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Design and development of Aceclofenac fast dissolving tablets by different techniques

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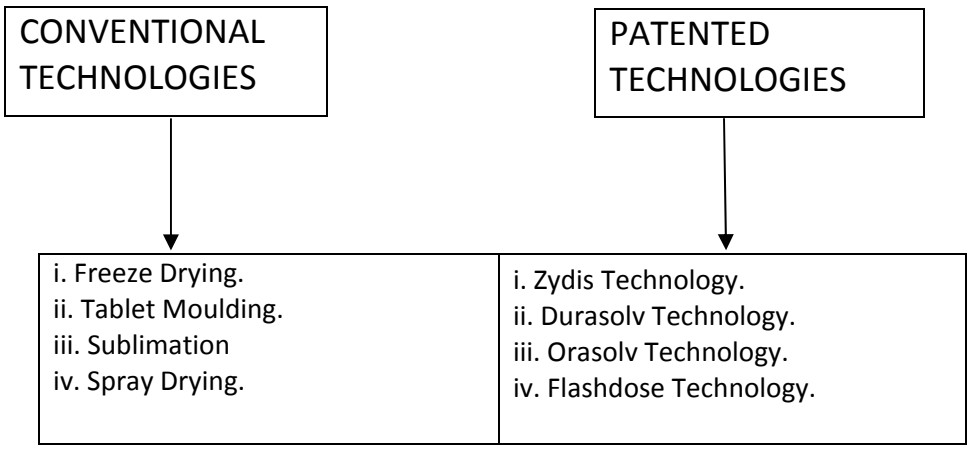
Abstract
Aceclofenac is [[[2-[(2, 6, Dichlorophenyl) amino] phenyl] acetyl] oxy] acetic acid. It is a novel nonsteroidal anti-inflammatory drug indicated for symptomatic treatment for pain and inflammation. In the present work fast dissolving tablets of Aceclofenac were prepared by direct compression, sublimation and effervescent methods. The prepared tablets were evaluated for various parameters like weight variation, hardness, friability, disintegration time, drug-polymer interaction by drug content, water absorption ratio, wetting time, *in vitro* drug release, FTIR studies and DSC studies, short term stability studies.

Keywords: Fast dissolving tablets, Aceclofenac, Superdisintegrants.

1. Introduction
Solid dosage forms like tablet and capsule are most popular and preferred drug delivery system because they have high patient compliance, relatively easy to produce, easy to market, accurate dosing, and good physical and chemical stability1

1.1. Technologies used to manufacture mouth dissolving tablets:
The technologies used to manufacture mouth dissolving tablets can be classified as: Various technologies used to manufacture mouth dissolving tablet.

1.2. Conventional technologies for preparing fast dissolving tablets
Freeze Drying: A process in which water is sublimated from the product after freezing is called freeze drying. Freeze dried forms offer more rapid dissolution than other available solid products. The lyophilization process imparts glossy amorphous structure to the bulking agent and sometimes to the drug, thereby enhancing the dissolution characteristics of the formulation. However, the use of freeze drying is limited due to high cost of the equipment and processing.



Other major disadvantages of the final dosage forms include lack of physical resistance in standard blister packs. A tablet that rapidly disintegrates in aqueous solution includes a partially collapsed matrix network that has been vacuum dried above the collapse temperature

of the matrix. The matrix is partially dried below the equilibrium freezing point of the matrix Vacuum drying of the tablet above its collapse temperature instead of freeze drying below its collapse temperature provides a process for producing tablets with enhanced structural integrity, while rapidly disintegrating in normal amounts of saliva.

1.3. Moulding
Tablets produced by moulding are solid dispersions. Physical form of the drug in the tablets depends whether and to what extent it dissolves in the molten carrier. The drug can exist as discrete particles or microparticles dispersed in the matrix. It can dissolve totally in the molten carrier to form solid solution or dissolve partially in the molten carrier and the remaining particles stay undissolved and dispersed in the matrix. Disintegration time, drug dissolution rate and mouth feel will depend on the type of dispersion or dissolution. Moulded tablets disintegrate more rapidly and offer improved taste because the dispersion matrix is, generally made from water-soluble sugars. Moulded tablets typically do not possess great mechanical strength. Erosion and breakage of the moulded tablet often occur during handling and opening of blister packs.

1.4. Sublimation
Because of low porosity, compressed tablets composed of highly water soluble excipients as tablet matrix material often do not dissolve rapidly in the water. Porous tablets that exhibit good mechanical strength and dissolve quickly have been developed. Inert solid ingredients (E.g. urea, urethane, ammonium carbonate, camphor, naphthalene) were added to other tablet excipients and the blend was compressed into tablet. Removal of volatile material by sublimation generated a porous structure. Compressed tablets containing mannitol and camphor have been prepared by sublimation technique. The tablets dissolve within 10-20 seconds and exhibit sufficient mechanical strength for practical use.

