

## Formulation of Sustained Release Aceclofenac Matrix tablets using *Prunus Armenica L.* Gum as a release retardant

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### ABSTRACT

In this study our main intention is to find out a best formulated sustained release matrix tablet of Aceclofenac using a natural gum *Prunus armenica L.* obtained from high altitude of Kumaun region (Mukteshwar) as well as evaluate its various parameters such as, Drug solubility study, Drug Excipients compatibility study, Drug content, Cumulative percent drug release, stability studies as well as compare it with marketed formulation (Aceclo- SR- Aristo pharmaceuticals). Phytochemical test and derived properties of powder gum was evaluated and compare its properties with Guar gum and Gum tragacanth as well as compare its IR spectra with reference standard molecule. Here we formulate 10 different formulations such as F1-F10 by varying the percentage of Gum content to find out the sustained release property throughout the 12 h dissolution study using *in vitro* USP type I dissolution test apparatus. The drug release study was carried out in 0.1 N HCl for initial 2 h, followed by in phosphate buffer pH 7.4 for 10 h. Each 900 ml of dissolution media maintained at 37±0.5°C and agitated at 100 rpm. Among the 10 formulations, Formulation F4 with *Prunus armenica* gum 25% was found to be most promising formulation as they showed sustained release (99.75 %) as well as maintained excellent matrix integrity during the period of 12 h study. Formulation F4 was selected as the best optimized formulation.

**Keywords:** Aceclofenac, *Prunus Armeniaca L.*, Matrix tablet, Drug release.

### INTRODUCTION

Matrix devices, due to their chemical inertness, drug embedding ability and drug release character, have gained steady popularity for sustaining the release of a drug. [1, 2]

Aceclofenac is newer derivative of diclofenac and having less GIT complication, with short biological half-life 4 h, and dosing frequency more than one time make it an ideal. [3]

Hydrophilic matrices are an interesting option when developing an oral sustained release formulation. The drug release from such matrices can be controlled through their physical properties. [4,5] Hydrophilic materials such as HPMC, Guar gum and Xanthan gum are used as a release retardant in the sustained formulations. The hydrophilic polymers are swells

and the drug was release through the diffusion method. [6, 7]

The aim of the present study is to develop matrix tablets of Aceclofenac with *Prunus armenica L.* gum and to study the functionality of *Prunus armenica L.* gum as a matrix forming/ release retardant for sustained release tablet formulations.

The drug for the present study is reported to have short half life 3-4 h, usually absorbed to a large extent in the region of small intestine and causes gastric irritation in stomach. Drug selected for the present study is an ideal candidate for formulation of sustained release matrix tablet, as it has short half life, absorbed from small intestine and for elimination of gastric irritation.

### MATERIALS AND METHODS

The main materials include the main active ingredient Aceclofenac, microcrystalline cellulose were especially sampled from Macleoid Pharmaceutical, Mumbai and the main apricot (*Prunus armenica L.*) gum was dried and powdered using a pestle mortar as well as passed through the sieve no 44 and after that hydrated in

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distilled water for one day with intermittent stirring, extraneous materials were removed by straining through a muslin cloth. The gum was precipitated from solution using absolute acetone. The precipitate was separated and dried at 50°C showed in (Fig .1). The dried gum was powdered using a pestle mortar and passed through the sieve no. 72. It was stored in tightly closed container. [8]

#### Derived properties of various Gums

As per the (Table 1) it was confirmed that *Prunus armeniaca L.* gum showed greater flow properties and swelling index as compared to the Guar gum and Gum tragacanth.

### CHARACTERIZATION OF ACECLOFENAC MATRIX TABLET

#### Preparation of sustained release matrix tablet using wet granulation method

The composition of ten different formulations of Aceclofenac sustained release matrix tablets is shown in (Table 2). The ingredients were weighed accurately and sifted through the sieve no. 40 and mixed manually except magnesium stearate. Granulation was done with a solution of PVP K-30 in sufficient isopropyl alcohol. The wet mass was passed through sieve no. 10 for the preparation of granules. The granules were dried in a conventional hot air oven at 40 °C for 2 h. The dried granules were then sized by mesh no. 2 and lubricated with magnesium Stearate and then compressed in single punch.

#### Evaluation of flow properties of granules (Table 4)

##### Angle of repose

Angle of repose is the angle of inclination, formed to the flat surface by the bulk powder when it is allowed to flow under gravitational force from a fixed height. It is a characteristic of dry mixed powder flow properties. [9]

The angle of repose of pure Aceclofenac and prepared mixture was determined by fixed funnel method.

$$\theta = \tan^{-1} \frac{h}{r}$$

Where,

$\theta$  - Angle of repose

h - Height of granules above the flat surface

r - Radius of the circle formed by the granule heap.

##### Bulk density

Bulk density of pure Aceclofenac and prepared granules was determined by pouring pre-weighed powder in to a graduated cylinder. Bulk density was determined by measuring poured volume of powder and mass of powder used.

$$\rho_b = \frac{V_b}{M}$$

Where,

$\rho_b$  - Bulk density

$V_b$  - Volume of bulk

M - Mass of powder.

