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IN-VITRO COMPARATIVE STUDY OF GENERIC VS BRANDED TABLETS – A REVIEW

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ABSTRACT

Generic medications have been shown to be therapeutically equivalent to their branded counterparts through in-vitro comparative studies. This means that they contain identical quantities of the active ingredient and produce comparable clinical effects in patients. To assess the quality of generic and branded tablets of a particular medication, we employed in-vitro methods. A series of in-vitro tests, including general appearance, thickness, diameter, hardness, friability, weight variation, content uniformity, disintegration, and dissolution tests, were performed on both generic and branded tablets of the same medication. The results of these tests were evaluated against the standards established in the relevant pharmacopoeia. If both sets of data corresponded, it served as evidence of the quality, therapeutic efficacy, and safety of generic drugs.

KEYWORDS: Generic drug, Branded drug, comparative study, Content uniformity, Disintegration, In-vitro drug release.

1. INTRODUCTION

Drugs or medicines are used for treatment, diagnosis, mitigation and prevention of diseases. India is the 4th largest producer and 10th largest exporter of drugs in world. When the new

drug is discovered, the pharmaceutical company creates a patent file to protect itself from other companies for manufacturing and marketing. After the original patent is expired, the generic pharmaceuticals can be produced and marketed the generic form of drugs. These medications have same active ingredient(s), strength, quality, purity and efficacy as branded medications. They are much less expensive than their branded counterparts because they do not require the extensive costs for research, development and testing. Generic drugs are safe and effective form of medications and is a suitable option when compared to branded. The government of developing countries are now focusing on the use of generics and much of emphasis is given to aware the general public about the rational use of generic drugs.[1,2]

1.1. Generic drug

Generic medicines are pharmaceutical drugs that contain the same active ingredient as a brand-name drug that has lost its patent protection. Generic drugs are manufactured by companies other than the original developer of the brand-name drug. They are typically less expensive than their brand-name counterparts but are just as effective and safe.

Here is a summary of the definitions of generic drugs from various agencies

World Health Organization (WHO)

A generic drug is a medicine that is usually intended to be interchangeable with an innovator product. It is manufactured without a license from the innovator company and is marketed after the expiry date of the patent or other exclusive rights.

U.S. Food and Drug Administration (FDA)

A generic medicine is a drug product that is comparable to a brand reference listed drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. It is a copy of a brand-name drug whose patent has expired and is no longer subject to exclusive rights to produce and distribute the drug strength.

European Union (EU)

A generic medicine is a medicine that is developed to be the same as a medicine that has already been authorized (reference medicine). A generic medicine contains the same active pharmaceutical ingredient (API) as the reference medicine and is used at the same dose to treat the same disease as the reference medicine. However, the name of the medicine, its appearance (such as color or shape), and its packaging can be different from those of the reference medicine.[3,4]

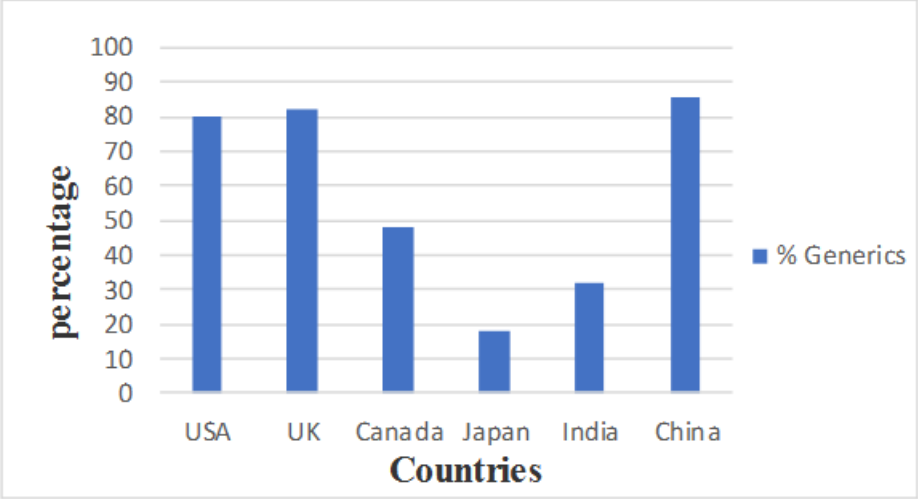


Fig. 01: Percentage of generic drug used in different countries.[5]

