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FORMULATION AND *IN VITRO* EVALUATION OF SALBUTAMOL SULPHATE SUSTAINED RELEASE TABLET BY USING FLOATING DRUG DELIVERY TECHNOLOGY

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ABSTRACT: The present study involves in the preparation and evaluation of floating tablets of Salbutamol sulphate by direct compression method by using the hydrophilic polymer such as hydroxy propyl methyl cellulose (HPMC), Sodium carboxy methyl cellulose, Dextrin and Carbopol. Sodium bicarbonate, Tartaric acid and citric acid were incorporated as gas generating agent. The study aims to achieve different formulations using different polymers in order to find out the most suitable and successful type of polymer. The prepared tablets were evaluated in terms of thickness, average weight, hardness, friability, drug content uniformity, swelling index, *in- vitro* buoyancy study and *in-vitro* dissolution study. The formulated tablet Hardness was found to being the range of 2.6 to 3.8 kg/cm^2, the % friability was in the range of 0.30 to 0.50. The Swelling Index and floating time of different formulations range from 1.78 to 16.15 and 8.15 to 12 hrs respectively. *In-vitro* release studies were carried out using USP XXII dissolution test apparatus. The tablet containing Salbutamol sulphate was released from batch F1-F10 found to be 78.55 to 98.55 %. The release of drug from tablets sufficiently sustained for 8 hours by *in vitro* release study. From the ten formulations we found that the formulation containing Carbopol (F_7) were showed the better sustain release when compared to the other formulations.

INTRODUCTION: Salbutamol sulphate is one of the widely used drugs for the treatment of bronchial asthma, chronic bronchitis and emphysema [1]. The drug undergoes extensive first-pass metabolism and thus requires frequent administrations by oral route [2].

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Salbutamol sulphate has a site-specific absorption in stomach and upper part of small intestine [3]. Reported oral bioavailability of Salbutamol sulphate is ~ 40 %; due to extensive metabolism via intestinal sulphonation, first pass metabolism in liver & also degradation in colon [4]. The metabolism is due to extensive sulphonation in gut as compared to liver [5]. The half-life of Salbutamol sulphate is about 4.5 hrs [6]. The relatively short term acting injectables and aerosol dosage forms of Salbutamol sulphate are recommended for instant relief in severe asthmatic attacks. Salbutamol sulphate is available in the form of aerosols.

The recommended dose in adults and children is 2-3 inhalations every 4-6 h. More frequent administration is not recommended [7]. Salbutamol sulphate is given by mouth in a dose of 2 to 4 mg three to four times a day [8]. Salbutamol sulphate requires multiple daily drug dosage in order to maintain adequate plasma concentrations. A gastro retentive drug delivery system may be advantageous over conventional oral dosage forms and inhalers due to its ability to maintain prolonged therapeutic concentrations in the systemic circulation. Asthma being a chronic disease, and as most of the patients suffer from nocturnal attacks [9], there is need for drug delivery systems which maintains therapeutic concentrations for long duration.

Floating drug delivery systems (FDDS) were first described by Davis in 1968. These systems were used to prolong the gastric residence time of drug delivery systems. They remain buoyant in the stomach for prolonged period of time without affecting the gastric emptying rate of other contents [10]. FDDS is suitable for drugs with an absorption window in the stomach or the upper small intestine [11], for drugs which act locally in the stomach [12] and for drugs that are poorly soluble or unstable in the intestinal fluid [13]. These systems help in continuously releasing the drug before it reaches the absorption window, thus ensuring optimal bioavailability [14]. FDDS or hydrodynamically balanced systems have a bulk density lower than gastric fluid and thus remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time [15]. Therefore, Salbutamol sulphate has all the characteristics suitable for developing floating dosage form which would increase its oral bioavailability. These systems help in continuously releasing the drug before it reaches the absorption window, thus ensuring optimal bioavailability. High solubility of Salbutamol sulphate was a major challenge in designing its controlled drug delivery system. In this study, methyl cellulose, HPMC, Carbopol and sodium alginate were used as a release-retarding polymer. In order to develop the floating matrix tablet of Salbutamol sulphate it is necessary to optimize both the residence time of the system in the gastro intestinal tract and release rate of the drug from the dosage.

MATERIALS AND METHODS:

Materials: Salbutamol sulphate obtained as gift sample from Sumac Pharma Pvt. Ltd., Hyderabad. The polymers Methylcellulose, HPMC, Microcrystalline cellulose were as gift samples from Micro Laboratory Limited, Bangalore. All other ingredients were of analytical grades and were used as procured.