##### Tapped density -

Tapped density was determined by placing a known mass of mixed powder into the graduated cylinder and which is operated for fixed number of taps (~100) until the powder bed volume has reached a minimum. Then by measuring the volume, tapped density was determined by using the formula

$$\rho_t = \frac{V_t}{M}$$

Where,

$\rho_t$  - Tapped density

$V_t$  - Tapped volume

M - Mass of powder

##### Compressibility (%)

Compressibility means reduction in the bulk volume of the material as a result of displacement of gaseous phase. It is also a characteristic of mixed powder flow properties. It was calculated by using the formula

$$I = \frac{\rho_t - \rho_b}{\rho_b} \times 100$$

Where

I - Compressibility index

$\rho_t$  - Tapped density

$\rho_b$  - Bulk density

### Hausner ratio

It is a simple index that can be determined on small quantity of powder and flow properties of powder may be interpreted. It was calculated by using following formula

$$\text{Housners Ratio} = \frac{TBD}{LBD} \times 100$$

### Carr's index (%)

It is a simple index that can be determined on small quantity of powder and flow properties of powder may be interpreted. It was calculated by using following formula

$$\text{Carr's Index} = \frac{TBD - LBD}{TBD} \times 100$$

### Degree of homogeneity of blending

The standard deviation is presented here as a representative index. Quantity of dry mixed powder equivalent to 100 mg of drug was taken and dissolved in Phosphate buffer (pH 7.4), filtered through whatman filter paper and analyzed spectrophotometrically at 274 nm.

### Evaluation of Tablet Characteristics (Table 5) [10]

#### Weight variation

Twenty tablets were selected at random and weighed individually. The average weight of 20 tablets was calculated. Individual weights of the tablets were compared with the average weight.

#### Hardness

Tablet hardness has been defined as the force required breaking a tablet in a diametric compression test. A tablet was placed between two anvils of hardness tester, force was applied to the anvils, and the crushing strength that causes the tablet to break was recorded in kg/cm<sup>2</sup>.

#### Friability -

Tablets require certain amount of strength or

hardness and resistance to withstand mechanical shock of handling in manufacturing, packaging, and shipping. The friability should be not more than 1%. A pre-weighed sample (20 tablets) were placed in the friabilator, and operated for 100 revolutions, then again weighed the tablets and % friability was calculated using the formula

$$F = \left( 1 - \frac{W_0}{W} \right) \times 100$$

Where

$W_0$  – Weight of tablet before test

$W$  – Weight of tablet after test

### Drugs content

To evaluate a tablet potential for efficacy, the amount of drug per tablet needs to be monitored from tablet to tablet, and batch to batch. To perform the test, 10 tablets were crushed using mortar pestle. Quantity equivalent to 100 mg of drug was dissolved in 100 ml phosphate buffer pH 7.4, filtered and diluted up to 50 µg/ml, and analyzed spectrophotometrically at 274 nm. The concentration of drug was determined using standard calibration curve.

### In vitro Dissolution Study

The *in vitro* dissolution test was performed using USP type I dissolution test apparatus. The drug release study was carried out in 0.1 N HCl for initial 2 h, followed by in phosphate buffer pH 7.4 for 10 hr, each 900 ml of dissolution media, maintained at 37±0.5°C and agitated at 100 rpm. Periodically 10 ml samples were withdrawn and filtered through Whatmann filter paper and samples were replaced by its equivalent volume of dissolution media. The concentration of Aceclofenac was measured by spectrophotometrically at 274 nm.

### Stability studies [11]

The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a

variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a self life for the dug product and recommended storage conditions (Table 7).

#### Accelerated stability testing

Tablets were packed in a suitable packing and stored under following conditions in humidity chamber for a period as prescribed by ICH guidelines for accelerated stability studies.

1 =  $40 \pm 2^\circ\text{C}$

2 =  $50 \pm 2^\circ\text{C}$

3 =  $40 \pm 2^\circ\text{C}$  and RH 75 %  $\pm$  5%

The tablets were withdrawn after a period of 3 month and analyzed for physical characterization and drug content was determined by using UV spectrophotometer at 274 nm.

Stability studies should include testing of those attributes of the drug substance that are susceptible to change during storage and are likely to influence quality, safety, and efficacy.

#### Drug solubility study

The available literature on solubility profile of Aceclofenac indicated that the drug is freely soluble in acetone, methanol and practically insoluble in water. The results of Aceclofenac solubility in various media is given in Table no. 7.5. The solubility of Aceclofenac in water was very less. Aceclofenac showed pH dependent solubility. At lower pH, the solubility was less and as the pH was raised from acidic pH 1.2 to pH 6.8 & 7.4 the solubility drastically improved showed in (Table 3).

#### Flow properties of Granules

From the above observation the flow property of granules increases by increasing gum concentration. In *Prunus armeniaca* gum formulations F5 were having greater flow properties than F1, and in guar gum formulations F10 were having greater flow properties than F6.

#### Evaluation of prepared tablets [12]

A result of above observation indicates that by increasing the polymer concentration hardness increases while friability decreases and all are in the

limit. Thickness, weight variation, and % drug contents of prepared tablets were also in the limit.

#### Cumulative Percent drug release of formulations

All formulations were investigated for the dissolution test. Market formulation (M.F.) is also investigated for dissolution profile. Formulations of *prunus armeniaca* gum (F1 – F5) and guar gum (F6 – F10) compared for Cumulative percent drug release. Best formulation is compared with market formulation (Aceclo- SR-Aristo pharmaceuticals) (Table 6).