Requirements of generic drugs have to meet with a branded drug[4,6]

- Contain the same pharmaceutical active components.
- Use the identical dosage form (oral, topical, intravenous, etc.)
- Have the same strength and purity.
- Share the same usage guidelines.
- Share the proprietary counterpart's action and dissolving rate.
- Be produced in accordance with the tight guidelines established by the good manufacturing practices (GMP) programme of the food and drug administration (FDA) for the patent counterparts.

Advantages[7]

Lower cost

Generic drugs are typically 80-85% less expensive than their brand-name counterparts. This makes them more affordable for patients and can help to reduce healthcare costs.

Same efficacy and safety

Generic drugs are just as effective and safe as their brand-name counterparts. They undergo rigorous testing to ensure they meet the same high standards of quality.

Increased competition

Generic drugs help to increase competition in the pharmaceutical industry, which can lead to lower prices for both generic and brand-name drugs.

Disadvantages[1]

Potential for contamination

There is a small risk that generic drugs could be contaminated due to subpar manufacturing practices or poor storage conditions. However, this risk is minimized by regulatory oversight and GMP guidelines.

Consumer confusion

The variety of generic names and appearances can lead to confusion among patients and healthcare providers. This is why generic names and proprietary names must be distinct to prevent medication errors.

Potential for allergic reactions

In rare cases, patients may experience allergic reactions to the inactive ingredients in generic drugs. These reactions are typically mild and short-lived.

1.2. Branded drug

Branded name is a drug that a pharmaceutical company has invented, developed and marketed. Once the new drug is discovered, the company creates a patent file to protect itself from coping and selling companies from other companies.[6]

Advantages[1]

- They are patented drug in their class.
- They might posses a newly found medicine with advantages.
- Not all medicines are available in generic form.
- It might be simple to memorise and write brand names.

Disadvantages[1]

- Branded drugs are high cost. Because of we have to pay for the drugs purchase, development, safety testing, marketing and transportation charges.

Table 01: Difference between Generic and Branded drug.[1]

Features	Generic drug's	Brand name drug's
Patent	Off patent	Patent protected
Trade Name	Marketed under the generic original trade name of drug	Marketed under a unique branded name given by company
Manufactured by	Manufactured by several pharmaceutical companies	Developed manufactured by an innovator company

Animal and clinical study	Not required to perform	Essential to perform
Price	Cheaper	Costly than generic drug
Appearance (colour, shape, size)	Look different from relevant brand name drug	Unique look as design during product development
Name variation	Same generic drug name in any country	Same or different brand names
Excipient	Same or altered but acceptable excipient	Uses acceptable excipient
Availability	After expiration of patents and exclusivities	From product launch after proving the safety and effectiveness
Examples	Naproxen	Naprosyn

Table 02: Examples of Generic and Branded drugs & its manufacturers.[1,2]

S.NO	Generic Drug	Class of drug	Manufacturer	Branded drug	manufacturer
1	Aceclofenac Tablets IP 200mg	NSAID	Edmund Healthcare Pvt Ltd, Chandigarh (Punjap)	Aceroc	Wockhardt
2	Acyclovir 400 mg Tablets	Anti-Viral	Vega Biotech Pvt Ltd,Vadodra (Gujrat)	Acivir DT	Cipla
3	Metformin Hcl 1000 mg SR Tablets	Anti-Diabetic	Care Formlation Labs Pvt Ltd, New-Delhi	GeminorM Forte	Macleods Pharmaceutical Ltd
4	Omeprazole 20 mg Capsules	Proton Pump Inhibitor	Schwitz Biotech,Ahmedabad	Acichek	Sanofi Aventis Pharma India
5	Cefuroxime Injection 750 mg	Antibacterial	Talent Healthcare,Ahmedabad (Gujrat)	Supacef Injection	GlaxoSmithkline
6	Vincristine Injection IP 1 mg	Anti-Cancerous	Lexicare Pharma Pvt. Ltd, Ankleshwar, Gujrat	Oncocristin - AQ	Sun Pharmaceuticals
7	Progesterone 200 mg SR Tablets	Progestins	Tissue Overseas, Surat, Gujrat	Algest	Cadila Pharmaceuticals Ltd
8	Gabapentin Capsules USP 300mg	Antiseizure	Dycott Healthcare,	Gabator 300 mg	Torrent Pharmaceuticals Ltd
9	Montelukast Sodium Tablets IP 5 mg	Antiasthmatic	Curelife Pharmaceuticals, Ambala (Haryana)	Singulair	MSD Pharmaceuticals Pvt Ltd

