as tablets. All medications are available as tablets, with the exception of those that are challenging to prepare or deliver.

General properties of Tablet dosage forms

1. A tablet should have elegant appearance while free of defects like chips, cracks, discoloration, and contamination.
2. It should have sufficient strength to withstand mechanical shock during its production packaging, shipping and dispensing.
3. Should have the chemical and physical stability to maintain its physical attributes over time. The tablet must be able to release the medicinal agents in a predictable and reproducible manner.
4. Tablet must have a chemical stability over time so as not to follow alteration of the medicinal agents.

Advantages of the Tablet dosage form

1. They are unit dosage form and have greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
2. Cost of tablet is lowest than other dosage form.
3. Lighter and compact.
4. Tablets are Easiest and cheapest to packed.
5. It is easily palatable.
6. Sustained release product is possible by enteric coating.
7. Odour and bitter taste can be masked by coating technique.
8. Suitable for large scale production.
9. tablets have great chemical and microbial stability.
10. Product identification is easy and rapid requiring no additional steps when employing an embossed and/or monogrammed punch face.

Disadvantages of Tablet dosage form

1. Difficult to swallow in case of children and unconscious patients.
2. Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
3. Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet
4. Bitter testing drugs, drugs with an objectionable odour or drugs that are sensitive to oxygen cannot be given in tablet dosage form
5. Its undergo first past metabolism so can't attend 100% bioavailability

Tablet details

Sr no	Tablet name	Drug name	MRP [In Rs]	Tablet manufacturer
1.	Calpol 650	Paracetamol IP 650mg	Rs 30.74	GlaxoSmithKline pharmaceutical limited
2.	Jan aushadhi Paracetamol IP	Paracetamol 650mg	IPRs 12	Pharmaceutical and Medical Devices Bureau of India [PMBI]

Table 1: tablet detail**DRUG INFORMATION**

As an analgesic and antipyretic, paracetamol is an over-the-counter (OTC) non-steroidal anti-inflammatory drug (NSAID) that is used extensively throughout the world. However, due to its poor ability to inhibit Cyclooxygenase (COX) in the presence of high concentrations of peroxides, paracetamol has little anti-inflammatory effects. The analgesic effect of phenacetin is attributed to its active metabolite, paracetamol. In peripheral tissues, paracetamol is a poor prostaglandin inhibitor and has no discernible anti-inflammatory effects. When an anti-inflammatory effect is not required, one of the most significant medications for treating mild to moderate pain is paracetamol. When used as an analgesic/antipyretic, paracetamol is preferable over aspirin for patients with contraindications to aspirin, such as those with a history of stomach ulcers. Acetaminophen is another name for paracetamol. The source of acetaminophen is synthetic.

Advantages and disadvantages of paracetamol therapy.**Advantages**

(When the drug is administered in the recommended therapeutic doses max. 4 g/24 h)

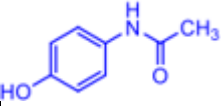
1. Wide therapeutic application
2. checked and examined 3. well tolerated
4. Good bioavailability after oral administration (t_{1/2} 2h)
5. fast elimination
6. Cheap
7. A small number of interactions with other drugs
8. Low toxicity at low doses (≤ 2 g / d) to the digestive tract and kidney
9. low toxicity in children
10. Rare side effects (main allergic skin reactions)
11. available in different pharmaceutical form

Disadvantages

metabolized to a toxic metabolite (N-acetyl-p-benzoquinone imine) therapeutic index (often not efficient at a low dose)
Long-term application may cause:

1. renal functioning disorder
2. higher blood pressure
3. low therapeutic efficiency
4. analgesic action at a dose of 1 g administered 2, 3, and 4 times a day
5. low anti-inflammatory action
6. hepatotoxicity
7. hepatic failure in the case of overuse (two-fold overuse of a therapeutic dose)
8. Enhanced previous liver damage caused by alcohol consumption
9. combinations with traditional NSAIDs can result in a higher prevalence of digestive tract ulceration