As per the results of dissolution study formulations F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, and M.F. showed 99.64, 99.13, 99.35, 99.68, 99.75, 88.18, 100.46, 100.54, 99.89, 99.24, 90.68, 99.86 % respectively. This showed that the drug release from the tablet was sustained for 4 to 12 h. F1 with 10% *Prunus armeniaca* gum showed 99.64 % release within 7 hr. F2 with 15% *Prunus armeniaca* gum showed 99.13 % release within 9 hr. F3 with 20% *Prunus armeniaca* gum showed 99.35% release within 10 hr. F4 with 25% *Prunus armeniaca* gum showed 99.75 % release within 12 hr. F5 with 30% *Prunus armeniaca* gum showed 88.18 % release within 12 hr. F6 with 10% Guar gum showed 100.46 % release within 7 h. F7 with 15% Guar gum showed 100.54 % release within 8 hr. F8 with 20% Guar gum showed 99.89 % release within 9 hr. F9 with 25% Guar gum showed 99.24 % release within 11 hr. F10 with 30% Guar gum showed 90.68% release within 12 hr. This is mainly due to increasing polymer concentration or increasing path length diffusion, showed in (Fig. 2) and (Fig. 3).

Formulation F4 with *Prunus armeniaca* gum 25% was found to be most promising formulation as they showed sustained release (99.75 %) as well as maintained excellent matrix integrity during the period of 12 h study. Formulation F4 was selected as the optimized formulation.

#### RESULTS AND DISCUSSION

As per the results obtained Aceclofenac shows maximum absorbance at 274 nm and in ethanol at 279 nm.

In the pure *Prunus armenica* gum only carbohydrates and mucilage is present. And from compatibility study using IR it was shown that all excipients were compatible with drug. So it is suitable for develop the formulations.

The solubility of Aceclofenac in water was very less. Aceclofenac showed pH dependent solubility. At lower pH, the solubility was less and as the pH was raised from acidic pH 1.2 to pH 6.8 & 7.4 the solubility drastically improved more than 7 times. In acidic pH 1.2 solubility was 0.93 mg/ml and in pH 7.4 was 7.531mg/ml.

The all formulations were passed all parameters including hardness, thickness, weight variation, and friability tests. Hardness increases and friability decreases by increasing the concentration of polymer in the formulations.

The results of dissolution study formulations F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, and M.F. showed 99.64, 99.13, 99.35, 99.68, 99.75, 88.18, 100.46, 100.54, 99.89, 99.24, 90.68, 99.86 % respectively. This showed that the drug release from the tablet was sustained for 4 to 12 h. F1 with 10% *Prunus armenica* gum showed 99.64 % release within 7 h. F2 with 15% *Prunus armenica* gum showed 99.13 % release within 9 h. F3 with 20% *Prunus armenica* gum showed 99.35% release within 10 hr. F4 with 25% *Prunus armenica* gum showed 99.75 % release within 12 h. F5 with 30% *Prunus armenica* gum showed 88.18 % release within 12 hr showed in (Fig .4). F6 with 10% Guar gum showed 100.46 % release within 7 h. F7 with 15% Guar gum showed 100.54 % release within 8 h. F8 with 20% Guar gum showed

99.89 % release within 9 h. F9 with 25% Guar gum showed 99.24 % release within 11 h. F10 with 30% Guar gum showed 90.68% release within 12 h. This is mainly due to increasing polymer concentration or increasing path length diffusion. [13]

By using the different concentrations of *Prunus armenica* gum and Guar gum as a release retardant, drug release from *Prunus armenica* gum and Guar gum showed sustained for 4 to 12h by varying the concentration of polymer matrix composition. Formulation F4 and F5 with *Prunus armenica* gum showed reasonable release 99.68, 88.18 % in 12 h respectively. And formulation F9 and F10 with Guar gum showed release 99.24, 90.68 % in 12 h respectively, where as in formulation M.F. showed 99.86% release up to 11h. Cumulative percent release of various formulations showed in (Fig .5 – Fig .10).

From the above results, it was found that the drug release is depleted as the concentration of *Prunus armenica* gum and Guar gum polymer was increased in polymeric matrix composition.

Hence, formulation F4 with *Prunus armenica* gum 25% was found to be most promising formulation as they showed sustained release (99.75 %) as well as maintained excellent matrix integrity during the period of 12 h study. Formulation F4 was selected as the optimized formulation.

