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Comparative dissolution study of branded aceclofenace tablet with generic aceclofenace tablet.

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ABSTARCT

Aceclofenac is a newer non-steroidal anti-inflammatory drug (NSAID's) with good analgesic And anti-rheumatic properties. In the present study two brands of Aceclofenac (One generic Acenextp and one standard brand Zerodol p) were taken and subjected to evaluate the different parameters as well as to perform. The dissolution study of the same tablets for their comparison. The preformulation studies were carried out first. The drug showed a at 275 nm in phosphate buffer pH 6.8. The FTIR spectra of Aceclofenac also comply with the standard Monographs and principle peaks were shown. After the preformulation studies of the drug, the Tablets were evaluated for the uniformity of weight, hardness, friability, drug content and in-vitro Release study. All tablets were found within the acceptance criteria as per the official standards. The in- vitro dissolution test was carried out for 1 hours using dissolution test Apparatus at 50 rpm. All tablets have shown the excellent in-vitro release profile. The both Marketed tablets released the drug in a sustained pathway.

On the basis of in-vitro release study, the both marketed Formulation of aceclofenac were foundto be bio-equivalent And both brand of Aceclofenac show slight difference in dissolution test.

I. INTRODUCTION

Aceclofenac has higher anti-inflammatory action than convention a NSAIDs. It is used for the relief of pain and inflammation in rheumatoid arthritis, osteoarthritis and ankylosing spondylitis with minimum side effects. Since Aceclofenac tablet is not an official product of I.

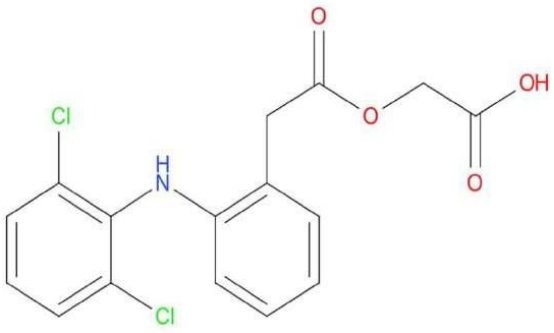
P. and practically insoluble in water, it was thought to necessary to carryout in vitro testing of the commercial products with special attention to dissolution rate studies[1]

Aceclofenac is used for pain relief. It relieves pain and inflammation in conditions like rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis. Aceclofenac is a non-steroidal anti-inflammatory drugs (NSAID). It works by blocking the release of certain chemical messengers that cause pain and inflammation (redness and swelling). This drug works by blocking the effect of cyclooxygenase (COX) enzymes that make chemical prostaglandins at sites of injury or injury causing pain, swelling, and inflammation[4]

The aim of the research project study is to conduct the comparative dissolution studies to find out generic-to-brand variation by applying comparison approaches to the dissolution profile of marketed aceclofenac tablet formulations. Commercially available one generic tablet of aceclofenac tablets and one brand aceclofenac tablets were selectively sampled from medical shops.The study protocol was designed as per Indian Pharmacopeia. All the products met the requirements as per general specifications of Indian pharmacopoeia for tablet formulation[5]

KEYWORDS: Aceclofenac, Indian Pharmacopeia, Dissolution, Commercial, Tablet formulation.

Structure of Aceclofenac:



Molecular formula of Aceclofenac: $C_{16}H_{13}Cl_2NO_4$

Molecular weight of Aceclofenac: 354.19[7]

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Mechanism of action:

The mechanism of action of aceclofenac is largely based on the inhibition of prostaglandin production by selectively inhibiting COX-2 (half maximal inhibitory concentration [IC50] COX-2/COX-1 ratio 0.26)[8] In clinical studies, aceclofenac inhibited prostaglandin synthesis in synovial fluid from patients with acute knee OA and in peripheral blood leukocytes from patients with OA.1 NSAID treatment with aceclofenac (100 mg twice daily) for 3 months inhibited COX-2 synthesis in the knee synovial membrane of 30 patients with OA scheduled for total knee replacement surgery versus patients with OA who did not want to be treated with NSAIDs (control group). Results showed that aceclofenac reduced PGE2 in the synovial fluid($p<0.05$ vs control), and protein expression ($p<0.05$ vs control) at the synovial membrane[8] In another study in 30 patients with OA scheduled for knee replacement surgery, 3-months' treatment with aceclofenac decreased IL-1β-induced release of PGE2 and decreased the synthesis of COX-2 and microsomal prostaglandin E synthase (mPGES)-1 in the cartilage andchondrocytes. In addition, aceclofenac reduced IL-1β-induced expression of TNFα and IL-1β in cultured OA chondrocytes[10] Aceclofenac also reduced lymphocyte adhesion in in vitro studies and increased glycosaminoglycan production in cartilage from OA patients.Oral aceclofenac is rapidly and completely absorbed, with peak plasma concentrations reached approximately 1.25 to 3.0 h after dosing. After penetrating into the synovial fluid, aceclofenac concentrations reach approximately 57% of those in the plasma. Aceclofenac is highly (>99%) protein bound and has a volume of distribution of approximately 25 L. Aceclofenac circulates mainly as unchanged drug. Aceclofenac is metabolized into its main metabolite 4′- hydroxyaceclofenac and several minor metabolites, including 5-hydroxyaceclofenac, diclofenac, 4′-hydroxydiclofenac. Approximately 75% of an administered aceclofenac dose isexcreted via urine, largely as hydroxymetabolites. Aceclofenac mean elimination half-life is approximately 4 h. Some studies suggest that diclofenac and other metabolites of aceclofenac may cause toxicity in aquatic and terrestrial organisms, such as mussels and Gyps vultures. However, data currently available are inconclusive and additional studies are required to betterassess the fate and toxic effects of aceclofenac and its metabolites. It has also been suggested that wastewater treatment plants should be equipped with more advanced treatment methods to more effectively remove potential contaminants, such as aceclofenac metabolites[10]