DRUG MONOGRAPH -

Sr. No.	Parameters	Descriptions
1.	Common name	Paracetamol
2.	Chemical name	s N-(4- hydroxyphenyl) ethanamide
3.	Therapeutic class	Analgesic antipyretic
4.	Structural formula:	
5.	Molecular weight:	151.163 g/mol
6.	Molecular formula:	C ₈ H ₉ NO ₂
7.	Appearance	white crystalline solid
8.	Taste Odour	Bitter Odourless
9.	Solubility	freely soluble in water, acetone, alcohol
9.	Stability and storage	below 25° c in a dry place Dry, pure paracetamol is stable at 45°c
10.	Side effect	Paracetamol may produce potentially life-threatening effects in overdose which include Blood dyscrasias liver damage (hepatotoxicity) ventricular necrosis.
11.	Warning	1.If patient have been diagnosed with liver or kidney impairment, seek medical advice before taking medication. If symptom persists consult doctor.
12.	Contraindication	It is contraindicated in condition like hypersensitive.
13.	Use	This drug is used to treat - To reduce fever - Mild to Moderate Pain - Osteoarthritis

EXPRIMENTAL WORK

1. Organoleptic study of drug
2. Assay of paracetamol drug
3. Hardness test
4. Disintegration test
5. Friability test
6. Weight variation
7. Dissolution test

1. Organoleptic study of drug

The tablets had a nice appearance and were not sticky.

With the naked eye, the tablets' color and shape were examined.

Three tablets from each formulation were measured for thickness and diameter using a vernier caliper as part of the investigation.

2. Assay of paracetamol drug

Twenty tablets—ten branded and twenty generic—were weighed and finely powdered. Weigh a portion of the powder that has roughly 0.15 g of paracetamol in it.

After diluting 50 ml of 0.1 M NAOH with 100 ml of water and shaking for 15 minutes, add enough water to make 200 ml.

Using a UV spectrophotometric technique set to test this solution at a wavelength of 257 nm, the concentration of paracetamol in the tablet formulation was determined.

The solution was diluted appropriately and filtered through Whatman filter paper to produce a solution with a concentration of 10 mcg/ml.

3. Hardness test

The load necessary to crush or break a tablet resting on its edge is known as the tablet hardness. It is also referred to as tablet crushing strength occasionally.

The MONSANTO HARDNESS TESTER was used to conduct the hardness test. The device calculates the amount of force needed to shatter the tablet when anvils are applied to it. Grab the single tablet. Place the tablet vertically between the fixed and movable jaws.

Apply pressure to the tablet by turning the screw knob. Take note of the moment at which the tablet breaks down and record it using a scale. expressed in kilograms per square centimeter A test of crushing strength was conducted on three tablets of each formulation.

4. Disintegration test

This test establishes if, when placed in a liquid medium under the specified experimental conditions, dosage forms such as tablets, capsules, boluses, pessaries, and suppositories dissolve within the specified period (disintegration time).

The study employed the disintegration apparatus that is detailed in IP. There are two basket rack assemblies included. Six glass tubes, spaced three inches apart at the top and pressed up against ten mesh screens at the bottom, make up each basket rack assembly.

Every tablet was placed within a tube, and the basket rack was placed inside a lighted beaker of distilled water. Throughout the investigation, the temperature was kept at 37 +/- 2 OC.

IP Cap: The limits specified by the Pharmacopoeia span 2.5 to 9.0 minutes.