1.5. Spray Drying
Highly porous and fine powders can be produced by spray drying, as the processing solvent is evaporated rapidly during spray drying. Spray drying technique is based upon a particulate support matrix and other components to form a highly porous and fine powder. This is then mixed with above ingredients and compressed to tablet. The fast dissolving tablets prepared form Spray drying technique disintegrated within 20 seconds.

1.6. Mass Extrusion
This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

1.7. Direct compression
It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Directly compressed tablets disintegration and solubilisation depends on single or combined action of disintegrants, water-soluble excipients and effervescent agent. Disintegrant efficacy is strongly affected by tablet size and hardness. Large and hard tablets have disintegration time more than that usually required. As consequences, products with optimal disintegration properties often have medium to small size and/or high friability and low hardness. Breakage of tablet edges during handling and tablet rupture during the opening of blister alveolus, all result from insufficient physical resistance.

Various commercially available superdisintegrants along with their properties.

Sr. no.	Name	Properties	Type	Brand name
1	Crospovidone Polyvinylpyrrolidone	Crossed linked Poly vinyl pyrrolidone Rapidly disperses and swells in water	Polyvinylpyrrolidone	Polyplasdone XL, Kollidon CL
2	Croscarmellose	Cross linked sodium carboxymethylcellulose. Excellent swelling and water wicking properties	Modified cellulose	Ac-di-sol, Primellose, Solutab.
3	Sodium starch	Sodium salt of carboxy methyl ether of starch. High swelling capacity and rapid water uptake.	Modified Starch	Primogel, Explotab, Glycolys

2. Materials and Methods
Aceclofenac, Croscarmellose sodium Crospovidone Sodium starch glycolate microcrystalline cellulose Mannitol Camphor. Aspartame, Magnesium stearate Talc, Potasium Dihydrogen Pthalate, Sodium hydroxide,

2.1. Analytical methods for estimation of Aceclofenac:
Identification of drug was carried out by Fourier transform infrared spectrophotometer (JASCO FT/IR-5300) and Differential scanning colorimetry. Standardization of the drug was carried out by using UV visible spectrophotometer (T80UV/VIS- Spectrophotometer).

2.2. Determination of λ_{max} for Aceclofenac:
A 5 mcg/ml of Aceclofenac in phosphate buffer pH 6.8 was scanned in UV range between 200-400 nm. Aceclofenac showed maximum absorbance at 274 nm (Fig. 1) in phosphate buffer pH 6.8. Thus 274 nm was used as wavelength (max) for further analysis.

1. Preparation of fast dissolving tablets by Direct Compression method

Ingredients (mg)	Formulations code											
	G1	G2	G3	G4	G5	G6	G7	G8	G9	G10	G11	G12
Aceclofenac	50	50	50	50	50	50	50	50	50	50	50	50
Crosprovidone	3	6	9	12	-	-	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	-	3	6	9	12	-	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	-	-	3	6	9	12
D- Mannitol	40	37	34	31	40	37	34	31	40	37	34	31
Aspartame	5	5	5	5	5	5	5	5	5	5	5	5
Mg stearate	1	1	1	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100	100	100	100	100	100	100

2. Preparation of fast dissolving tablets by Sublimation method:

Ingredients	Formulation code											
	GS1	GS2	GS3	GS4	GS5	GS6	GS7	GS8	GS9	GS10	GS11	GS12
Aceclofenac	50	50	50	50	50	50	50	50	50	50	50	50
Croscarmellose sodium	6	6	6	6	6	6	6	6	6	6	6	6
Menthol	3	6	9	-	-	-	-	-	-	-	-	-
Urea	-	-	-	3	6	9	-	-	-	-	-	-
Ammonium bicarbonate	-	-	-	-	-	-	3	6	9	-	-	-
Camphor	-	-	-	-	-	-	-	-	-	3	6	9
D- Mannitol	34	31	28	34	31	28	34	31	28	34	31	28
Aspartame	5	5	5	5	5	5	5	5	5	5	5	5
Mg stearate	1	1	1	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100	100	100	10	100	100	100

3. Preparation of fast dissolving tablets by Effervescent method

Ingredients	Ge1	Ge2	Ge3	Ge4	Ge5	Ge6	Ge7	Ge8	Ge9	Ge10	Ge11	Ge12
Aceclofenac	50	50	50	50	50	50	50	50	50	50	50	50
ssg	6	6	6	6	6	6	6	6	6	6	6	6
Sodium carbonate	3	6	9	12	3	6	9	12	3	6	9	12
Citric acid	3	6	9	12	-	-	-	-	1.5	3.0	4.5	6
Tartaric acid	-	-	-	-	3	6	9	12	1.5	3	4.5	6
Aspartame	5	5	5	5	5	5	5	5	5	5	5	5
Mannitol	31	25	19	13	31	25	19	13	31	25	19	13
Talc	1	1	1	1	1	1	1	1	1	1	1	1
Magnesium sterate	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight	100	100	100	100	100	100	100	100	100	100	100	100