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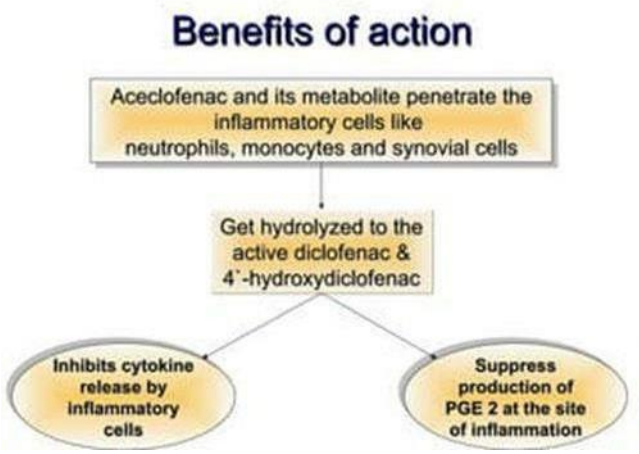

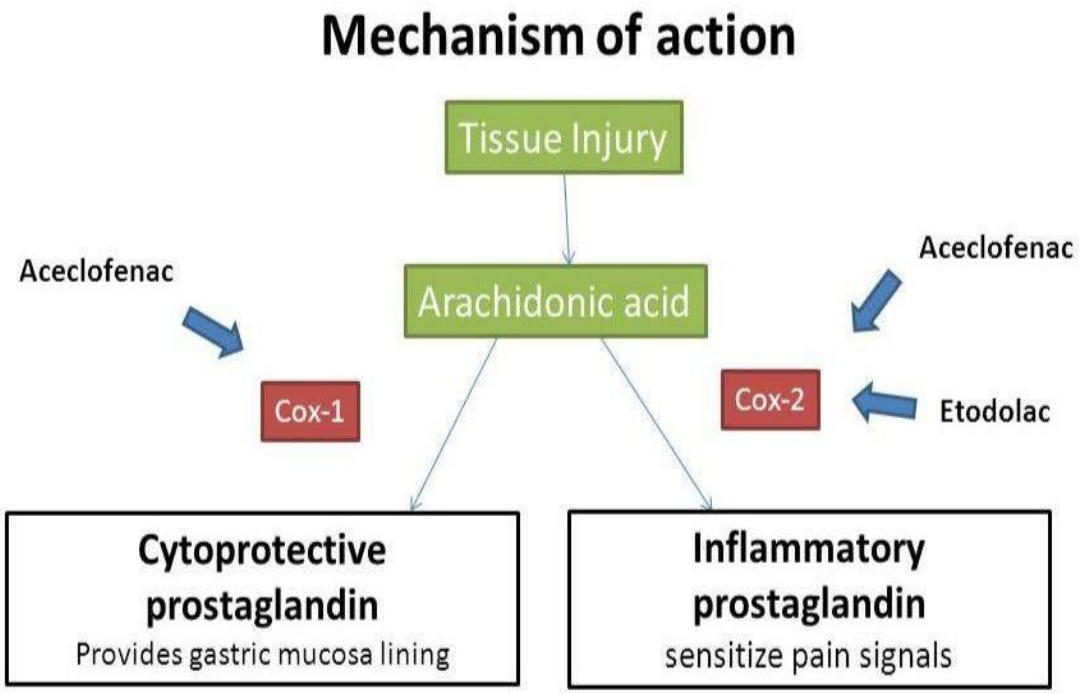

Side Effect: Nausea Diarrhea Vomiting Flatulence Constipation Dyspepsia Somnolence Confusion Abdominal pain
Increased liver enzymeSkin rash
Dizziness
Visual disturbanceFlushing
Stomach pain Loss of appetiteHeartburn[3]

Uses of Aceclofenac tablet:

1. Aceclofenac is used to relieve pain.
2. It relieves pain and inflammation in conditions such as rheumatoid arthritis, ankylosing spondylitis, and osteoarthritis.
3. Rheumatoid arthritis- Aceclofenac is used to treat symptoms such as swelling, pain, and stiffness of the joints associated with rheumatoid arthritis
4. Osteo-arthritis- Aceclofenac is used to treat symptoms such as tender and painful joints associated with osteoarthritis.
5. Ankylosing Spondylitis - Aceclofenac is used to treat symptoms such as stiffness and pain associated with Ankylosing Spondylitis[7]

Precautions for Aceclofenac:

a) Allergies

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b) Avoid if you have a known allergy to Aceclofenac or other ANSIDs.
c) Asthma
d) Bleeding
e) Pregnancy
f) Breast-nutrition
g) Gastrointestinal bleeding
h) Cardiac surgery
i) Asthma
j) Impaired function of the kidney
k) Impaired function of the liver[4]

Aceclofenac Directions:

a) Aceclofenac has been prescribed to relieve pain and inflammation.
b) Take this medicine with food or milk only to prevent stomach upset.
c) Take it according to the dosage prescribed by your doctor and correct the time duration. Long-term use may cause some serious complications such as stomach bleeding and kidney problems.
d) It may cause dizziness, somnolence, or visual disturbances. Use caution while driving or doing anything that needs to be concentrated.
e) Avoid drinking alcohol while taking Aceclofenac because it can cause excessive sleepiness and increase your risk of stomach problems.
f) Tell your doctor if you have a history of heart disease or stroke.
g) Your doctor may monitor your kidney function, liver function, and blood component levels on a regular basis if you are taking this medicine for long-term treatment[4]

Disadvantages of tablet dosage form are;
Some medicines are not suitable for people with certain conditions, and sometimes a medicine can only be used if extra care is taken. For these reasons, before you start taking aceclofenac, it is important that your doctor knows:

- If you have ever had an allergic reaction to any other NSAID (such as aspirin, naproxen, diclofenac, and indometacin), or to any other medicine.
- If you have ever had a problem with stomach or duodenal bleeding, such as if you have had an ulcer.
- If you have asthma or any other allergic disorder.
- If you have a heart condition, or a problem with your blood vessels or circulation.
- If you are pregnant, trying for a baby, or breast-feeding. If you have any problems with the way your liver works, or if you have any problems with the way your kidneyswork.
- If you have high blood pressure.
- If you have ever had blood clotting problems.
- If you have an inflammatory bowel disorder such as Crohn's disease or ulcerative colitis.
- If you have a connective tissue disorder such as systemic lupus erythematosus. Thisis an inflammatory condition which is also called lupus or SLE.
- If you have a rare inherited blood disorder known as porphyria.
- If you are taking any other medicines. This includes any medicines you are taking which are available to buy without a prescription, as well as herbal and complementarymedicines.
- Before you start the treatment, read the manufacturer's printed information leaflet from inside the pack. It will give you more information about aceclofenac, and it will also provide you with a full list of the side-effects which you could experience fromtaking it.

- Take aceclofenac exactly as your doctor tells you to. The usual dose is one 100 mgtablet twice daily, taken preferably morning and evening.
- Take aceclofenac with food; during a mealtime is ideal. This will help to protect your
stomach from side-effects such as indigestion and stomach irritation.
- Swallow the tablet with a drink of water.do not chew or crush the tablets.

If you forget to take a dose, take it as soon as you remember (unless it is nearly time foryour next dose, in which case take the next dose when it is due and leave out the forgotten dose). Do not take two doses together to make up for a missed dose.it will cause many side effects on the body[5]

Combination tablet of Aceclofenac and Paracetamol:
Aceclofenac and paracetamol are non-steroidal anti-inflammatory drug (NSAID) that is generally used to reduce pain and inflammation. The presence of the two most popular and effective medicines makes this drug effective in lowering body temperature as well.It works on the same principle of inhibiting the enzymes causing

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inflammation, fever, and pain. Let's have a look at its uses, dosage, overdose, cautions, side effects, and other aspects[6]

Direction to take Aceclofenac + Paracetamol:

Take Aceclofenac + Paracetamol as per the doctor's prescription. It is usually prescribed by the doctor once or twice a day. It is important to leave a gap of 4-6 hours between two doses. Aceclofenac + Paracetamol should be taken with food or milk. If you have acidity problems, then it is better to take an antacid with it.You should take the medicine at the same time everyday. If there is any reaction after taking it, you should immediately consult your doctor.

Side effects of Aceclofenac and Paracetamol:

There could be some common Aceclofenac Paracetamol side effects such as;

Fatigue, Nausea and vomiting, Gastric ulcers, Abdominal pain, Diarrhoea, Cloudy urine with blood, Mouth ulcers, Allergic skin reactions and skin rash, Constipation, Drowsiness ,Heartburn.Usually the side effects go away in some time. But if you find that the symptoms are worsening, you should see your doctor.