Formulation of Floating Sustained Release Tablets: Floating matrix tablets were prepared by direct compression using different polymers like HPMC, Sodium carboxy methyl cellulose, Carbopol and other polymers. The compositions of the formulations are given in **Table 1**.

TABLE 1: FORMULATION OF SALBUTAMOL FLOATING SUSTAINED RELEASE TABLETS

Sl. No.	Ingredients	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9	F_{10}
1.	Salbutamol	20	20	20	20	20	20	20	20	20	20
2.	HPMC	100	-	125	200	200	-	-	100	130	-
3.	Na CMC	150	250	125	-	-	-	-	-	-	-
4.	Peg 6000	-	-	-	50	-	-	-	-	-	-
5.	Sodium Alginate	-	-	-	-	50	-	50	-	-	-
6.	MCC	-	-	-	-	-	200	-	-	-	-
7.	$NaHCO_3$	-	-	-	-	-	50	-	50	65	50
8.	Carbopol	-	-	-	-	-	-	200	-	-	-
9.	Dextrin	-	-	-	-	-	-	-	20	20	-
10.	Cetyl Alcohol	-	-	-	-	-	-	-	80	-	
11.	Polyvinyl Alcohol	-	-	-	-	-	-	-	-	-	75
12.	Citric Acid	-	-	-	-	-	-	-	-	35	-
13.	Tartaric Acid	-	-	-	-	-	-	-	-	-	50
14.	Shell Lac	-	-	-	-	-	-	-	-	-	75
15.	Maize Starch	50	50	50	50	50	50	50	50	50	50
16.	Lactose	150	150	150	150	150	150	150	150	150	150
17.	Talc	25	25	25	25	25	25	25	25	25	25
18.	Magnesium Stearate	5	5	5	5	5	5	5	5	5	5

Evaluation of the Floating Sustained Release Tablets of Salbutamol sulphate:

Pre-compression Parameter:

A) **Angle of Repose** [16]**:** The frictional forces in a loose powder or granules can be measured by angle of repose. "This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane". The granules were allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of granules formed.

$$\theta = \tan^{-1}(h/r)$$

Where θ = angle of repose; h = height; r = radius

B) **Compressibility index** [17, 18]**:** The flow ability of powder were evaluated by comparing the bulk density (d_0) and taped density (d_f) of powder and the rate at which it packed down. Compressibility index is calculated by,

$$\text{Compressibility index (\%)} = \frac{df - do \times 100}{df}$$

Where d_o = bulk density, d_f = tapped density

Post-compression parameters [19, 20]**:**

A) **Tablet dimensions:** Thickness and diameter were measured using a calibrated dial caliper. Three tablets of each formulation were taken randomly and thickness was measured individually.

B) **Hardness:** Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm^2. Three tablets were randomly picked and hardness of the tablets was determined.

C) **Friability test:** The friability of tablets was determined using Roche friabilator. It is expressed in percentage (%). Ten tablets were initially weighed (W_0 initial) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (W final). The % friability was then calculated by,

$$\text{Percentage of friability} = 100\,(1 - W_0/W)$$

Percentage friability of tablets less than 1% is considered acceptable.

D) **Tablet density** [18]**:** Tablet density is an important parameter for floating tablets. The tablet will float when its density is less than that of gastric fluid (1.004g/cc). The density was determined using following formula.

$$V = \pi r^2 h$$

$$d = m/v$$

Where V = volume of tablet (cc); r = radius of tablet (cm); h = crown thickness of tablet (mm); m = mass of tablet

E) **Weight variation test** [18]**:** Twenty tablets were selected randomly from each batch and weighed individually to check for weight variation. The following percentage deviation in weight variation is allowed.

F) **Buoyancy / floating test** [21, 22, 28]**:** The time between introduction of dosage form and its buoyancy on the simulated gastric fluid and the time during which the dosage form remain buoyant were measured. The time taken for dosage form to emerge on surface of medium called Floating Lag Time (FLT) or Buoyancy Lag Time (BLT) and total duration of time by which dosage form remain buoyant is called Total Floating Time (TFT).