5. Friability test

In order to pass the friability test, a tablet with a mass of at least 650 mg should be utilized. The friability test is highly correlated with the hardness of the tablet and the binding agent concentration. We chose ten tablets, took them out, and weighed them. The friability tester's drum was filled with tablets, and it revolved at a rate of 25 revolutions per minute for four minutes. In order to determine the percentage of friability in each brand, the tablets were taken out, re-weighed, and weighed. A tablet's range for weight loss ought to be less than or equal to 1%. Because this test is unofficial, reject the tablets if more people do not

Lose (%) = Total initial weight – Total final weight

Total initial weight ×100

NOTE: If the size or shape of the tablet causes irregular tumbling, adjust the drum base so that it forms an angle of about 10o with the horizontal and the tablets do not bind together when lying next to each other, which prevents them from falling freely

6. Weight variation test

Weight variation was carried out to ensure that, each of tablets contains the proper amount of drug. The test was carried out by weighing 20 tablets individually using analytical balance, then calculating the average weight, and comparing the individual tablet weights to the average.

The percentage of weight variation is calculated by using the following formula

% of weight variation = Individual weight- Average weight 100

Average Weight

Dissolution test

Paddle kind of apparatus No. 1 [IP]

Medium: 900 milliliters of pH 5.8 phosphate buffer Time and speed: 50 rpm and one hour

Fill each of the apparatus's four containers with 900 milliliters of 5.8 PH PHOSPHATE BUFFER (dissolution medium), devoid of any dissolved air.

Put the equipment together and preheat the dissolving medium to 36.5° to 37.5°.

Once the testing apparatus is prepared, insert one tablet into each of the vessel's branded and generic tables. Start the device right away and rotate it at the 50 rpm speed recommended in the respective monograph.

Remove a sample (5 mL) from a zone halfway between the revolving blade's top and the dissolution medium's surface within the allotted time, and replace it with a volume of

INSRUMENT USED-

Analytical weighing balance



UV spectrophotometer



Monsanto hardness tester



Disintegration apparatus



Disintegration test apparatus

Roche friabilator



RESULT AND DISCUSSION



Fig

1. Organoleptic
2. Assay of paracetamol drug
3. Hardness test
4. Disintegration test
5. Friability test
6. Weight variation
7. Dissolution test

Organoleptic character

SR NO	PARAMETER	BRANDED DRUG	GENERIC DRUG
1.	Colour	White	White
2.	Shape	Cylindrical	Round oval
3.	Odour	Characteristic	Characteristic

Table no: 2

Assay

The assay procedure on both the Branded and Generic tablets were performed using UV spectrophotometer by taking absorbance of 10mcg/ml at 293 nm

Below table shows the result of assay performed

Sr no	Tablet name	Average weight	absorbance
1.	Generic tablet	16.54 gm	0.898
2.	Branded tablet	14.29 gm	0.047

Table no 3. Absorbance of table

Sr no	Tablet name	Percentage of assay
1.	Generic tablet	96.53%
2.	Branded tablet	102%

Table no 4. % assay

Conclusion

The assay result show that branded tablet has 102 % assay while Generic tablet has 96.53% assay according to ip limit is 95 – 105% so both tablet pass the test

Hardness test

Tablet 1	3.5 kg/cm ²
Tablet 2	3.0 kg/cm ²
Tablet 3	3.2 kg/cm ²
Average	3.233 kg/cm ²

Table no 5:For generic tablet pressure applied

Tablet 1	6.0 kg/cm ²
Tablet 2	6.5 kg/cm ²
Tablet 3	5.8 kg/cm ²
Average	6.8 kg/cm ²

Table no 6: For Branded tablet pressure applied

IP standard NLT 4kg/cm.sq - NMT10kgcm.sq

Conclusion

Hardness test result shows that branded tablet required 6.8 kg/cm² pressure so passes the test and generic tablet required 3.233 kg/cm² pressure so fails the test

Disintegration test

Observation table

Tablet	Time
Generic tablet	4 min
Branded tablet	3 min

Table no: 7 Disintegration time

IP Limit : The Pharmacopoeia limits ranging from 2.5 min to 9.0 minutes.