Precautions to take Aceclofenac + Paracetamol:

Tell your doctor if you have an allergic tendency to the medicine. Even if you are allergic to other medicines, you should discuss them with your doctor.Alcohol consumption must be avoided as it can cause stomach bleeding.Pregnant women are not supposed to take Aceclofenac + Paracetamol, more so in the advanced stages of pregnancy. The foetus may develop heart defects, or there may be a delay in birth.Those with ongoing symptoms or a history of stomach ulcers or bleeding anywhere in the digestive tract must not take this medicine.Patients who suffer from heart disease, have a liver or kidney problem, or have high blood pressure must take caution.If you have any pre-existing health conditions, like Asthma, Hypersensitivity, Peptic Ulcers, Stroke, Heart, Liver, or Kidney-related conditions, etc., speak with your doctor. Breastfeeding women must take care and consume the medicine only after seeking a doctor's advice[11]

What if we missed the dose of Aceclofenac + Paracetamol ?

if you miss a dose of Aceclofenac + Paracetamol, you can take it as and when you remember. If the next dose is due sometime soon, then you should skip the missed dose. Taking a double dose, in any case, to make up for the missed dose is not recommended.

Overdose of Aceclofenac + Paracetamol causes ;

An overdose of Aceclofenac + Paracetamol can cause confusion, chest pain, and other health-related complications. As far as possible, follow the doctor's instructions and avoid taking double doses of the medicine. If you overdose on Aceclofenac + Paracetamol, you should immediately consult your doctor.

Storage conditions for Aceclofenac + Paracetamol :

- Store Aceclofenac + Paracetamol in a cool, dry place, protected from heat, light, and moisture.
- Also, do not put them in a place where children can reach them.
- Keep them at room temperature, between 20 and 25 C (68-77F).Medications interact with Aceclofenac + Paracetamol:

People who are allergic to Aceclofenac, Paracetamol or any other ingredients present it shouldnot use this medicine.

The following can interact with Aceclofenac + Paracetamol:

Leflunomide, Phenytoin, Corticosteroids, Lithium, Carbamazepine, Digoxin, Sodium Nitrite. If you are taking any of the above medication, you should inform your doctor about it as they will provide you with the alternatives if necessary.

How quickly does Aceclofenac + Paracetamol show results?

Aceclofenac + Paracetamol medicine usually starts working in a few minutes, rangingfrom 10–30 minutes.

Aceclofenac + Paracetamol works effectively against the pain as well as the fever. It is advisable to strictly follow the prescription, and patients with pre-existing medical conditions should be more careful with its intake[11]

II. MATERIALS AND METHODS

Reagents and chemicals:

Standard tablet of Aceclofenac and generic tablet of Aceclofenac tablet where purchasedfrom local drug store of clinical pharmacy.The samples were properly checked for their manufacturing licence numbers, batch numbers, production and expiry dates[2]

Solvents and reagents:

Potassium dihydrogen phosphate and disodium hydrogen phosphate were used to from saline phosphate buffer[3]

Distilled water was used during the study.

1. Generic Aceclofenac Tablet:

Acenext p 100mg/325mg strip of 10 tablets

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Contains	Aceclofenac (100.0 mg) + Paracetamol(325.0 mg)
Uses	Pain, inflammation
Side effects	Nausea, vomiting, stomach upset,indigestion
Therapy	Analgesic/Antipyretic

Containdications of ACENEXT P Tablet:

- You have been prescribed this combination medicine for relieving pain and inflammation.Take Acenext P 100mg/325mg Tablet it with food to avoid getting an upset stomach.
- Do not take Acenext P 100mg/325mg Tablet with any other medicine containing paracetamol (drugs for pain/fever or cough-and-cold) withoutasking your doctor first.
- It may cause dizziness and sleepiness. Do not drive or do anything thatrequires mental focus until you know how it affects you.
- Avoid consuming alcohol when taking Acenext P 100mg/325mg Tablet as it may cause excessive drowsiness and increase the risk of liver damage.
- In case of muscle pain, your doctor might advise you to undergo physiotherapy to get relief along with taking Acenext P 100mg/325mg Tablet.
- Inform your doctor if you have a history of stomach ulcers beforetaking this medicine.

2. Branded/standard Aceclofenac Tablet: Zerodol p 100mg/325mg strip of 10 tablets

Contains	Aceclofenac (100.0 mg) + Paracetamol(325.0 mg)
Uses	Pain and inflammation
Side effects	Stomach pain, indigestion, Nausea
Therapy	Analgesic/Antipyretic

Contraindications of ZERODOL P Tablet:

- If you are allergic to aceclofenac, paracetamol or any of the ingredients ofZerodol p tablet.
- If you have a history of asthma, skin rashes, swelling & nasal congestion aftertaking painkillers.
- If you have a history of or currently have stomach ulcers or bleeding in anypart of the digestive tract.