2. COMPARATIVE STUDY OF TABLET

Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. Tablet is defined as a compressed solid dosage form containing medicaments with or without excipients.

They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of tablet.[8]

Ideal Properties[8]

- Should be elegant product having its own identity while being free of defects such as chips, cracks, discoloration and contamination.
- Should have strength to withstand the rigors of shocks encountered in its production, packaging, shipping and dispensing.
- Should have the physical stability to maintain its physical attributes over time.
- Must be able to release the medicament agent(s) in the body in a predictable and reproducible manner.
- Must have a suitable chemical stability over time so as not to allow alteration of the medicinal agent(s).

Advantages[8,9]

- Tablets are unit dosage form and offer the greatest capabilities of all oral dosage form for the greatest dose precision and the least content variability.
- Their cost is lowest amongst all the oral dosage forms.
- They are easiest and cheapest for packaging and transportation.
- Tablets are better suited to large-scale production than the other unit dosage forms.
- Having greatest chemical and microbial stability over all oral dosage forms.
- Easy to swallow with least tendency for hang-up.
- Odor and bitter taste can be masked by coating technique.

Disadvantages[8,9]

- Difficult to swallow in case of children and unconscious patients.
- Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.
- Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.
- Irritant effects on the GI mucosa by some solids (e.g., aspirin).
- Possibility of bioavailability problems resulting from slow disintegration and dissolution.

3. EVALUATION OF TABLET

During the comparative study of tablet following evaluation tests are performed and its results are compared.

3.1. General Appearance[10]

General appearance is the physical (visual) appearance of tablet would include a number of aspects like size, shape, odor, taste, texture, legibility, and identifying marks.

3.2. Organoleptic Properties[10]

The color of a tablet serves as a key identifier and contributes to consumer acceptance. It allows manufacturers to differentiate between batches of tablets. Color uniformity is crucial, and tablets should be free from mottling. Spectrophotometers, tristimulus colorimetric measurements, and micro-reflectance photometers are used to evaluate the color uniformity and gloss of tablets. The odor of a tablet reflects its stability. For instance, the presence of acetic acid in an aspirin tablet indicates degradation. Taste is another critical factor, and each company has a taste panel that assesses the taste of tablets. Machines that can provide taste reports are yet to be developed.

3.3. Hardness Test (Crushing Strength)

The resistance of the tablet to chipping, abrasion, or breakage under conditions of storage, transportation and handling, before usage is depends on its hardness. Hardness generally measures the tablet crushing strength.[12]

Generally used hardness tester are[13]

- ✓ Monsanto hardness tester
- ✓ Strong cobb hardness tester
- ✓ Pfizer hardness tester
- ✓ Erweka hardness tester
- ✓ Schleuniger hardness tester.

Fig. 02: Monsanto tester.

Fig. 03: Pfizer tester.

Fig. 04: Erweka tester.

Procedure[20]

- The tablet is placed between the spindle (plunger) and the anvil.
- The knurled knob is turned until the tablet sufficiently fits into the space.

- The scale is then adjusted to zero. The pressure on the tablet is increased by further turning the knurled knob until the tablet breaks.
- This force is read from the scale which is in kg/cm^2 or Newton.

