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FORMULATION AND EVALUATION OF ACECLOFENAC EFFERVESCENT GRANULES

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ABSTRACT

The aim of this study is to develop and physicochemically evaluate the effervescence granules of aceclofenac. In this study we adopted salt formation technique to enhance the drug and also we can get other advantages like better patient compliance and avoid the first pass effect**.** In this study the aceclofenac effervescent granules were prepared with different excipients in five formulation and evaluated each for effervescent test and pre compressibility parameters. Here aceclofenac is used which shows anti-inflammatory drug release rate.

KEYWORDS: Effervescent granules, Aceclofenac, dissolution study, salting form, release rate, granules.

INTRODUCTION

Granules are a unique type of dosage form which are composed of dried aggregates of powder solid particles which contain one or more Active Pharmaceutical Ingredients, with or without other ingredients.[1] Effervescence is derived from a Latin word which means the escape of gas from an aqueous or water solution.[2]

Effervescent salts are granules, or coarse to very coarse powders, containing the medicinal agent in a dry mixture usually composed of sodium bicarbonate, citric acid, and tartaric acid. When added to water, the acids and the base react to liberate carbon dioxide, resulting in effervescence. Effervescent granules are having high solubility, high stability, fast dissolving property and are also convenient dosage forms. Just before administration these granules are

to be mixed in a glass of water and this solution or dispersion should be immediately drunk. The granules are quickly dispersed by the evolution of Carbon dioxide in water due to interaction between acid and base in the presence of water. Due to the liberation of Carbon dioxide gas, we observe the dissolution of the API in water as well as taste masking effect is also enhanced.[3,4] Aceclofenac is a nonsteroidal anti-inflammatory drug (NSAID), inhibits enzyme cyclooxygenase which is responsible for the production of prostaglandins. It is the glycolic acid ester of diclofenac. The present work is based in designing effervescent granules of Aceclofenac. In this study the aceclofenac effervescent granules were prepared with different excipients in five formulation and evaluated each for effervescent test and pre compressibility parameters. Here aceclofenac is used which shows anti-inflammatory effect, which is poor water soluble drug. By formulating effervescent granules we can increase drug release rate.

FORMULATION METHODOLOGIES

Calibration curve for pure aceclofenac

100mg of aceclofenac was accurately weighed and taken in a 100ml volumetric flask. The drug was dissolved and diluted to volume with buffer to obtain the Concentrations range of 5,10,15&20µg/ml for aceclofenac. The absorbance of these solutions was measured at 275nm by UV spectrophotometer, using 7.4ph buffer as blank. The absorbance values were plotted against concentration to obtained the standard graph.

Preparation of granules

The wet granulation method was used to prepare the effervescent granules of aceclofenac. The quantity of each ingredient used is shown in table 1. According to geometrical dilution, all ingredients of the formulation will be mixed thoroughly to maintain good distribution of the drug with other ingredients, and then pass the powder through sieve no 20 after that suitable amount of binding agent added the powder mixture to fabricate a moist mass. Then moisten mass was passed through sieve no. 22/44 to get granules. These granules were be dried at 40 ^{o}C overnight.

Table I: Batches of Effervescent Granules Formation (mg).

Sl no.	Ingredients	F1	F2	F3	F4	F5
1.	Aceclofenac	250	250	250	250	250
2.	Citric acid	217	217	217	217	217
3.	Tartaric acid	434	434	434	434	434
4	Sodium bicarbonate	738	738	738	738	738
5	Sodium carbonate	□	□	240	240	□
6	Saccharine	15	15	15	15	15
7	Sodium citrate	□	15	15	15	15
8	Sodium benzoate	□	20	20	20	20
9.	Mannitol	□	□	220	220	□
10.	Avicel	5	5	5	5	5
11.	HPMC in alcohol 2٪	5	5	5	5	5

Evaluation of effervecent granules

[1] Angle of repose

The prepared granules were allowed to pass through a funnel and the height of the pile (h) and radius of the pile (r) are measured. From this, the angle of repose, i.e., the angle between the height of the pile and radius of the pile is calculated with the help of the following formula. Tan Θ = h/r $\theta=\tan^{-1}(h/r)$

Here, h= height of the powder pile r = radius of the powder pile

Table II: Standard limits for the measure of angle of repose.