The optimized formulation and all other formulations were investigated for the accelerated stability testing for 3 months at 40±2°C and 75±5 Relative humidity. Formulations did not shown any sign of physical and chemical instability. [14]

**Table 1:** Derived properties of various Gums

Sl. No.	Properties	<i>Prunus armenica L. Gum</i>	Guar Gum	Gum Tragacanth
1	Bulk Density	0.625	0.625	0.710
2	Tapped Density	0.714	0.833	0.990
3	Carr's Index	12.46 %	25.01 %	29 %
4	Hausner's ratio	1.14	1.33	1.39
5	Angle of Repose	18.53	27.74	Rat holing
6	Swelling Index	5.5	5.3	5.0

**Table 2:** Table of Formulations

Sl. No.	INGREDIENTS	F-1	F-2	F-3	F-4	F-5	F-6	F7	F-8	F-9	F-10
1	Aceclofenac	200	200	200	200	200	200	200	200	200	200
2	<i>Prunus armeniaca</i> L.gum	40	60	80	100	120					
3	Guar gum						40	60	80	100	120
4	MCC	145	125	105	85	65	145	125	105	85	65
5	PVP-K30	10	10	10	10	10	10	10	10	10	10
6	Magnesium Stearate	4	4	4	4	4	4	4	4	4	4
7	Talc	1	1	1	1	1	1	1	1	1	1

**Table 3:** Solubility of Aceclofenac in different solution media

Medium	Solubility (mg/ml)
Distilled Water	0.085±0.001
0.1 N HCl	0.932 ± 0.564
Phosphate buffer pH 6.8	5.034± 0.321
Phosphate buffer pH 7.4	7.531 ± 0.400
Ethanol	29.59 ± 0.023

**Table 4:** The flow properties of all the formulation

Formulation	Angle of Repose (°)	Loose Bulk Density(g/ml)	Tapped Bulk Density(g/ml)	Carr's Index (%)	Hausener's Ratio
F-1	30.0±1.50	0.605±0.05	0.769±0.0543	21.32±1.5	1.27±0.07
F-2	29.22±1.57	0.615±0.035	0.733±0.054	19.18±1.4	1.19±0.1
F-3	27.32±1.29	0.595±0.059	0.725±0.0234	17.73±1.1	1.21±0.05
F-4	24.78±1.42	0.526±0.0943	0.625±0.0432	15.84±0.9	1.19±0.05
F-5	24.31±1.31	0.535±0.056	0.625±0.0213	14.40±1.2	1.16±0.03
F-6	29.90±1.52	0.655±0.021	0.833±0.0321	21.36±1.6	1.27±0.09
F-7	28.79±1.34	0.615±0.07	0.750±0.0321	18.00±1.3	1.21±0.08
F-8	27.43±1.37	0.550±0.043	0.705±0.0231	17.73±1.1	1.21±0.03
F-9	25.97±1.42	0.625±0.023	0.750±0.0432	17.21±1.4	1.20±0.06
F-10	25.03±1.39	0.565±0.053	0.675±0.0653	16.29±1.2	1.19±0.05

**Table 5:** Evaluation of prepared tablets their hardness, thickness, friability, weight variation and drug content.

Formulation	Hardness (kg.cm <sup>2</sup> )	Thickness (mm)	%Friability	Weight Variation(mg)	%Drug Content
F-1	6.2±0.12	3.75±0.13	0.48±0.13	400.9	98.97
F-2	6.4±0.21	3.78±0.12	0.42±0.32	401.2	99.53
F-3	6.5±0.32	3.80±0.09	0.36±0.21	400.2	100.03
F-4	6.8±0.25	3.76±0.10	0.32±0.19	400.4	99.94
F-5	7.2±0.18	3.75±0.11	0.28±0.22	400.7	99.90
F-6	6.3±0.21	3.74±0.12	0.65±0.32	400.5	99.02
F-7	6.6±0.31	3.76±0.09	0.53±0.16	400.3	100.04
F-8	6.7±0.28	3.77±0.13	0.42±0.32	401.1	99.36
F-9	7.0±0.31	3.81±0.10	0.41±0.24	400.6	99.76
F-10	7.3±0.32	3.75±0.11	0.35±0.25	400.3	99.92



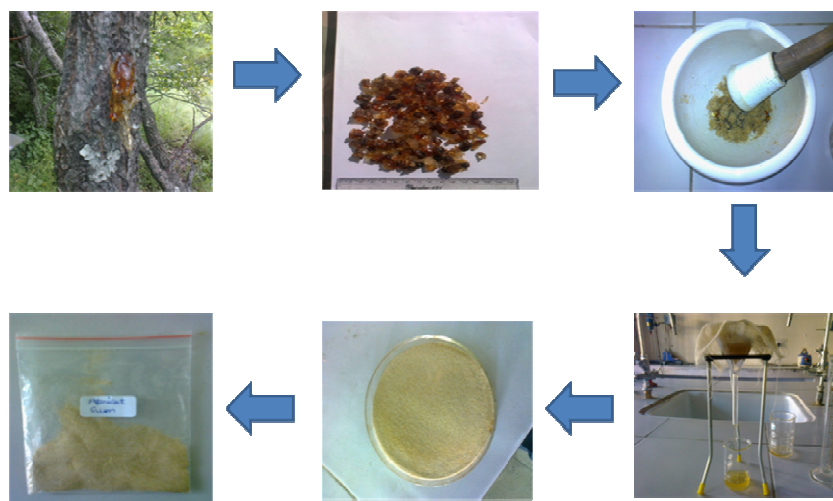
**Table 6:** Cumulative Percent drug release of formulations & Marketed Formulation (MF)