Conclusion

Result are complies the IP limit so both generic tablet and branded tablet passes the test

Friability test

For generic tablet

Initial weight	7.19 gm
After friability final weight	7.07gm
% Weight loss	1.6689%

Table no: 8

For branded tablet

Initial weight	8.26gm
After friability final weight	8.24gm
% Weight loss	0.242%

Table no: 9

IP Limit: The limits of the friability test shall not be more than 1.0

Conclusion

- This is under limit of friability which states that none of the tablet should be having friability more than 1%
- Branded showed friability below 1% so its complies test
- Generic tablet showed friability above 1% so does not complies the test

Weight variation

Sr no	Wt of tablet	Sr no	Wt of tablet
1	0.83	11	0.80
2	0.83	12	0.81
3	0.83	13	0.82
4	0.83	14	0.83
5	0.81	15	0.82
6	0.83	16	0.83
7	0.83	17	0.83
8	0.84	18	0.83
9	0.83	19	0.80
10	0.83	20	0.83

Sr no	Wt of tablet	Sr. no	Wt of tablet
1	0.69	11	0.80
2	0.69	12	0.81
3	0.69	13	0.72
4	0.72	14	0.71
5	0.71	15	0.69
6	0.66	16	0.71
7	0.71	17	0.69
8	0.72	18	0.72
9	0.72	19	0.72
10	0.69	20	0.69

Table no 10 weight of branded tablet Average wt. 16.14 gm Weight of each tablet 0.82 gm

Table no 11 weight of generic tablet Average weight 14.03 gm Weight of each tablet 0.7015gm

Conclusion

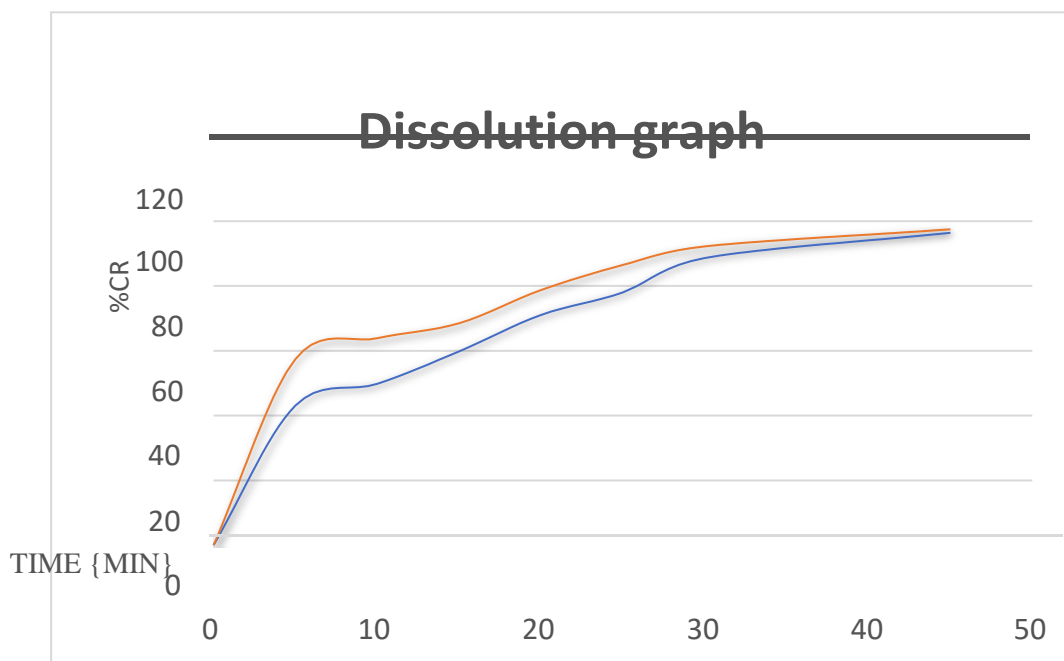
- The weight variation test was performed according to IP.
- For, Branded tablet, the average % deviation of all the tablets were in the range of 0.80 g to 0.84 g.
- So according to the observation there is less weight variation between branded tablet
- For generic tablet the average % deviation of all tablets were in the range of 0.69 g to 0.80 g
- So according to the observation there is a large weight variation between generic tablet
- Hence Branded tablet pass weight variation test and Generic tablet does not pass the test
- Weight variation was carried out to ensure that each tablet contains proper amount of drug intended with little variation among tablets within batch