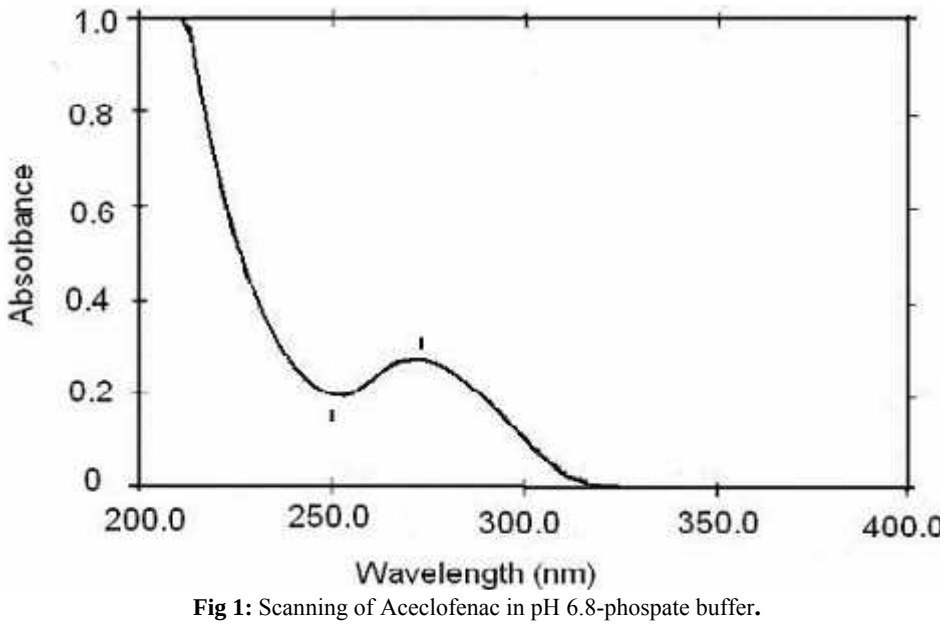


Fig 1: Scanning of Aceclofenac in pH 6.8-phospate buffer**.**

2.3. Standard calibration curve of Aceclofenac in phosphate buffer pH 6.8

Preparation of phosphate buffer pH 6.8: Fifty ml of 0.2M potassium dihydrogen phosphate was taken in 200 ml volumetric flask, to which 22.4 ml of 0.2 M sodium hydroxide solution was added and the volume was made up to the mark with distilled water.

2.4. Potassium dihydrogen phosphate (0.2 M) solution: Potassium dihydrogen phosphate, 27.218 gm was added to 1000 ml volumetric flask containing distilled water and the volume was made up to the mark with distilled water.

2.5. Sodium hydroxide (0.2 M) solution: 8.0 gm of sodium hydroxide was taken in 1000 ml volumetric flask containing distilled water and volume was made up to the mark with distilled water.

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2.6. Procedures.

100 mg of pure drug transferred into 100 ml of distilled water in a volumetric flask. Withdrawn 10 ml from this solution and diluted to 100 ml it make 100 mcg/ml (stock solution) then concentration made by withdrawing from stock solution and diluted to 10 ml it makes solution of concentration 6 µg/ml, 8 µg/ml, 10 µg/ml, 12 µg/ml, 14 µg/ml, 16 µg/ml, 18 µg/ml, 20 µg/ml. From the standard curve of Aceclofenac (Fig 2.), it was observed that the drug obeys Beer's law in concentration range of 6–20 µg/ml in phosphate buffer pH 6.8. The linear regression equation generated was used for the calculation of amount of drug