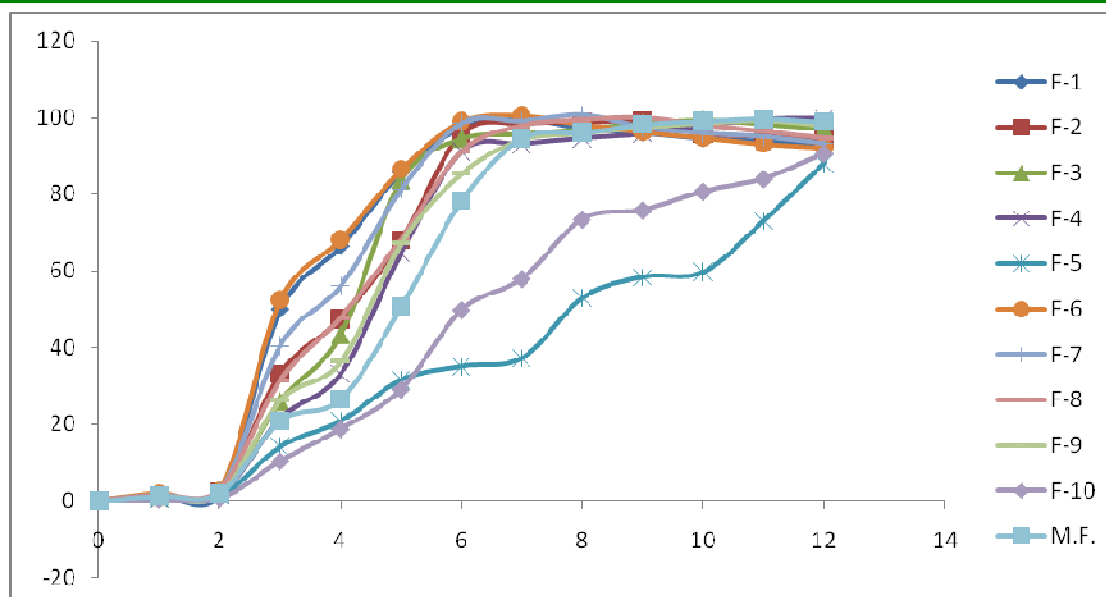
TIME (h)	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8	F-9	F-10	M.F.
0	0	0	0	0	0	0	0	0	0	0	0
1	1.57	1.35	1.19	0.77	0.68	2.005	1.71	1.51	0.95	0.41	1.34
2	1.98	2.27	2.15	1.58	1.42	2.71	2.56	2.98	1.77	0.61	2.07
3	50.03	33.21	26.06	21.57	14.28	52.34	40.54	31.49	26.31	10.4	20.97
4	66.47	47.56	43.47	33.26	20.94	68.1	56.02	47.88	36.42	18.79	26.62
5	85.82	68.08	83.82	64.78	31.64	86.4	81.2	68.36	67.33	29.12	50.68
6	97.42	95.88	94.49	91.11	35.19	98.91	98.39	91.13	85.45	49.81	78.32
7	99.64	98.5	95.76	93.06	37.38	100.46	98.95	97.79	94.23	57.96	94.55
8	97.28	98.79	97.02	94.54	53.04	98.1	100.54	99.34	95.91	73.51	95.97
9	96.12	99.13	98.57	95.71	58.45	96.18	97.32	99.89	97.59	75.84	98.06
10	94.62	95.95	99.35	97.79	59.73	94.67	95.81	97.89	98.5	80.74	98.98
11	93.91	95.15	98.31	99.49	73.24	92.99	94.92	96.29	99.24	84.07	99.56
12	93.24	94.32	97.02	99.75	88.18	92.11	93.09	94.55	97.88	90.68	98.75

**Table 7:** Stability studies data of all the formulations

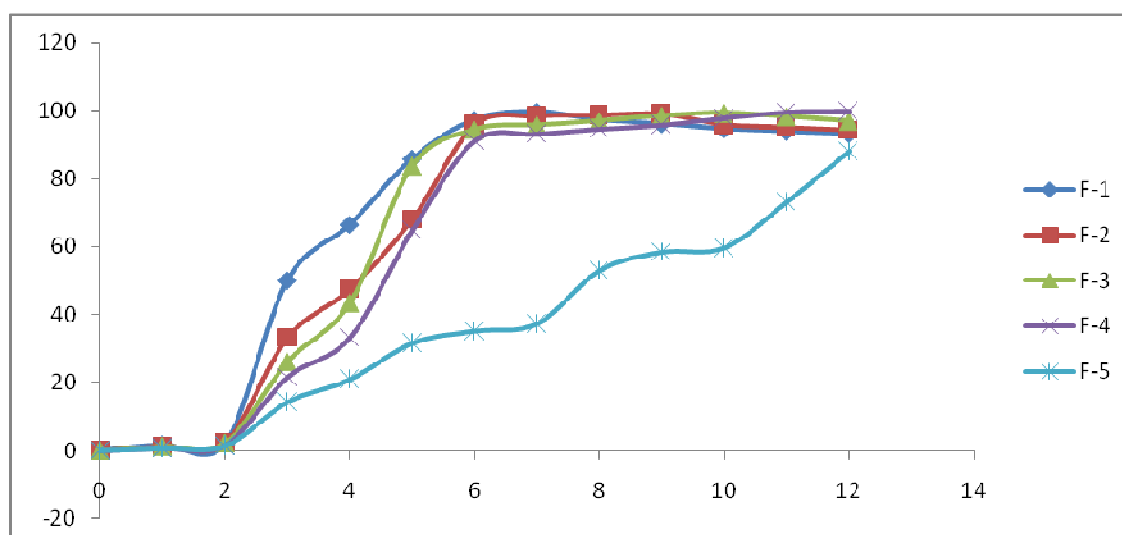
S. No.	Formulation	Physical appearance	% Drug content
1	F-1	No significant change were seen	97.35
2	F-2	No significant change were seen	98.12
3	F-3	No significant change were seen	97.99
4	F-4	No significant change were seen	98.55
5	F-5	No significant change were seen	97.79
6	F-6	No significant change were seen	97.91
7	F-7	No significant change were seen	98.54
8	F-8	No significant change were seen	98.43
9	F-9	No significant change were seen	97.54
10	F-10	No significant change were seen	98.42
11	M.F.	No significant change were seen	98.32