Methods:

- If you have a heart failure problem, high blood pressure, liver or kidney-related problem.
- If you are pregnant, this medicine should not be taken, especially in the thirdtrimester of pregnancy.

Preparation of phosphate buffer pH 6.8:
Dissolve 13.872 g of potassium dihydrogen phosphate and 35.084 g of disodium hydrogen phosphate in sufficient water to produce 1000 ml. store in a cold place.

Determination of Aceclofenac melting point
The melting point was determined according to the method stated by USP. A compact column of Aceclofenac powder was prepared through inserting a small quantity of drug powder into capillary tube. The tube was put in stuart electrical apparatus until complete melting of powder and reading the temperature[5]

Determination of λ max of Aceclofenac
Aceclofenac solutions of 20µg/ml of Saline Phosphate buffer (pH 6.8) then the solutions were scanned by spectrophotometer from 200-400 nm, and then the λmax of the drug was determined[6]

Calibration curve of Aceclofenac
Calibration curves of Aceclofenac in Saline Phosphate buffer (pH 6.8) were constructed separately; by preparing a serial of dilution with different concentrations (4,8,12,16,ug/mL) from stock solution containing 20 µg/ml Aceclofenac. The absorbance was then measured at the λmax of the drug. The measured absorbance was plotted against the respective concentrations[8]

Hardness Test of Aceclofenac
The hardness of three tablets from generic tablet of aceclofenac and three tablets from standardbrand of aceclofenac was measured individually. An anvil driven by electric motor presses the tablet at a horizontal position and constant load until the

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tablet breaks. The hardness was measured in terms of kg/cm^2[7]

Friability test of Aceclofenac

This test was done for 20 tablets, starting by weighing them and then operating the friabilator at 25 r.p.m. for 4 minutes, re-weighing the tablets to determine the loss in their weight. Where first we have to weigh 20 tablets of generic aceclofenac and then operating them in friabilator at 25r.p.m for 4 minutes , and then reweight the tablets and record the loss in their weight.

Secondly,We have to weigh 20 tablets of standard aceclofenac and then operating them in friabilator at 25r.p.m for 4 minutes , and then reweight the tablets and record the loss in their weight [10]

Determination of weight variation

Twenty tablets from generic aceclofenac and twenty tablets from standard brand of aceclofenac were weighted individually with the mentioned analytical balance and average weight and the percent deviation was determined for both brand[9]

Dissolution test of Aceclofenac

The dissolution test was undertaken using tablet dissolution tester in 6 replicates for generic aceclofenac and 6 replicates for standard brand of aceclofenac. Dissolution media were IP buffer solutions at pH 6.8 (phosphate buffer solution).The medium was maintained at 37 ± 0.5°C. In all the experiments, 5 ml of dissolution sample was withdrawn at 0, 10, 20, 30, 40, 50 and 60 min and replaced with equal volume to maintain sink condition. Samples were filtered and assayed by UV spectroscopic method. The concentration of each sample was determined from a calibration curve obtained from pure samples of aceclofenac[9]

Disintegration test of Aceclofenac

The disintegration time was determined in Saline Phosphate buffer (pH 6.8) at 37˚C. Disintegration apparatus with a basket rack assembly containing six open-ended tubes and 10-mesh screen on the bottom was used. A tablet was placed in each tube of the basket and the time for complete disintegration of the six tablets was recorded for each brand (for generic aceclofenac and standard aceclofenac)[11]

Uniformity of dosage units

Two tablets of generic aceclofenac and two tablets of standard aceclofenac were weighed individually and powdered.The powder equivalent to1000mg of aceclofenac was weighed and dissolved in 200mL of Saline Phosphate buffer (pH 6.8). The solution was then filtered and from this solution 1mL was taken and makes up with Saline Phosphate buffer (pH 6.8) in 250 mL standard volumetric flask. The amount of drug present in each tablet was determined spectrophotometrically at 243 nm using UV– spectrophotometer.The percentage content was determined using standard graph[13]

III. RESULT AND DISCUSSION:

Determination of Aceclofenac melting point

1) For Generic Aceclofenac:

Melting point of generic aceclofenac tablet (Acenext p tablet) was determined byusing digital melting point apparatus.

The melting point was found to be 148.7^{0}C.

2) For standard (branded) Aceclofenac:

Melting point of branded aceclofenac tablet (Zerodol p tablet) was determined byusing digital melting point apparatus.

The measured melting point of standard aceclofenac tablet was found to be 149^0 C.

Determination of λ max of Aceclofenac

Scanning the solution of both generic and standard aceclofenac tablet of which 20 µg/mL of Aceclofenac in Saline Phosphate buffer (pH 6.8) by UV- spectrophotometer at 200-400 nm.