Acceptance criteria

Tablet hardness should lies between 5 to 10 kg/cm^2(result limit: ±5%).[10]

3.4. Thickness and Diameter Test

The tablet thickness is influenced by the amount of fill material in the die-cavity, diameter of the die and the compaction force applied. The shape and size of a tablet is vary based on tooling used in the tablet manufacturing.[11]

The tablet thickness is measured by using,

- ✓ Micrometer
- ✓ Digital readout calipers
- ✓ Sliding caliper scale method

Fig. 05: Vernier caliper and Screw Gauge.

Procedure[16]

- Inspect the tablets, remove any powder debris.
- Measure the tablet thickness and diameter of each tablet by using Vernier caliper.
- Record the thickness and diameter.
- Calculate the average tablet thickness and diameter of tablet.

Acceptance criteria

Tablet thickness and diameter should be controlled within a ±5% variation of standard value.[20]

3.5. Friability Test

A tablet property related to hardness is friability and the measurement is made by use of the Roche friabilator. Rather than a measure of the force required to crush a tablet, the instrument is designed to evaluate the ability of the tablet to withstand abrasion in packaging, handling and shipping.[12]

"Roche Friabilator" specification[10]

- ✓ Made up of plastic drum fixed with a machine
- ✓ Revolution speed – 25 rpm
- ✓ Total revolution – 100 (4 minutes)
- ✓ Distance of dropping the tablet – 6 inches

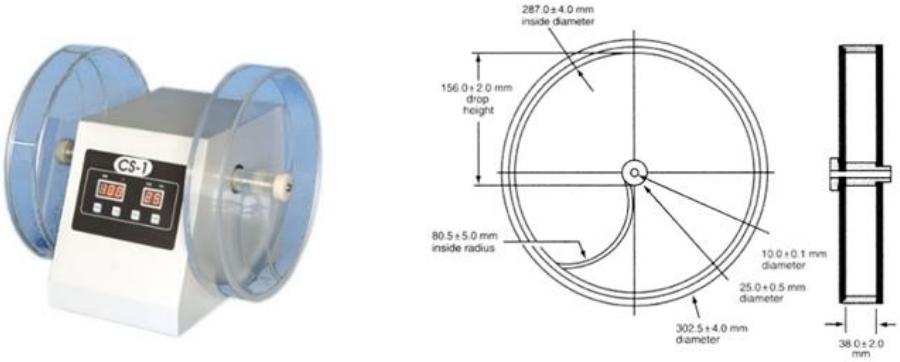


Fig. 06: Roche Friabilator.

Procedure[10]

- The 10 tablets are weighed accurately in digital balance (w_1) and the weighed tablets are placed in the drum of Roche friabilator.
- The friabilator is allowed to rotate for 4 mins i.e 100 revolution.
- The tablets then removed from the drum. These tablets are dusted and weighed again (w_2).
- To calculate percentage of friability by using following formula

  Percentage friability = $W_1 – W_2 / W_1 \times 100$

  Where, W_1 = Weight of tablets before testing.

  W_2 = Weight of tablets after testing.

Acceptance criteria[10]

According to B.P / I.P = Percentage of friability should be not more than 0.8% - 1.0%.

According to U.S.P = Percentage of friability should be not more than 4%.

3.6. Weight Variation Test

Weight variation test is performed to check that the manufactured tablets have a uniform weight.

Fig. 07: Digital Weighing Balance.

Procedure[20]

- Randomly select 20 tablets and weight individually (x_1, x_2, x_3, …., x_{20}).
- Determine the average weight of tablets (x_1, x_2, x_3, …, x_{20}/20).
- The weight variation of individual tablet is determined with respect to average weight and % weight deviation.
- Then to calculate upper and lower limit by using following formula,
  Upper limit = Average weight + (average weight × % weight variation)
  Lower limit = Average weight – (average weight - % weight variation)

Table 03: Specification for Weight Variation Test.[10]

Average weight of tablets (mg) (as per USP)	% Weight variation	Average weight of tablets (mg) (as per IP)
130 or less	10%	80 or less
130 – 324	7.5%	80 – 250
More than 324	5%	More than 250

Acceptance criteria[20]

If two tablets fall out of the permissible % weight variation, the tablets fail the test and none of the tablet have twice the % weight variation value, the tablets passes the test.