### Overview of Extraction and Purification of *Prunus armeniaca L.* Gum

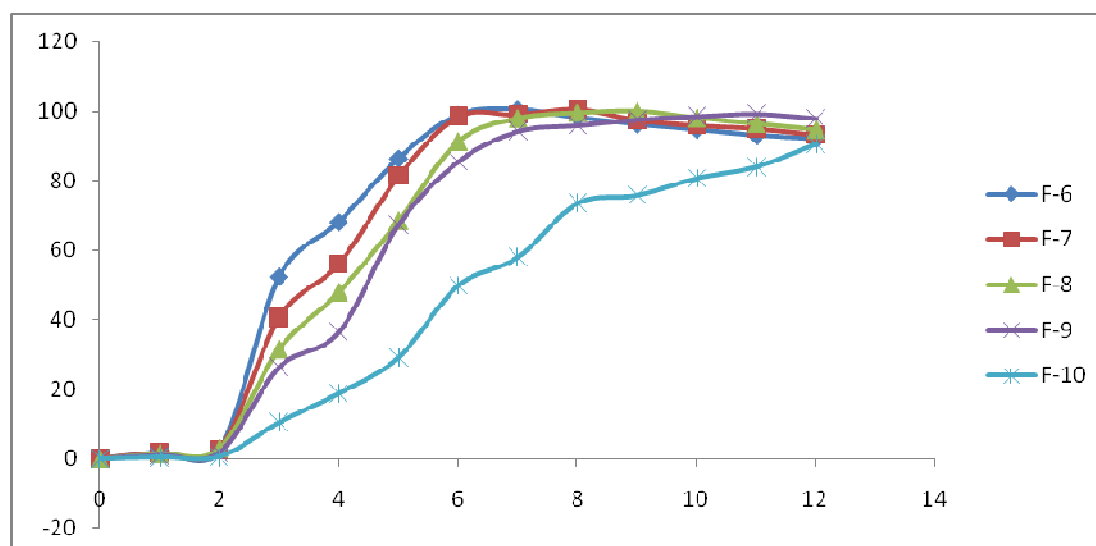
**Fig 1:** Overview of extraction and purification of *Prunus armeniaca L.* gum