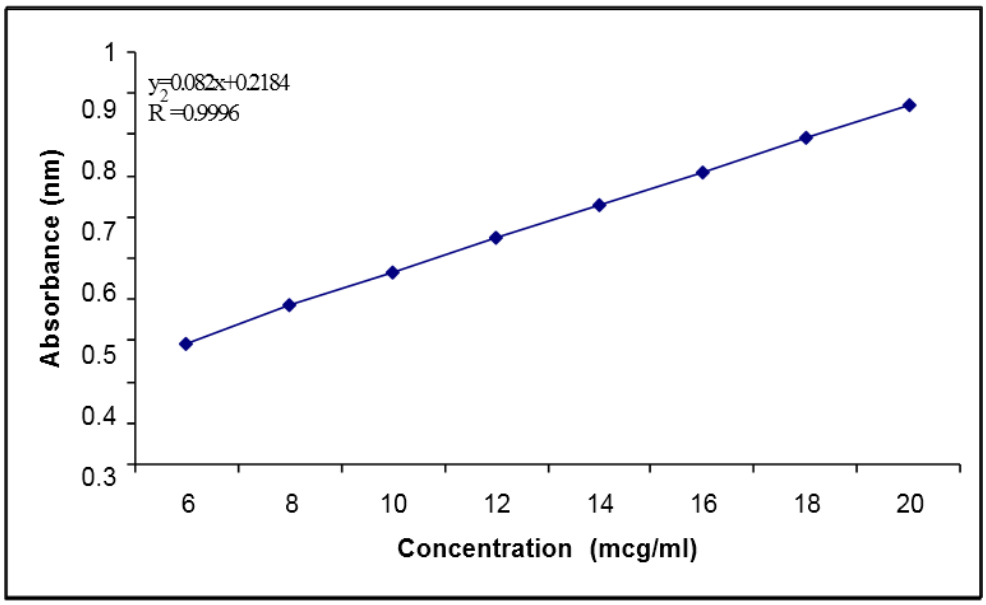
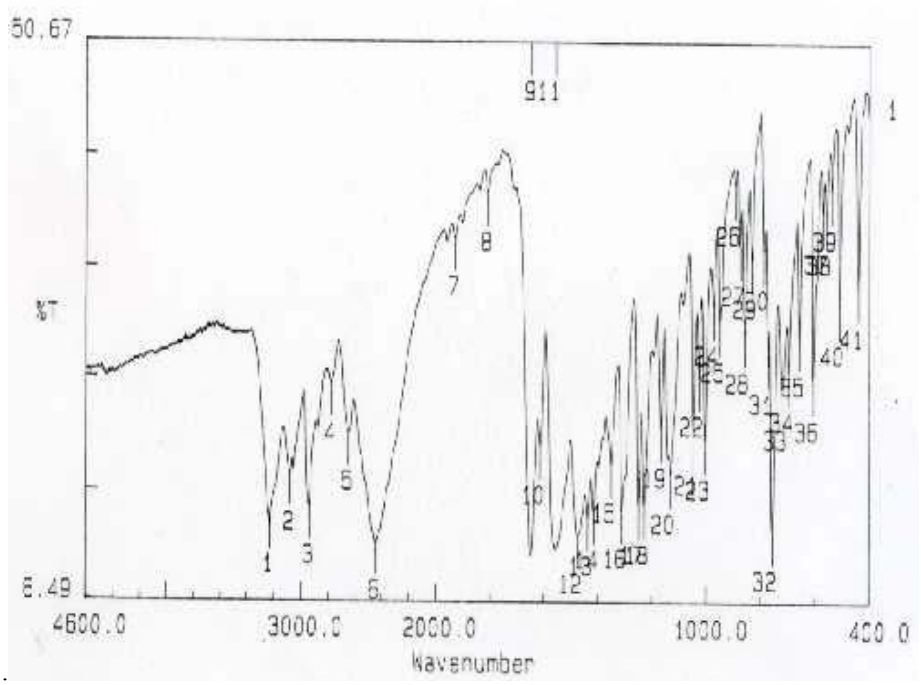
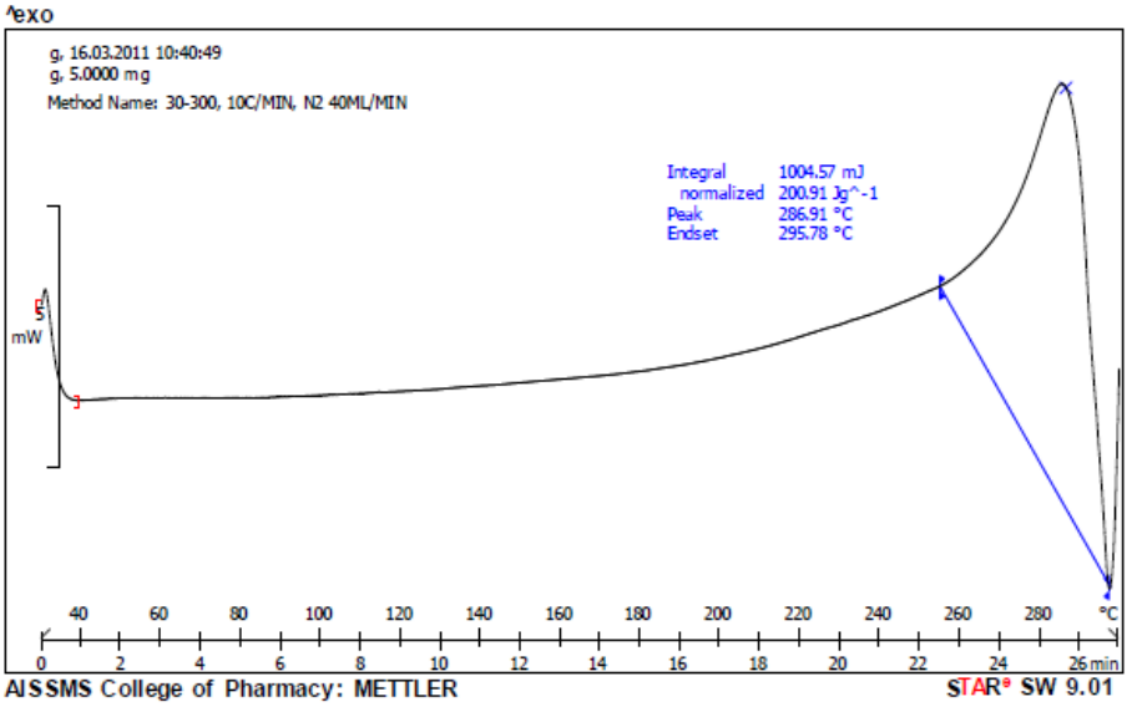