Dissolution test

Observation table

Sr. no	Time [min]	% Drug cumulative range	
		Generic	Branded
1	0	0	0
2	5	43.084	57.4
3	10	49.80332222	63.83555556
4	15	59.83554444	68.47166667
5	20	71.0661	78.70944444
6	25	78.00165556	86.45222222
7	30	88.64054444	92.19722222
8	45	96.428	97.4624

Table no .12 Observation table for dissolution of tablet



Conclusion

- The Invitro drug dissolution test was performed for the branded and generic tablet
- The % drug release in the time interval of 60 minutes for Branded tablet was found 97.46%
- For generic tablet the % drug release was 96.42%
- This showed that there was a very small difference in amount of drug released from Branded and Generic tablet
- Besides both the formulation show % drug release which complies with the IP limit which stated that NLT % of the amount of drug should be released of paracetamol tablet

Result table

Sr. No.	Test	IP Limits	Branded Tablet	Generic Tablet
2	Assay of drug	Limit 95% – 102%	Pass the test	Pass the test
3	Hardness of tablet	not 4kg/cm.sq nmt10kgcm.sq	Pass the test	Fail the test
4	Disintegration test	2.5 min to 9.0 min	Pass the test	Pass the test
5	Friability	shall not be more than 1.0%	Pass the test	Fail the test
6	Weight variation	Maximum %difference allowed is +5	Pass the test	Fail the test
7	dissolution	--	Pass the test	Pass the test

Table no 13

Conclusion

- To conclude, we can say that the following evaluation test of tablets such as weight variation, hardness, friability, when compared of both the tablets its show a major difference.
- Generic tablet does not pass the IP limit and Branded tablet pass all the IP limit
- On the other hand, some test such as Dissolution and Disintegration showed negligible difference among these tests of the tablet.
- Thus, not a major difference between the results was observed however it was concluded that the Branded tablet are good in quality than Generic tablet

REFERENCES:

1. Lachman/ Lieberman's The Theory and Practical Industrial Pharmacy.
2. . The Indian Pharmacopoeia 2018, Government of India, Ministry of health and family welfare, Controller of publication, New Delhi, vol. III, Page No 2858
3. British Pharmacopoeia Commission. British Pharmacopoeia,
4. Ahmida N H S, Abu – Naja M S, Doghman Y S A. Determination of paracetamol in tablet by Different Spectrophotometric Method. Asian Journal of Chemistry, 2009; 21(3): 2233 – 2240
5. FDA. Post marketing surveillance programs. United State Food and Drug Administration.
6. Chandra R and Verma Z. Comparative quantitative determination of paracetamol by RP- HPLC and UV-spectrophotometry from its formulated tablets. Int J Pharm Pharm Sci. 2013;5:863-865.
7. Karmakar P and Kibria MG. In-vitro comparative evaluation of quality control parameters between paracetamol and paracetamol/caffeine tablets available in Bangladesh.
8. .Oscier CD and Milner QJ. Peri-operative use of paracetamol. Anaesthesia2009;64:65- 72.
9. Karmakar P and Kibria MG. In-vitro comparative evaluation of quality control parameters between paracetamol and paracetamol/caffeine tablets available in Bangladesh.
10. Badri HS and Gazi M. Comparative in vitro study of paracetamol tablets sold in pharmacies Altaif city Ksa. World J Pharm Pharm Sci.
11. Farooq MA and Khan DH. Comparative study of commercially available brands of Acetaminophen in Lahore, Pakistan. World J Pharm Pharm Sci
12. .hayas S and Sheraz MA. Factors influencing the dissolution testing of drugs. J. Health Res. 2013;1: 01-11. 34. Gupta MM and Gupta M. Comparative pharmaceutical quality control testing of different brands of paracetamol tablets