**Fig 2:** Cumulative Percent drug release of all formulations

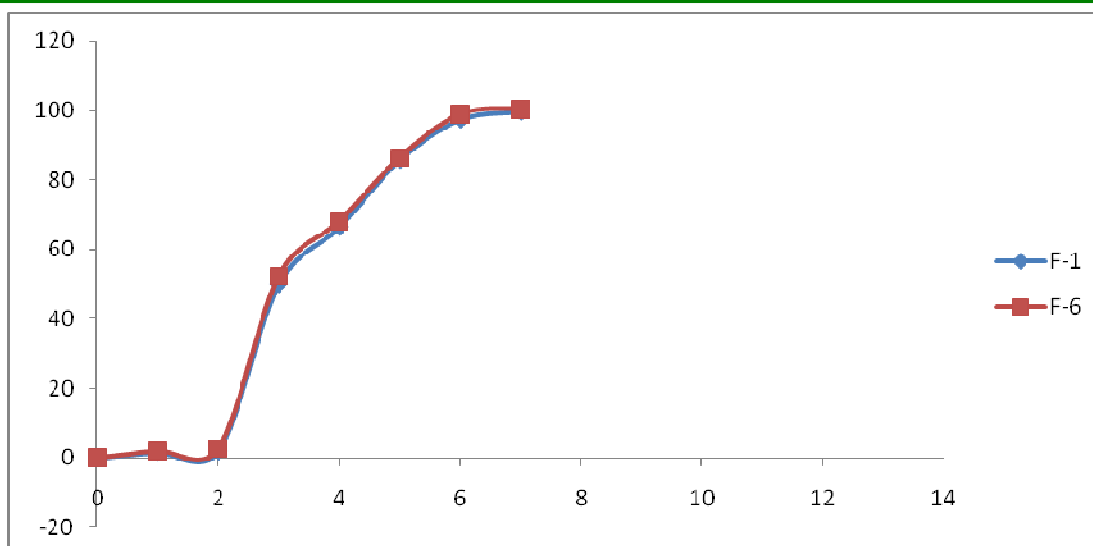


**Fig 3:** Cumulative percent drug release of Aceclofenac using *Prunus armeniaca* gum in various concentrations

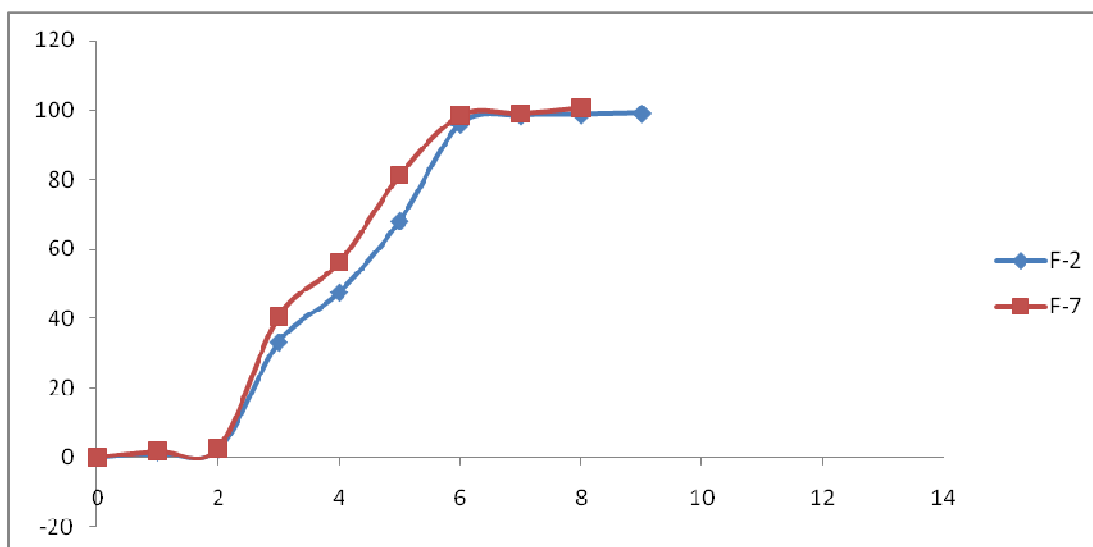


**Fig 4:** Cumulative percent drug release of Aceclofenac using guar gum in various concentrations

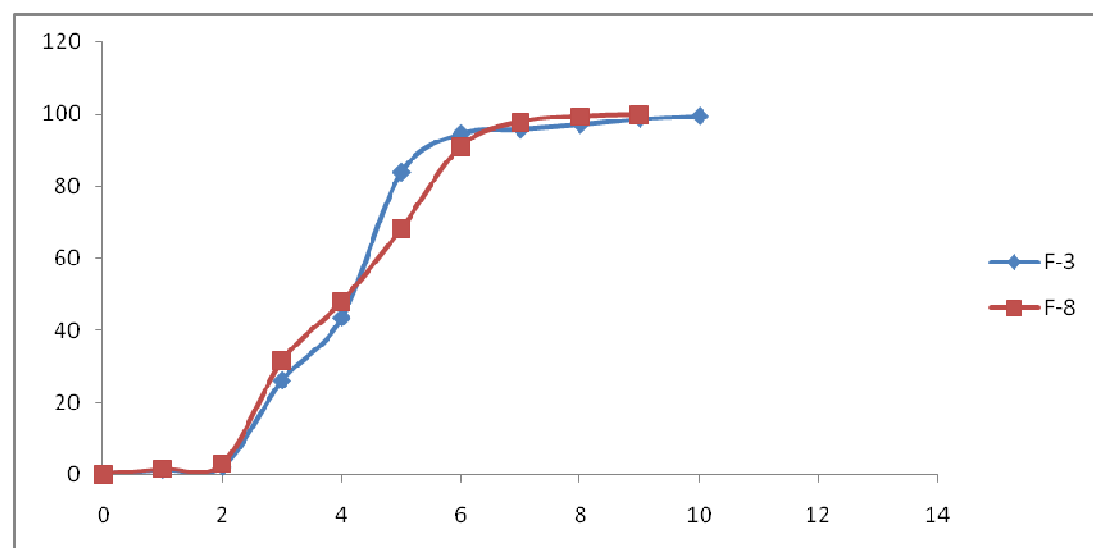




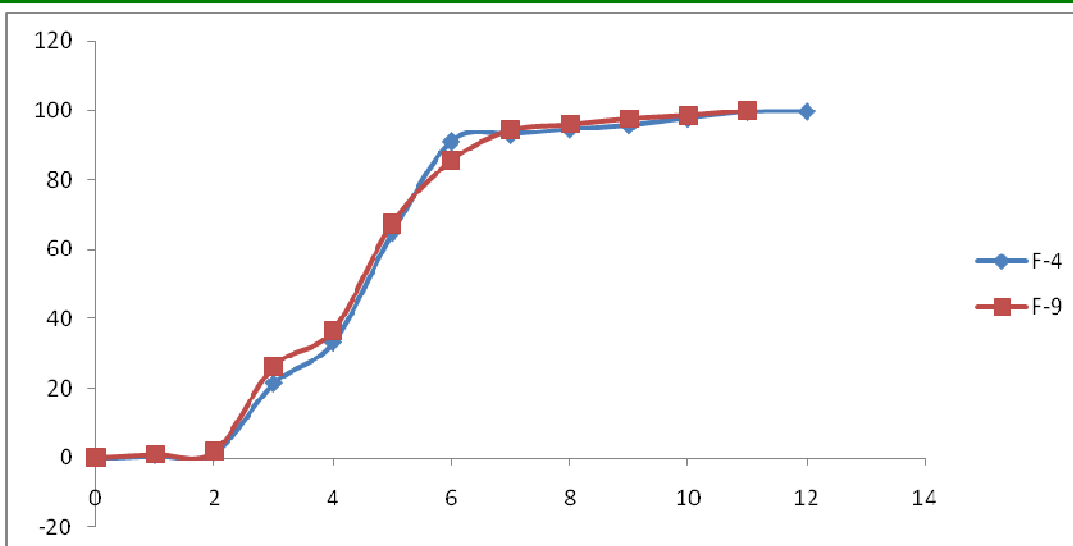
**Fig 5:** Cumulative percent drug release of F-1 & F-6