Fig 2: Standard calibration curve of Aceclofenac in 6.8 pH buffer solutions at µmax 274nm



Ir spectra of Aceclofenac



DSC of pure drug

1) Post - compression parameters of Aceclofenac fast dissolving tablets prepared by Direct compression method :

Formulation Code	Hardness* (Kg/cm²) ± SD	Friability (%)	Thickness* (mm) ± SD	Weight variation* (mg) ± SD
G1	3.5 ± 0.11	0.45	3.26 ± 0.09	099 ± 0.61
G2	3.0 ± 0.10	0.56	3.38 ± 0.10	098 ± 0.13
G3	3.5 ± 0.15	0.71	3.37 ± 0.20	101 ± 0.47
G4	4.0 ± 0.20	0.52	3.43 ± 0.21	102 ± 1.25
G5	3.0 ± 0.10	0.61	3.28 ± 0.28	101 ± 1.37
G6	4.0 ± 0.21	0.52	3.29 ± 0.12	100 ± 0.61
G7	3.5 ± 0.05	0.42	3.27 ± 0.17	98 ± 0.42
G8	3.0 ± 0.18	0.47	3.40 ± 0.10	099 ± 1.49
G9	3.1 ± 0.12	0.59	3.27 ± 0.15	097 ± 1.05
G10	3.0 ± 0.14	0.67	3.27 ± 0.13	100 ± 1.60
G11	3.0 ± 0.10	0.49	3.30 ± 0.25	101 ± 0.50
G12	3.5 ± 0.10	0.73	3.25 ± 0.20	102 ± 0.43

* Average of three determinations

2) Post - compression parameters of Aceclofenac fast dissolving tablets prepared by Sublimation method:

Formulation Code	Hardness * (Kg/cm²) ±SD	Friability (%)	Thickness* (mm) ±SD	Weight variation* (mg) ±SD
GS1	3.1 ± 0.09	0.59	3.18 ± 0.15	98 ± 0.64
GS2	3.0 ± 0.05	0.63	3.25 ± 0.10	97 ± 0.92
GS3	2.5 ± 0.20	0.41	3.31 ± 0.05	99 ± 1.38
GS4	2.5 ± 0.15	0.27	3.43 ± 0.09	101 ± 1.36
GS5	2.5 ± 0.30	0.44	3.17 ± 0.10	101 ± 0.20
GS6	2.5 ± 0.29	0.37	3.07 ± 0.14	102 ± 1.40
GS7	2.0 ± 0.37	0.45	3.14 ± 0.02	101 ± 0.29
GS8	2.5 ± 0.07	0.58	3.15 ± 0.19	99 ± 0.60
GS9	2.5 ± 0.21	0.49	3.20 ± 0.25	98 ± 1.49
GS10	2.0 ± 0.12	0.62	3.12 ± 0.20	97 ± 1.20
GS11	2.7 ± 0.17	0.51	3.24 ± 0.30	102 ± 0.93
GS12	2.3 ± 0.25	0.47	3.26± 0.18	100 ± 1.60

* Average of three determinations

3) Post - compression parameters of Aceclofenac fast dissolving tablets prepared by Effervescent method:

Formulation Code	Hardness * (Kg/cm²) ±SD	Friability (%)	Thickness* (mm) ±SD	Weight variation* (mg) ±SD
GE1	3.5 ± 0.10	0.51	3.13 ± 0.10	101 ± 1.02
GE2	3.0 ± 0.15	0.67	3.08 ± 0.02	100 ± 1.35
GE3	2.5 ± 0.19	0.81	3.14 ± 0.10	98 ± 0.60
GE4	2.5 ± 0.20	0.72	3.08 ± 0.20	97 ± 1.39
GE5	2.8 ± 0.11	0.38	3.10 ± 0.14	99 ± 0.30
GE6	3.0 ± 0.17	0.45	3.05 ± 0.19	100 ± 1.57
GE7	3.0 ± 0.23	0.40	3.03 ± 0.12	102 ± 0.78
GE8	3.5 ± 0.25	0.37	3.10 ± 0.25	99 ± 1.29
GE9	3.1 ± 0.30	0.35	3.17 ± 0.30	101 ± 0.40
GE10	3.2 ± 0.32	0.29	3.25 ± 0.09	100 ± 1.49
GE11	3.3 ± 0.27	0.60	3.15 ± 0.05	99 ± 1.30
GE12	2.9 ± 0.12	0.58	3.11± 0.10	99 ± 1.50