And it gave the spectrum shown in figure (1) with peak for λmax at 273 nm in Saline Phosphate buffer (pH 6.8) solution. The result is in agreement with the reported one.

For generic and standard aceclofenac tablet was found to be same.

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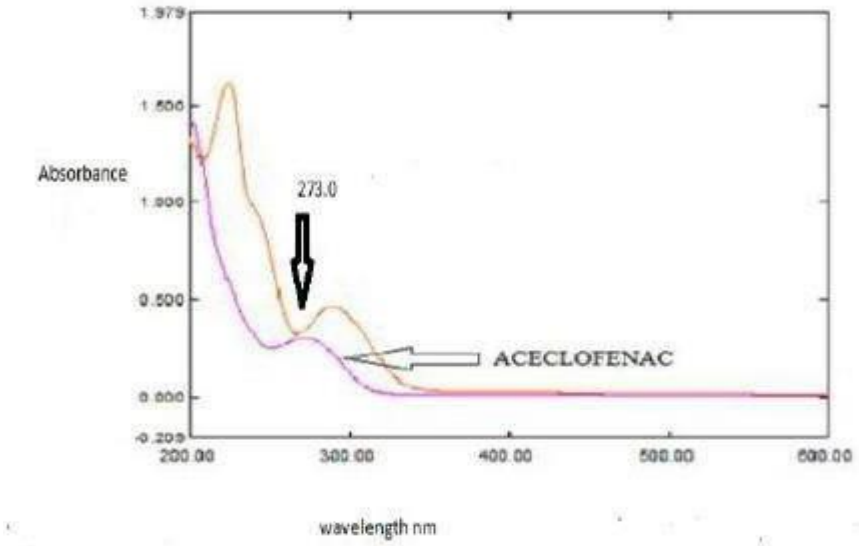
Figure 1: The UV Spectrum of ACE in saline phosphate buffer (pH 6.8)



Calibration Curve of Aceclofenac

The Calibration Curve of generic and standard Aceclofenac pH 6.8 saline phosphatebuffer. A straight line was obtained by plotting the absorbance versus concentration.this indicates that calibration curve obeys beer`s law within the range of concentration used.

1) For generic Aceclofenac:

The calibration curve of generic acenext p Aceclofenac tablet in pH 6.8 salinephosphate buffer was found to be as follows table 1;

Table 1: Calibration curve of generic acenext p Aceclofenac tablet in pH 6.8 salinephosphate buffer

Sr . no	Concentration (µg/ml)	Volume(ml)	Y (absorbance)	x2	Xy	Y (regression)
1	0	0.1	0	18	0.206	0.133
2	20	0.3	0.2	36	0.812	0.241
3	40	0.5	0.4	56	1.764	0.3496
4	60	0.7	0.6	76	3.408	0.4567
5	80	0.9	0.8	95	4.880	0.5656
6	100	1.1	1	114	7.368	0.6736
7	120	1.3	1.2	114	10.76	0.7816

2) For standard brand of Aceclofenac:

The calibration curve of standard zerodol p Aceclofenac tablet in pH 6.8 salinephosphate buffer was found to be as follows table 2;

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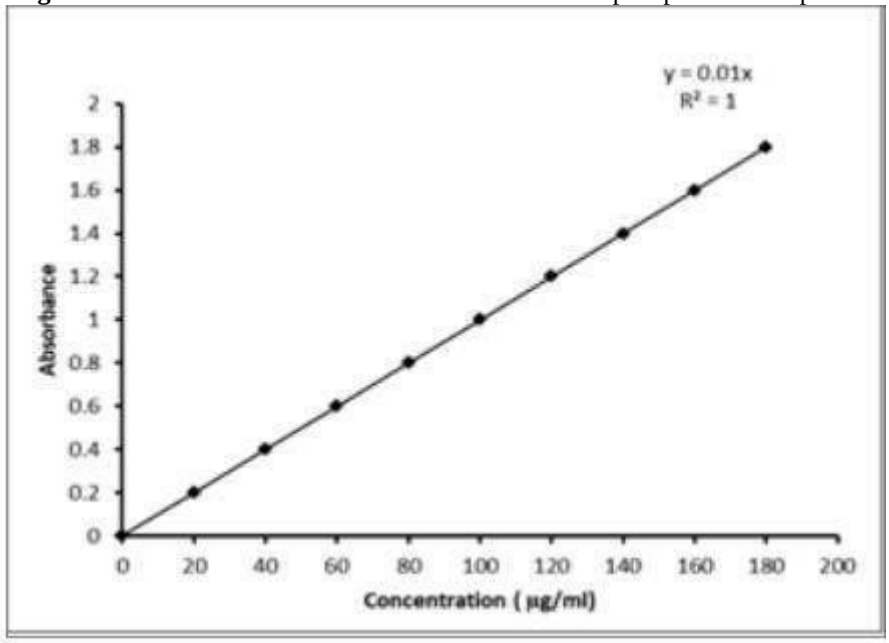
Table 2: Calibration curve of standard zerodol p Aceclofenac tablet in pH 6.8 salinephosphate buffer

