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Comparative study of three different brands of aceclofenac tablets

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ABSTRACT

Aceclofenac is a non-steroidal anti- inflammatory drug (NSAIDs) along with analgesic and anti-pyretic properties. The main concept of the study is to finding the comparative between the three different brands of Aceclofenac. In this we can compare three marketed brands of aceclofenac 100mg tablets. The parameters can conducted by these three brands of aceclofenac tablets as thickness, weight variation, hardness, friability. The results obtained by these parameters comply within limits as per I.P. Aceclofenac is used as an anti-inflammatory as well as rheumatoid arthritis and osteoporosis. And it is belongs to the (BCS) class-II drugs while it has low solubility and high permeability.

Keywords: Aceclofenac, Comparative study, Evaluation tests, Weight variation, Friability, Hardness, Thickness.

INTRODUCTION

Aceclofenac tablet is a solid dosage forms which is freely soluble in the Gastro Intestinal tract and then it can produce the pharmacological effects. Solid dosage form is mainly preferred because a certain amount of drug should be administered in the body. But in some cases it fails to give the same therapeutic effects based on the insufficient dissolution and subsequent absorption of the drug from GIT. Chemically aceclofenac is said to be [(2-{2, 6-dichloro phenyl) amino} phenyl acetoxy acetic acid]. It is a non-steroidal anti-inflammatory drug (NSAIDs) this drug are mostly

used for inflammation. Quality control test should be done for Aceclofenac marketed drugs to ensure the safety, efficacy and quality acceptance rationality of use to protect public health. It provides symptomatic relief in a variety of painful conditions and helps to reduce inflammation. It is a cytokine inhibitor. It works by blocking the action of substance in the body is called as cyclooxygenase. Aceclofenac tablet is not official in B.P or U.S.P till now, but products are available in the markets. While it is practically insoluble in water with good permeability and belongs to class-II drugs [1-7].

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Fig no: 1.0

MATERIALS AND METHODS

Aceclofenac 100 mg tablets from the following three different brands.

Aceclo from Aristo

C-acec from cross bell

Zerodol from Ipca

These three brands are evaluated by using these following tests as per required apparatus

- Weight variation test- By using high precision balance
- Hardness- By using Monsanto hardness tester
- Friability- By using Roche friabilator
- Thickness- By using vernier caliper

By the following tests the results are obtained within limits as per I.P. and the tests are explained as

Weight variation

Weigh individually 20 tablets selected at random and calculate the average weight. Not more than two of the individual weight deviates from the average weight by more than the percentage given in pharmacopeia and none deviates by more than twice that percentage.

I.P/B.P/U.S.P limits for tablet weight variation is given below table no: 1.1

Table no: 1.1		
Weight of tablet	% deviation	
80mg	±10%	
>80mg -<250mg	±7.5%	
250mg or more than	±5%	

Hardness

The tablet should show sufficient mechanical strength to with stand fracture and erosion during manufacture and handling. It is the load required to crush the tablet when placed on its edge. The apparatus used for hardness is Monsanto tester. Normal tablet hard ness ranges from 2-4 kg (1kg=10newtons)

Friability

Friability is a property that is related to the hard ness of the tablet and also add weight variation, content uniformity problems an instrument is used for friability is called friabilator is used evaluate the ability of tablet to with stand abrasion in packaging, handling and shipping.

Tablet friability apparatus is used for the test remove any loose dust from the tablets and accurately weigh 10 tablets they are placed in a drum which rotate at 25±1rpm rotate the drum 100 times and remove the tablets the sample fails the test if any of the tablets cracked, cleaved or broken is present if the weight loss is more than 1.0% the test is repeated for twice and mean of three tests is calculated the mean not more than 1.0% is considered acceptable according to BP –percentage of friability should not be more than 0.8%. According to the USP- percentage of friability should not be more than 4%.

Thickness

The appearance of tablet should be elegant and also consistent. It is done by using vernier calipers.