* Average of three determinations

2.7. *In vitro* disintegration time

The *in vitro* disintegration time is measured by the time taken to undergo uniform disintegration. Rapid disintegration within several minutes was observed in all the formulations. The *in vitro* disintegration data is tabulated in the table. The *in vitro* disintegration time of Aceclofenac Prepared by direct compress Table: Release profile of Aceclofenac fast dissolving tablets prepared by direct compression method

1. Release profile of Aceclofenac fast dissolving tablets prepared by direct compression method:

Formulation Code	t50% (min)	t90% (min)
G_1	0.97 ±1.42	6.52 ±0.65
G_2	0.85 ± 1.08	3.59 ±1.11
G_3	0.76 ±0.67	2.57 ±1.84
G_4	0.66 ±0.54	1.58±0.56
G_5	1.42 ± 1.97	6.45 ±0.75
G_6	1.6 ± 0.89	4.54 ±0.71
G_7	2.44 ±1.08	4.47 ±1.21
G_8	0.97 ± 0.65	3.51 ±1.08
G_9	3.7 ± 0.21	8.32 ±1.46
G_{10}	1.56 ± 0.42	6.51 ±1.69
G_{11}	1.41 ± 0.57	5.47 ±1.03
G_{12}	0.98 ± 1.02	4.49 ±0.42

2. Release profile of Aceclofenac fast dissolving tablets prepared by Sublimation method :

Formulation Code	t50% (min)	t90% (min)
GS_1	4.13 ± 0.12	6.54 ± 0.29
GS_2	3.48 ± 0.21	6.19 ± 0.32
GS_3	1.58 ± 0.39	4.30 ± 0.56
GS_4	4.45 ± 0.51	7.42 ± 0.18
GS_5	3.58 ± 0.54	6.22 ± 0.27
GS_6	2.54 ± 0.45	5.28 ± 0.34
GS_7	4.13 ± 0.43	7.53 ± 0.54
GS_8	3.39 ± 0.29	7.06 ± 1.25
GS_9	3.04 ± 0.43	9.40 ± 0.59
GS_{10}	2.58 ± 0.39	4.55 ± 1.03
GS_{11}	1.43 ± 0.16	3.51 ± 0.22
GS_{12}	1.05 ± 0.38	2.42 ± 0.18

3. Release profile of Aceclofenac fast dissolving tablets prepared by Effervescent method

Formulation Code	T50% (min)	t90% (min)
GE_1	6.48 ± 0.12	13.63 ± 0.29
GE_2	4.10 ± 0.21	10.35 ± 0.32
GE_3	3.61 ± 0.39	8.28 ± 0.56
GE_4	3.15 ± 0.51	7.23 ± 0.18
GE_5	5.48 ± 0.54	14.60 ± 0.27
GE_6	4.61 ± 0.45	12.18 ± 0.34
GE_7	3.25 ± 0.43	9.13 ± 0.54
GE_8	2.11 ± 0.29	7.25 ± 1.25
GE_9	4.40 ± 0.43	13.63 ± 0.59
GE_{10}	3.40 ± 0.39	9.13 ± 1.03
GE_{11}	2.65 ± 0.16	7.05 ± 0.22
GE_{12}	2.61 ± 0.38	6.25 ± 0.18

ion, sublimation method and effervescent methods were found to be in the range of 16 to 80 sec fulfilling the official requirements. Based on the *in vitro* disintegration time, formulation G4 and G8 were found to be promising and showed a disintegration time of 28 and 43 sec respectively. Disintegrating study showed that the disintegrating times. Tablets decreased with increase in the concentration of croscarmellose sodium, crospovidone. However disintegration times increased with increase in the concentration of sodium starch glycolate in the tablets. It indicates that increase in the concentration of sodium starch glycolate had a negative effect on the disintegration of the tablets. *In vitro* disintegration time increased with increase in the concentration of sodium starch glycolate in tablets, at higher level formation of viscous gel layer by sodium starch glycolate might have formed a thick barrier to the further penetration of the disintegration medium and hindered the disintegration or leakage of tablet contents. In case of tablet containing Crospovidone increasing the level of Crosspovidone had no much greater effect on *in vitro* disintegration times of the tablets. With increasing the concentration of Croscarmellose sodium, Crosspovidone, Sodium starch glycolate. The disintegration times of crospovidone and Sodium starch glycolate tablets are comparatively lower than tablets containing croscarmellose sodium and sodium starch glycolate due to its rapid capillary activity and pronounced hydration with little tendency to gel formation with crospovidone. Thus, these results suggest that the disintegration times can be decreased by using wicking type disintegrants (Crosspovidone). As the method of preparation of tablets changed to sublimation, the disintegration time decreased significantly regardless of the diluents used. It is because tablets prepared by sublimation method rapidly exhibits high pores and disintegrate the tablet rapidly. Above results shows that tablets prepared with 3 % superdisintegrant and 9 % camphor (sublimation method) showed least disintegration time in comparison with the all other formulations because of their lowest hardness and the porous structure is responsible for faster water uptake, hence it facilitates wicking action of croscarmellose sodium in bringing about faster disintegration.