3.7. Content Uniformity Test

Content uniformity test ensure the content consistency of Active pharmaceutical ingredients (API) within a narrow range around the label claim in dosage units. It performed for based on to refer the most recent Pharmacopeia for complying with the regulations.[12]

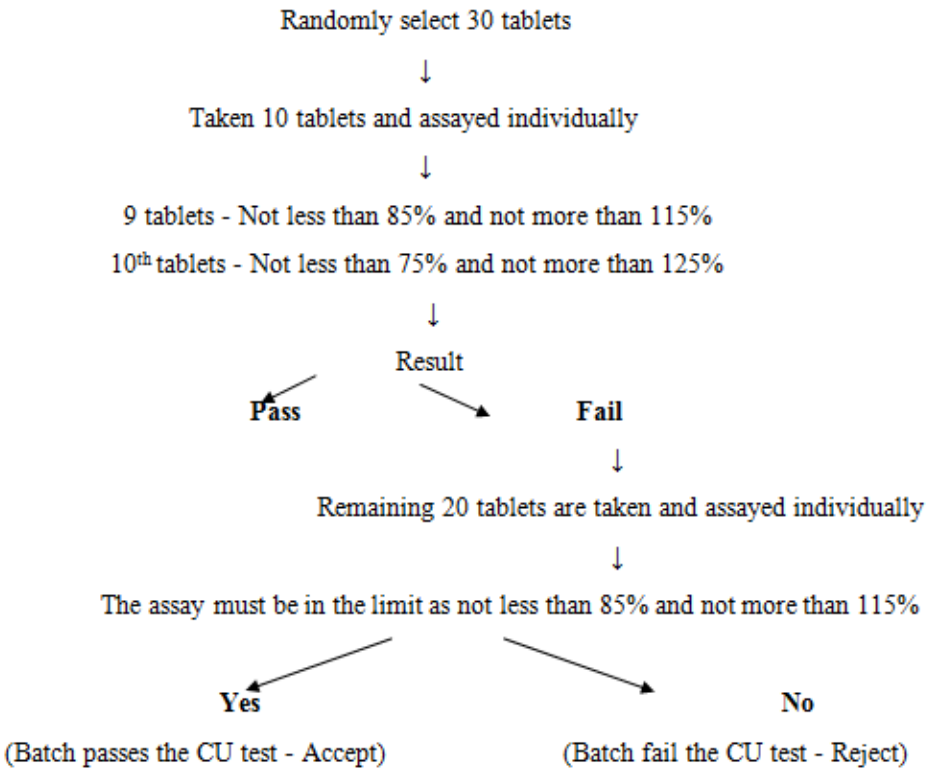
Procedure[18]

- Weigh 20 tablets (as per monograph) and then grind them using a mortar and a pestle.
- From this powder, take equivalent amount containing API and dissolved in suitable solvent (as per monograph).
- The solution is further diluted and filtered.
- The absorbance of filtrate is measured by to using UV Spectrophotometer.

Table 04: Weight of medicament in each tablet.[13,19]

Weight of medicament in each tablet	Subtract from the lower limit for sample of			Add to the upper limit for sample of		
	15	10	5	15	10	5
0.12gm or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12gm and less than 0.3gm	0.2	0.5	1.2	0.3	0.6	1.5
0.3gm or more	0.1	0.2	0.8	0.2	0.4	1.0

Acceptance criteria[18]



3.8. Disintegration Test

Disintegration is defined as the breakdown of solid dosage form into small particles after it is ingested. It is performed to identify the rate of disintegration of tablet in particular period. This test is not performed for controlled and sustained release tablets & chewable tablet. Disintegration is the first physical change observed for a drug when it enters into the body and its helps to knowing the API solubility in the gastric fluids of the digestive system.[17]

Apparatus Specifications[17,18]

- ✓ 6 glass tubes (77.5mm ±2.5mm long and 21.5mm internal diameter)
- ✓ 10 number mesh screen (1.8 – 2.2mm)
- ✓ 1liter Beaker
- ✓ System move up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minutes
- ✓ Tablet remain 2.5 cm below the surface of liquid.