Tablet thickness diameter should be controlled with in a 3.5-4mm of a standard value.

RESULTS AND DISCUSSION

Three brands of Aceclofenac 100mg tablets were purchased from apollo pharmacy at Guntur. All the brands of aceclofenac tablets used were within their self life during the study period as given below

Table no: 1.2

Samples	Brand name	Mfg date	Exp date	Labelled strength	Manufacture
A	Aceclo	6/2017	5/2019	100mg	Cross bell
В	C-acec	9/2017	8/2019	100mg	Aristo
C	Zerodol	5/2017	4/2019	100mg	Ipca

The evaluation tests of different brands of Aceclofenac 100mg the results was obtained within

limits. The results of evaluation tests are given below table no: 1.3

Table no: 1.3: Weight Variation: weight of 20 tablets of different brands

Tablets	Aceclo	C-acec	Zerodol
1	0.23	0.19	0.19
2	0.22	0.22	0.21
3	0.23	0.19	0.16
4	0.22	0.22	0.18
5	0.23	0.22	0.20
6	0.19	0.22	0.18
7	0.22	0.21	0.20
8	0.22	0.23	0.19
9	0.18	0.22	0.19
10	0.19	0.20	0.18
11	0.22	0.19	0.16
12	0.23	0.22	0.20
13	0.22	0.22	0.19
14	0.23	0.21	0.21
15	0.18	0.22	0.18
16	0.22	0.19	0.19
17	0.19	0.23	0.20
18	0.19	0.22	0.18
19	0.23	0.20	0.19
20	0.22	0.22	0.18

Table no: 1.4: Statistical weight variations

-	,
Average	Standard deviation
0.213	0.000321
0.212	0.0002
0.180	0.00021
	Average 0.213 0.212

 Table no: 1.5: Weight variation test

Tablets	Result(GM)	IP/BP/USP specifications	Deviation frIP/BP/USP
Aceclo	0.213		
C-acec	0.212	Deviation should be	Within specific limit
Zerodol	0.188	± 7.5%	

Table no: 2.0: Hardness Test: Hardness of 10 tablets from the three different brands

Tablets	Aceclo	C-acec	Zerodol
1	3	3.5	2.5
2	3.5	2.5	2
3	2.5	2	2.5
4	3	2.5	2
5	2.5	2	3
6	3.5	3	2
7	3	2.5	2.5
8	2	2.5	2.5
9	2.5	2	3.5
10	2	2.5	3

Table no: 2.1: Statistical hardness

Tablets	Average(kg)	Standard deviation
Aceclo	2.8	0.21
C-acec	2.55	0.22
Zerodol	2.5	0.2

Table no: 2.2: Friability test

Tablets	Result (%)	IP/BP/USP specifications	Deviation from IP/BP/USP specifications
Aceclo	0.4		
C-acec	0.20	Not more than 1%	In specified limit
Zerodol	0.25		

Table no: 3.0: Thickness Test: Thickness of 10 tablets

Tablets	Aceclo	C-acec	Zerodol
1	3.79	3.69	3.52
2	3.69	3.80	3.87
3	3.71	3.66	3.65
4	3.80	3.62	3.54
5	3.69	3.53	3.83
6	3.52	3.79	3.69
7	3.66	3.87	3.77
8	3.72	3.73	3.85
9	3.85	3.64	3.63
10	3.62	3.85	3.92

Table no: 3.1: Statistical thickness

Tablets	Average thickness(mm)	Standard deviation
Aceclo	3.67	0.9
C-acec	3.71	0.2
Zerodol	3.72	0.1

CONCLUSION

Based on the results obtained in this work, all the evaluation tests performed for the three different brands of aceclofenac (Aceclo, C-acec, Zerodol) are within the range as per I.P. the amount of active ingredient present in tablets are not meeting the label claim. The best brand was found to be Zerodol 100mg.

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