2.8. Wetting time

Wetting time is closely related to the inner structure of the tablet. The results of wetting time are shown in table. The wetting time of Aceclofenac Prepared by direct compression, sublimation method and effervescent methods were found to be in the range of 17 to 92 sec. promising formulations showed a range of wetting time between 58 to 110 sec, 64 to 112 respectively, which facilitate the faster dispersion.

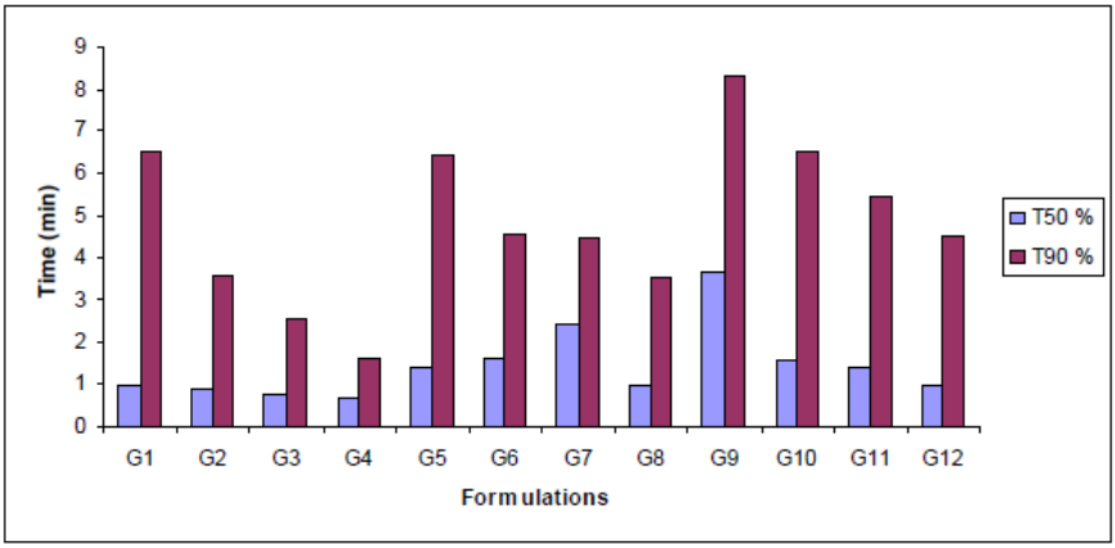


Fig 3: Comparison of release profile (t_{50} min and t_{90} min) formulations of direct compression method (G_1-G_{12})

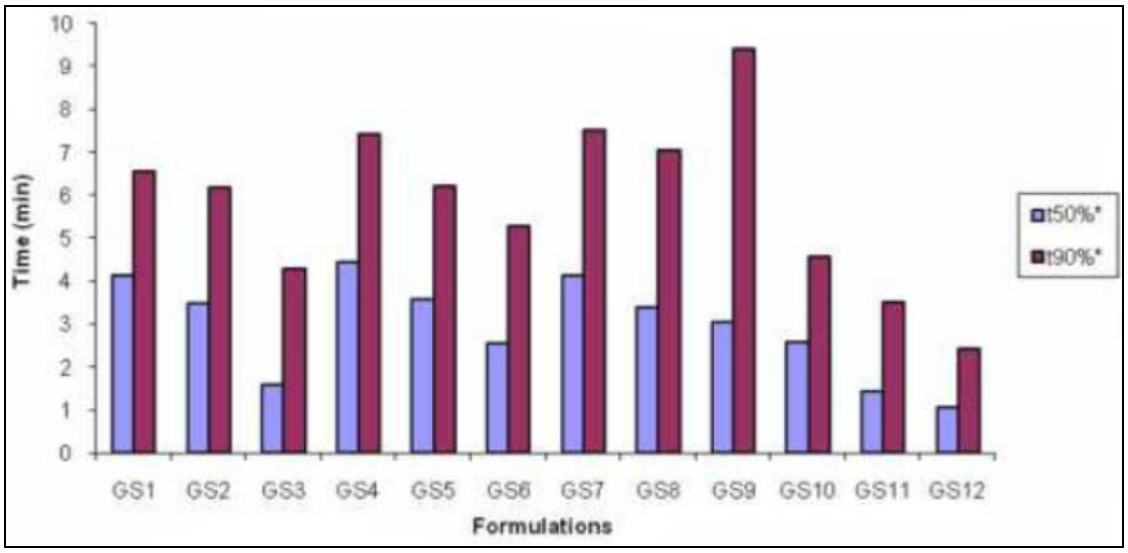


Fig 4: Comparison of release profile (t_{50} min and t_{90} min) formulations of sublimation method (GS_1-GS_{12})