Sr . no	Concentration (µg/ml)	Volume(ml)	Y (absorbance)	x2	Xy	Y (regression)
1	0	0.1	0	18	0.208	0.135
2	20	0.3	0.2	36	0.814	0.243
3	40	0.5	0.4	56	1.766	0.3456
4	60	0.7	0.6	76	3.410	0.4580
5	80	0.9	0.8	96	4.882	0.5666
6	100	1.1	1	115	7.370	0.6748
7	120	1.3	1.2	115	10.78	0.7916

Figure 2: the calibration curve of Aceclofenac in saline phosphate buffer pH 6.8



Hradness of Aceclofenac tablet

Hardness is most important physical feature for assessing tablet. In the study, it was found that both Acenext p and zerodol p brands of Aceclofenac group passed the test of tablet crushing strength or hardness. Both these brands have acceptable crushing strength of between 4 kg/cm2 to 10 kg/cm2.

Tablet hardness was measured by using hardness tester from both formulation tablets weremeasured for the hardness an average values.

1) For generic Aceclofenac tablet:
The hardness was found to be 5.5kg/cm^2

2) For standard Aceclofenac tablet:
The hardness was found to be 5.4kg/cm^2

Table 3: Hardness of Aceclofenac tablets

Sr no	Formulation of Aceclofenac tablet	Hardness
1	Acenext p tablet	5.5
2	Zerodol p tablet	5.4

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Friability test of Aceclofenac

In the friability test, both tablet brands showed impressive friability values. The friability values for both Aceclofenac tablet brands were ranged from 0.1 to 0.2%. In both formulations percentage of friability was less than 1% which ensures that all the tablets of both brands of formulas were mechanically stable[5]

The friabilator was operated at 25 rpm for 4 minutes or run up 100 revolutions. Than tablets were weighted again. The friability was calculated as the percentage weight loss.

% Friability = (W1 – W2) x 100/W1Where

W1 = Initial weight of the 10 tablets.

W2 = Final weight of the 10 tablets after testing

% friability of the tablets less than 1% are acceptable.

1) For generic Acenext p tablet:

The friability of generic acenext p tablet was found to be 0.1%

2) For standard zerodol p tablet:

The friability of standard zerodol p tablet was found to be 0.1%

Table 4: friability of Aceclofenac tablets

Sr no	Formulation of Aceclofenac	Before friability weight	After friability weight	Percent friability weight
1	Acenext tablet	6.98	6.88	0.1%
2	Zerodol tablet	5.88	5.70	0.1%

Determination of weight variation

During the study, at first the weight variation which is the key to controlling crushing strength and friability of tablet was assessed. The test stated that both the samples of Aceclofenac coded A and B have passed the weight variation uniformity test as specified in the USP (not exceed 5% deviation)[6]

Table 5: Weight variation test limit (mg) of Aceclofenac tablet

Sr no	Formulation of Aceclofenac tablet	Weight variation test limit(mg)
1	Acenext p tablet	1.9
2	Zerodol p tablet	1.3

Dissolution test of Aceclofenac

The dissolution study of generic Aceclofenac tablet and standard brand of Aceclofenac tablet was carried out using dissolution apparatus. The test was carried out for two hours. For the two hours phosphate buffer pH 6.8 was used as dissolution medium. The bath temperature of the dissolution apparatus was maintained 37^0 C.

The complete test was done at the 50 rpm. The time interval was taken as 0,10,20,30,40,50, and 60 minutes. And the one tablet was taken after each time interval respectively. Each observation was recorded properly and absorbance was checked out using UV spectrophotometer at 275 nm[9]

Aceclofenac tablet is not official in BP or USP. there is no official dissolution medium available in the literature.[13]

Drug release from both generic and standard brand was almost uniform around 80% drug was release within 30 min and almost 100% drug was realease within 60 min from both brand in phosphate buffer pH 6.8.Aceclofenac is a water insoluble drug but it is soluble in phosphate buffer pH 6.8.it is solubility in phosphate buffer is 1538.7+/- 1.215 mcg/ml.due to higher solubility in this media the entire drug dissolved with in 60 min. Drug release was found lower in branded Aceclofenac this is may due to lower solubility of Zerodol p Aceclofenac in phosphate buffer solution or may be due to presence of some alkalizing agents in the formulation which increase the pH of the dissolution media and facilitate drug release.from the dissolution result it can be concluded that release of tablet formulation is depended on dissolution medium.