Fig. 08: Disintegration apparatus.

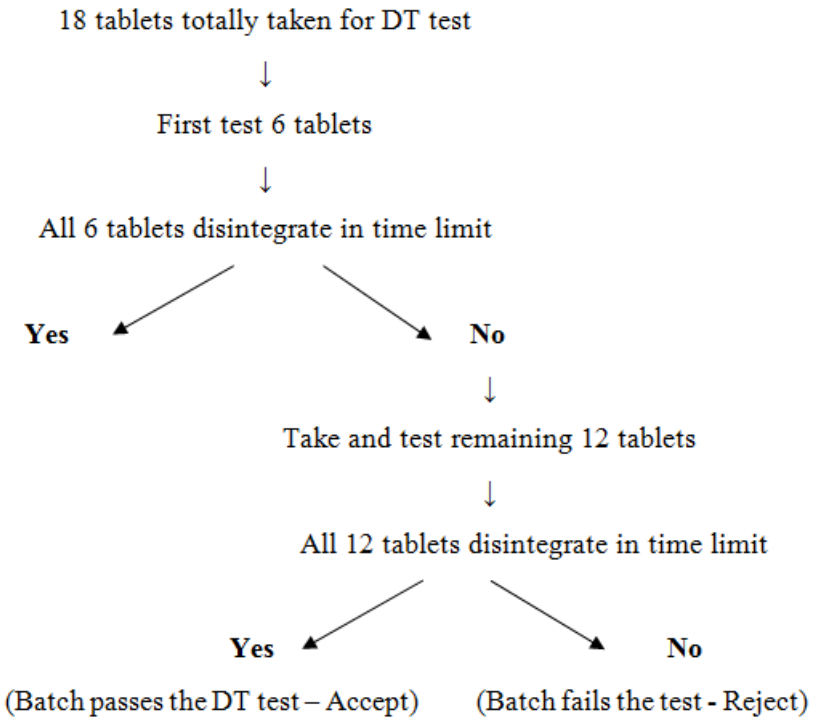
Table 05: Specification for Disintegration Test.[13]

Type of tablet	Medium	Temperature	Disintegration time (as per IP)
Uncoated Tablet	Water/Buffer	37±2ºC	15 mins or as per individual monograph
Film Coated Tablet	Water	37±2ºC	30 mins or as per individual monograph
Sugar Coated Tablet	Water/0.1N HCL	37±2ºC	60 mins or as per individual monograph
Dispersible Tablet	Water	25±1ºC	03 mins or as per individual monograph
Effervescent Tablet	Water	25±5ºC	05 mins or as per individual monograph
Enteric Coated Tablet	0.1M HCL mixed phosphate buffer (pH 6.8)	37±2ºC	02 hours in HCL: No disintegration. 60 mins in buffer: Disintegration
Soluble Tablet	Water	20±5ºC	03 mins or as per individual monograph

Procedure[17,18]

- Place one tablet into each of the six tubes of basket, if directed in the appropriate general monograph, add a disc to each tube.
- Suspend the assembly in the medium containing beaker.
- Operate the apparatus for the specified time and end of the time limit, lift the basket from the medium.
- Observe the tablets must disintegrate and all the articles must pass through the mesh within the time specified in the monograph.