Type of cohesion	Measure of Angle of repose
Very low cohesive	Less than 30°
Low cohesive	30 to 38°
Passable	38 to 45°
Cohesive	45 to 55°

[2] Bulk density

A certain quantity of granules was taken in a measuring cylinder without compacting. The proper level of Granules was maintained, the volume V1 (bulk volume) was measured and calculated according to the formula given below: Bulk density = Weight of the granules / V1.

[3] Tapped density

A certain amount of granules was taken and tapped for 100 times in a measuring cylinder. Then the tapped volume (V2) is measured and calculated according to the formula given below: Tapped density = Weight of the granules / V2.

[4] Carr's Index

Carr's Index is determined by using a formula44 Carr's index ratio = [(Tapped density– Bulk density)/Tapped density] × 100.

[5] Hausner's Ratio

Flow property of the powder can be determined using the Hausner's ratio. Lower the Hausner ratio betters the flow property or vice versa. Hausner's ratio is calculated by the formula: Hausner's Ratio = Tapped density/Bulk density.

[6] Effervescence Time

In vitro effervescence time was measured by dissolving some quantity of the granules in a beaker containing 50 ml of Water. Granules were randomly selected from the batch and Ivitro effervescence time was measured. Repeat the procedure for all the prepared formulations and measured the effervescent time for all the batches.

[7] Estimation of drug content

100mg of granules are weighed and added to 100ml phosphate buffer.(7.4) then the solutions are filtered and analysed UV spectrophotometer 275 nm to detect the % of drug content of aceclofenac in the prepared granules. The result obtained is showed in table no 5.

Table III: Estimation of drug content.

F1	89%
F2	90.2%
F3	93.45%
F4	91.32%
F5	92.34%

[8] Dissolution study

The % amount of drug released after 5 min obtained for the five formulations of effervescent granules of aceclofenc are presented in table 5. The results show that all five formulas had a good release profile within 5 min. The improvement of aceclofenc dissolution occurs due to bursting of the granules into minute particles which was facilitated by the production of effervescence. F4 shows the highest percentage of drug released, 99.1% within 5 min. The good release profile of F4 may be attributed to the presence of the combination of disintegrant.

RESULTS AND DISCUSSION

Table iv: Standard calibration curve for aceclofenac.

Concentration(mg/ml)	Absorbance
0	0
5	0.148
10	0.289
15	0.391
20	0.501
25	0.653

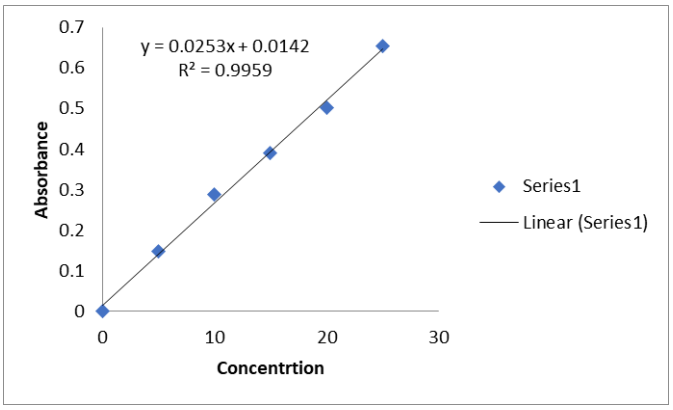

Fig. I: Standard curve for Aceclofenac.

Table V: Evaluation Parameter of Aceclofenac Effervsecent Granules.

Flow properties	F1	F2	F3	F4	F5
Bulk volume	3.04	4.00	3.06	4.02	5.01
Bulk density	0.52	0.51	0.55	0.55	0.52
Bulkiness	1.9209	1.9607	1.8181	1.8181	1.9101
%Compressibility	14.06%	9.80%	5.45%	8.72%	3.78%
Rate of flow	0.62	0.74	1.08	0.57	0.45
Angle of repose	26.56	42.92	19.29	30.50	34.99
Hausner's ratio	1.1636	1.1000	1.0556	1.0953	1.0393

Table VI: In-Vitro dissolution studies value.