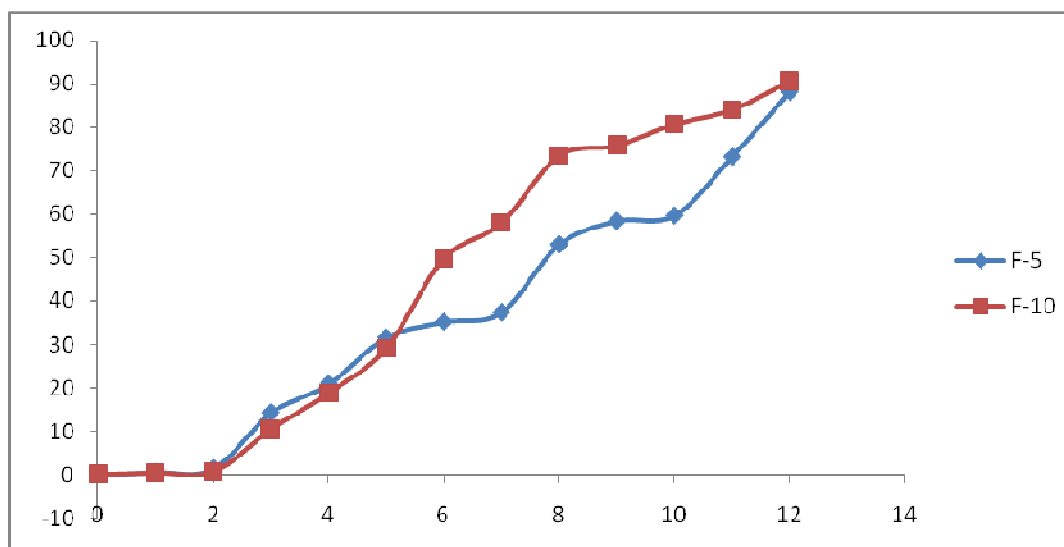
**Fig 6:** Cumulative percent drug release of F-2 & F-7



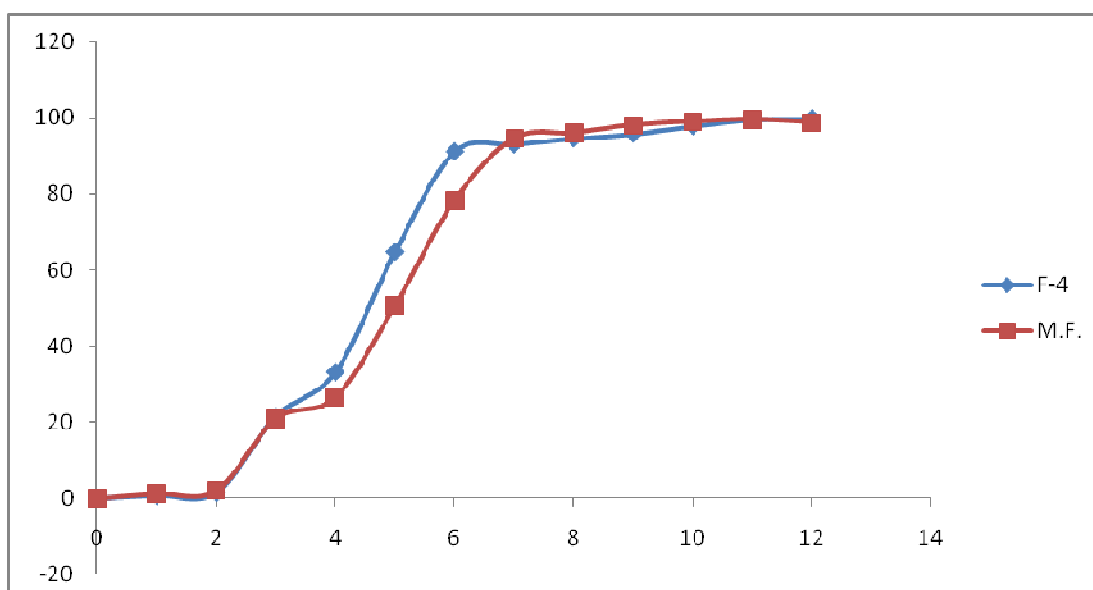
**Fig 7:** Cumulative percent drug release of F-3 & F-8



**Fig 8:** Cumulative percent drug release of F-4 & F-9



**Fig 9:** Cumulative percent drug release of F-5 & F-10



**Fig 10:** Cumulative percent drug release of F-4 & Marketed formulation (Aceclo-SR-Aristo pharmaceuticals)

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