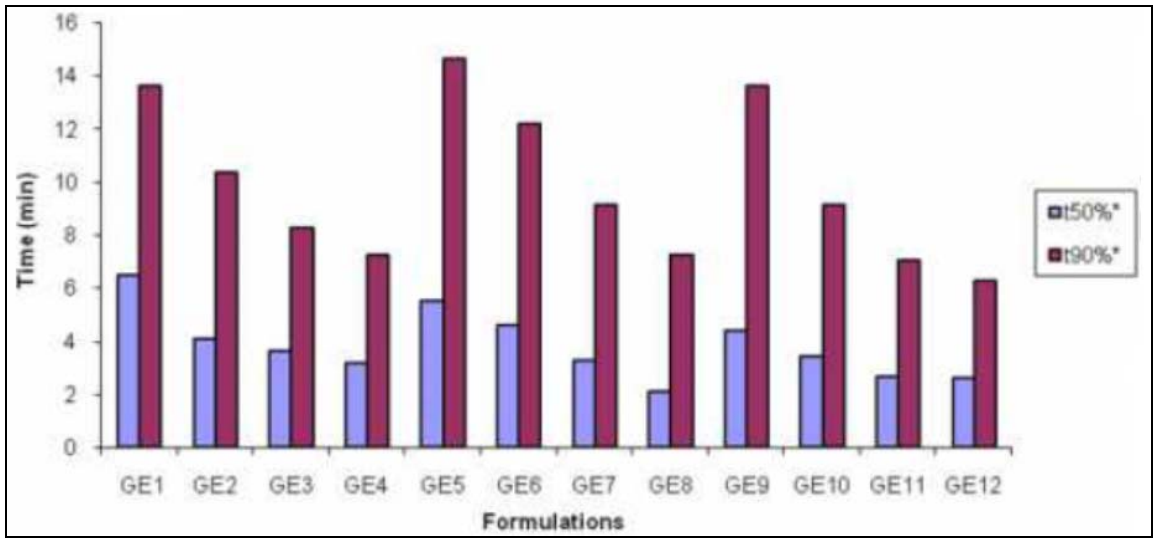


Fig 5: Comparison of release profile (t_{50} min and t_{90} min) formulations of Effervescent method (GE_1-GE_{12})

The crospovidone tablets containing comparatively higher t50% and t90% values are observed in dissolution. As the method of preparation of tablets changed to sublimation, the dissolution of the drug from the tablets prepared by camphor sublimation method was quicker than those prepared by other method. This may be due to their lowest hardness and the porous structure is responsible for faster water uptake, hence it facilitates wicking action of croscarmellose sodium in bringing about faster disintegration. All the formulations showed rapid % drug release (69.12% - 99.83%) due to fast disintegration of tablets. Effervescent method in this method also citric acid and tartaric acid combination used formula is faster release then other formulations. The most popular solid dosage forms are being tablets and capsules; one important drawback of these dosage form for some patients, is the difficulty to swallow. Drinking water plays an important role in swallowing of oral dosage forms. For these reasons tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Fast dissolving tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are those when put on tongue, disintegrates instantaneously releasing the drug, which dissolves or disperse in saliva. The FTIR studies of formulation shows that no interaction between drug and excipient. The DSC studies of formulation shows that no interaction between drug and excipients. The Stability study shows that no significant changes in the direct compression and effervescent method. Whereas decrease in the sublimation method.

3. Conclusion

- Tablets prepared by direct compression and sublimation and effervescent methods were found to be good and were free from chipping and capping.
- The low values of the standard deviation of average weight of the prepared tablets indicate weight uniformity within the batches prepared.
- The hardness of the prepared tablets was found to be in the range of 2 to 4 Kg/cm².
- The friability values of the prepared tablets were found to be less than 1%.
- FTIR and DSC, studies indicated that the drug is compatible with all the excipients.

- The *in vitro* dispersion time of Aceclofenac prepared by direct compression, sublimation and effervescent methods were found to be in the range of 16 to 80 sec fulfilling the official requirements.
- Based on the *in vitro* disintegration time, formulations G4 and G8 were found to be promising and showed a dispersion time of 28 and 43 sec, wetting time of 17 and 92 sec respectively, which facilitate the faster dispersion.
- The formulations G2 , GS7 and GE10 have displayed good water absorption ratio of 80.10 , 83.19% and 89.01% which indicate better and faster swelling ability of the disintegrants in presence of little amount of water.
- The drug content of tablets was uniform in all the batches and was between 98.10 to 100.27%.
- The drug release from fast dissolving tablets of Aceclofenac prepared by direct compression, sublimation and effervescent methods were found to be in the range of 75.52% to 99.65% within 4 min. The sublimation method showed 47.20% to 99.65 within 3 min. The effervescent method showed 35.27% to 99.10% within 7 min.

4. Summary

The most popular solid dosage forms are being tablets and capsules; one important drawback of these dosage form for some patients, is the difficulty to swallow. Drinking water plays an important role in swallowing of oral dosage forms. For these reasons tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Fast dissolving tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Fast dissolving tablets are those when put on tongue, disintegrates instantaneously releasing the drug, which dissolves or disperse in saliva.

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