Time	F1	F2	F3	F4	F5	Pure drug
0	0	0	0	0	0	0
1	86.34	87.21	90.12	88.14	87.25	4.31
2	96.43	96.12	97.23	97.11	96.42	5.23
3	97.31	98.11	99.44	99.24	97.43	7.11

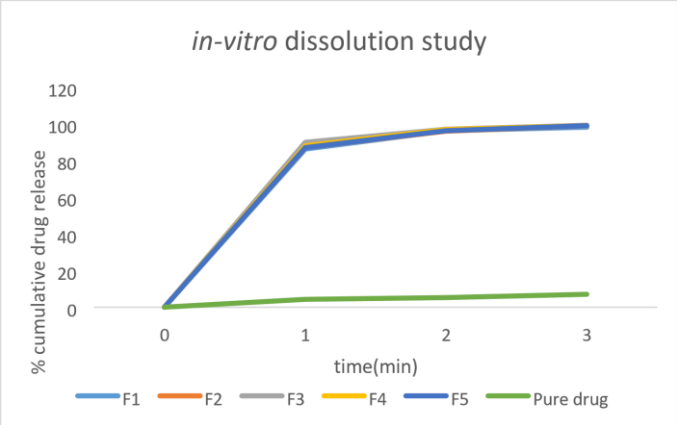

Fig. II: *In-Vitro* dissolution study chart.

CONCLUSION

Aceclofenac effervescent granules was prepared by wet granulation method. Effervescent granules of aceclofenac were well prepared by using citric acid, tartaric acid, sodium bicarbonate, saccharine, microcrystalline cellulose and HPMC in ethanol with different ratio of excipients in five formulation.

The results obtained from all the formulation shows that formulations achieved the desired purpose. All the formulation has shown good flow rate 0.57g/sec- 1.10g/sec and angle of repose less than 42.92^0. in that F3 formulation showed better rate of flow and angle of repose 1.08g/sec and 19.29^0 respectively. Five formulations also given good result in bulkiness and effervescent time and drug content. Among five formulation F3 formulation has very good flow property, drug content, dissolution rate and effervescent time.

REFERENCE

1. Patel SK, Kumar D, Waghmode AP, Dhabale AS. Solubility enhancement of ibuprofen using hydrotropic agents.Int J Pharm Life Sci 2. Srinath KR, Chowdary CP, Palanisamy P, Vamsy KA, Aparna S, Ali SS, et al, 2011; 2: 542-5.
2. Satapathy SR, Patra M, Patnaik M. Process and variation in effervescent formulation: A review. InnovInt J Med Pharm Sci, 2016; 1: 1-3.
3. Preparation and evaluation of effervescent tablets of paracetamol. Prabhakar C, Bala Krishna K. A review on effervescent tablets. Int J Pharm Tech, 2011; 3: 704-712.
4. Parikh, Dilip M. Effervescent granules. Hand book of pharmaceutical granulation technology. Edn 3, Informa Healthc, 365-384.

5. Lieberman H. A., Lachman L., Schwartz J.B. (Eds.), Pharmaceutical Dosage Forms: Tablets, Vol.1, 2, 285, Marcel Dekker, Inc. NY, 1993; 2.
6. Shet N, Vaidya I, Banerjee N. Formulation and evaluation of aceclofenac sodium effervescent taste masked granules. Int J Bio Pharm, 2014; 5: 50-8.
7. Palanisamy P, Rabi A, Kumar DY. Formulation and evaluation of effervescent tablets of aceclofenac. Int Res J Pharm, 2011; 2: 185-190.
8. Aslani A, Jahangiri H. Formulation, characterization and physicochemical evaluation of ranitidine effervescent tablets. Adv Pharm Bull, 2013; 3: 315-22.
9. Nagendra kumar D, Raju SA, Shirsand SB, Para MS, Ram pure MV. Fast dissolving Tablets of Fexofenadine HCl by Effervescent Method. Indian J Pharm Sci, 2009; 71(22): 116-9.
10. Shet N, Vaidya I, Banerjee N. Formulation and evaluation of aceclofenac sodium effervescent taste masked granules. Int J Bio Pharm, 2014; 5: 50-8.
11. Lieberman H. A., Lachman L., Schwartz J.B. (Eds.), Pharmaceutical Dosage Forms: Tablets, Vol.1, 2, 285, Marcel Dekker, Inc. NY, 1993; 2.