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Dissolution profile of both aceclofenac tablets was recorded as follows ;

1) For Generic Acenext p tablet :

Table 7: Dissolution profile for generic tablet

For Generic Acenext p tablet	
Time (minutes)	Percentage of drug release
0 min	0%
15 min	72.22%
20 min	106.02%
25 min	105.34%
30 min	103.86%
35 min	100.66%
60 min	103.76%

2) For standard brand Zerodol p tablet :

Table 8: Dissolution profile for standard branded tablet

For standard brand zerodol p tablet	
Time (minutes)	Percentage of drug release
0 min	0%
15 min	62.86%
20 min	68.08%
25 min	78.5%
30 min	108.28%
35 min	100.22%
60 min	100.69%

Figure 3: Dissolution profile of generic Acenext p tablet

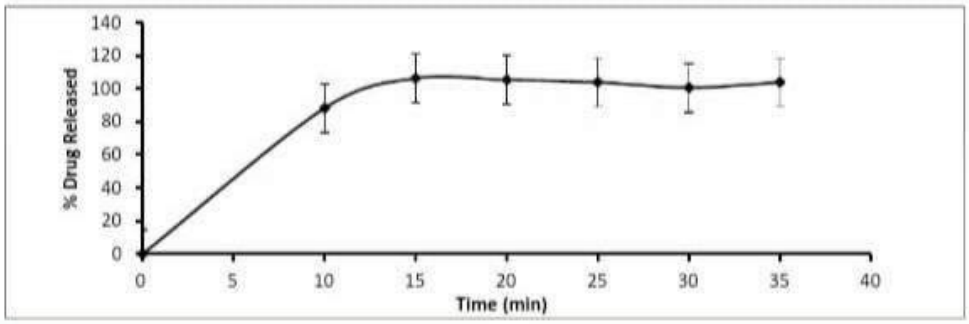

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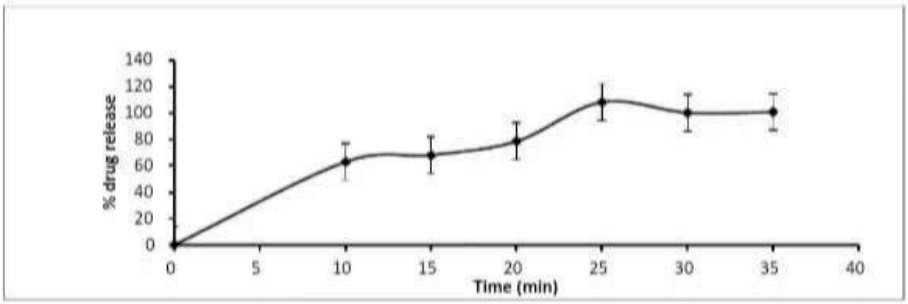
Figure 4: Dissolution profile of standard brand Zerodol p tablet



Disintegration test of Aceclofenac

The disintegration time of both generic and standard brand of aceclofenac Acenext p and Zerodol p was satisfactory as uncoated USP tablets have disintegration time standards as low as 5 min[8].

Table 9: Disintegration time for both Aceclofenac tablet

Sr.No	Formulation of Aceclofenactablet	DisintegrationTime (min/sec)
1	Acenext p	4 min 56 sec
2	Zerodol p	5 min 36 sec

Uniformity of dosage unit

Both tablet brands of aceclofenac Acenext p and Zerodol p contained in the aceclofenacwithin 100 ±5 % of the labelled claim. The IP specification for assay that are the aceclofenac contents should not be less than 95% and not more than 105%[10]

IV. CONCLUSION

In the present study we evaluated two brand of Aceclofenac tablets one of which is generic andsecond is of standard brand (acenext p and Zerodol p).The purpose of the study was to determine different evaluation parameters as well as to compare dissolution study of branded of tablet with generic aceclofenac tablet. This type of study is also sometime refferred as bioequivalence study. After performing this study with conclude that both generic and brand tablets are of good quality the tablet were evaluated for different parameters and all of them are under standard acceptance criteria or limit for different paramters. After performing different evaluation parameters with conclude that all tablets are under the acceptable limit for weight variation test, Determination of melting point test, Determination of λ max of Aceclofenac, Calibration curve, hardness test, Friability test, dissolution test, Disintegration test and Uniformity test.

Where we conclude that;

1) The Melting point of generic tablet was less than that of Melting point of brand Aceclofenac by 0.3^0C.
2) The λ max of aceclofenac of both generic and brand aceclofenac was same.
3) The Calibration curve of both generic and brand aceclofenac tablet was found to be equal.
4) The Hardness of generic tablet was more than that of hardness of brand aceclofenac by0.1.
5) The Friability of aceclofenac of both generic and brand aceclofenac was same.
6) The Weight variation of generic aceclofenac was more than that of standard aceclofenactablet.
7) The Rate Dissolution profile of generic tablet was higher than that of brand aceclofenac.The Acenext p tablet release drug in higher rate than that of Zerodol p tablet[8,11].
8) The Rate of disintegration of generic tablet was less than that of branded aceclofenac tablet[9].
9) The Uniformity of both tablets was equal.

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