Acceptance criteria[17,18]



3.9. Dissolution Test (In-vitro Drug Release)

The dissolution test is used for to measuring the amount of time required for a given percentage of the drug substance in a tablet to go into solution under a specified set of conditions.[18]

Apparatus Specifications[14]

- ✓ Capacity – 1000ml
- ✓ 900ml of dissolution medium
- ✓ pH - ±0.05 unit in specified monograph
- ✓ Distance between inside bottom of vessel and paddle/basket is maintained at 25±2mm
- ✓ Shaft position – NMT 2mm from vertical axis
- ✓ Allowable variation - ±4%
- ✓ Temperature

- Apparatus 1 to 4 – 37±0.5°C
- Apparatus 5 to 7 - 32±0.5°C

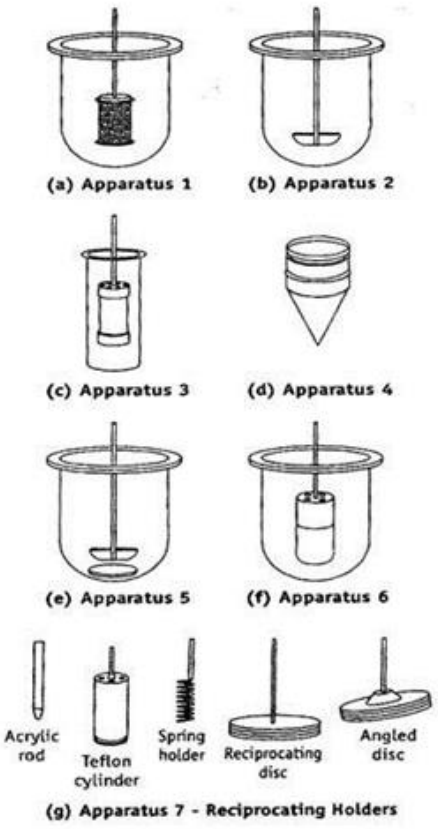
Fig. 09: Dissolution Apparatus.

Table 06: List of Official Dissolution Apparatus.[10]

Type	IP	USP	BP	EP	JP
Type 1	Paddle	Basket	Basket	Basket	Basket
Type 2	Basket	Paddle	Paddle	Paddle	Paddle
Type 3	-	Reciprocating Cylinder	Flow Through Cell	Flow Through Cell	Flow Through Cell
Type 4	-	Flow Through Cell	-	-	-
Type 5	-	Paddle Over Disc	-	-	-
Type 6	-	Rotating Cylinder	-	-	-
Type 7	-	Reciprocating Holder	-	-	-

Table 07: Types of USP Dissolution Apparatus and their Applications.[15]

Type	Name	Rotating speed	Drug formulation tested
Type 1	Basket	50 – 120rpm	Conventional tablets
Type 2	Paddle	25 – 50rpm	Tablets, capsules, suspensions, CRDDS products
Type 3	Reciprocating Cylinder	6 – 35rpm	CRDDS formulations
Type 4	Flow Through Cell	N/A	Formulation containing poorly soluble drugs
Type 5	Paddle Over Disc	25 – 50rpm	Transdermal products
Type 6	Rotating Cylinder	N/A	Transdermal products
Type 7	Reciprocating Holder	30rpm	CRDDS formulations



Procedure[18]

- Wash the dissolution apparatus vessel using water and then put 900ml of medium (as per monograph) in each.
- Add tablet in each vessel and operate the paddle (as per monograph for specific drug) on a rotation speed to 50 rpm.
- At specified time intervals withdraw a sample and calculate percentage of dug release by using UV Spectrophotometer.

Acceptance criteria[18,19]

Stage-1 → 6 tablets are tested (Tolerance limit Q+5%)

Stage-2 → If tablets fails the stage-1, additionally 12 tablets are tested (Tolerance Q-15%)

Stage-3 → If tablets still fails the test, additionally 24 tablets are tested (Tolerance for all 24 tablets Q-15%).

4. CONCLUSION

The in-vitro comparative study of generic and branded tablets typically summarizes the findings of the similarities (equivalence) and difference of the two types of medications. Generic and branded tablets are bioequivalent, meaning that they have same rate and extent

of absorption into the bloodstream. And also find that they are some minor differences in the pharmacokinetics and pharmacodynamics. These differences are typically not clinically significant and do not affect the overall safety and efficacy of the generic drug. These are identified by to performing different in-vitro tests like general appearance, thickness, diameter, hardness, friability, weight variation, content uniformity, disintegration, and dissolution test.

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