G) **Swelling study** [23, 24]**:** The swelling behaviour of a dosage form is measured by studying its weight gain or water uptake. The dimensional changes measured in terms of the increase in tablet diameter and/or thickness over time. Swelling Index is measured in terms of percent by using following formula.

$$\text{Swelling Index} = \frac{(\text{Width after 8hr}) - (\text{Initial width of tab})}{\textit{Initial width of tab}} \times 100$$

and;

$$\text{Swelling Index} = \frac{(\text{Diameter after 8hr}) - (\text{Initial diameter of tab})}{\text{Initial diameter of tab}} \times 100$$

H) **Test for content uniformity** [25]**:** Weigh and powder 20 tablets, weigh accurately a quantity of powder equivalent to 200mg of Salbutamol sulphate, shake with 70 ml of water and diluted to 100 ml with water. Dilute 10 ml of the stock and diluted to 100ml with water. Further dilute 10 ml to 100ml and measure the absorbance at about 525nm.

I) ***In-vitro*** **drug release study** [26, 27]**:** 400ml of 0.1N HCl was taken in a beaker and Teflon was placed in it. Then one tablet was taken and placed into it. The rpm of stirred was settled at 50 rpm and temperature $37^0 \pm 2^0$C. After 1hr 7ml of dissolution medium was taken out. The medium was again replaced with 0.1N HCl. The samples were collected at every 1hr internal up to 8hr. To the collected samples 1ml of 3%sodium nitrate, 1ml of copper sulphate and 0.2ml of 1N HCl were added. Then it was warmed on a water bath for 10min and cooled to room temperature. Then the final volume is made up to 10 ml with 0.1N HCl. After 25 min the absorbance was measured at 525 nm against blank.

RESULTS AND DISCUSSION: Floating tablets of Salbutamol sulphate were prepared and evaluated to increase its bioavailability. In the present study ten formulations using different polymer with variable concentration were prepared and evaluated for physico-chemical, *in-vitro* drug release studies.

Standard calibration curve of Salbutamol sulphate: Standard calibration curve of Salbutamol sulphate was determined by plotting absorbance Vs. concentration at 525nm and it follows the Beer's law. The results were show in **Table 2** and **Fig. 1**.

TABLE 2: CALIBRATION CURVE OF SALBUTAMOL SULPHATE AT 525nm BY UV SPECTROPHOTO METER

Sl. No	Concentration in mcg/ml	Absorbance at 525nm
1	50	0.364
2	100	0.456
3	150	0.552
4	200	0.643
5	250	0.734

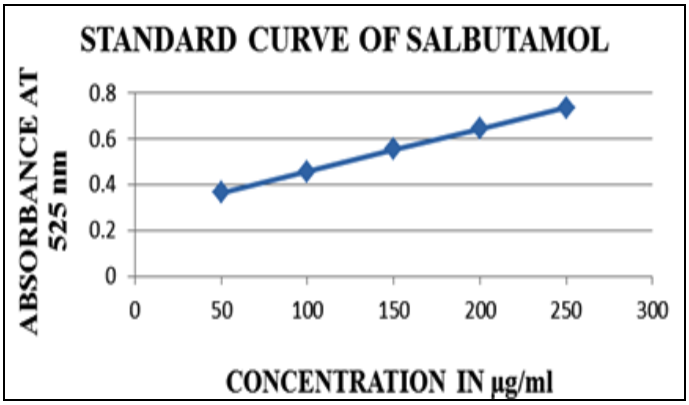

FIGURE 1: STANDARD CURVE OF SALBUTAMOL

Pre-compression parameters: The values obtained for angle of repose and compressibility index for all formulations were found to be in the range from 24.30±1.26 to 29.88±1.84 and 12.30±0.60% to 16.34± 0.56% respectively. This indicates good flow property of the powder blend for direct compression. The data for angle of repose and compressibility index was given in **Table 3.**

TABLE 3: EVALUATION OF POWDER OF FLOATING TABLET

Sl. No.	Formulation Code	*Angle of Repose (θ) (S.D. ±)	*Compressibility index (%) (S.D. ±)
1	F_1	24.30±1.26	12.30±0.60
2	F_2	26.77±0.68	15.67±0.36
3	F_3	25.77±2.69	16.34±0.56
4	F_4	28.56±3.05	15.41±0.79
5	F_5	29.88±1.84	13.25±0.84
6	F_6	24.36±1.9	14.16±0.67
7	F_7	25.22±2.10	12.45±0.35
8	F_8	27.29±2.35	15.56±0.26
9	F_9	26.54±2.57	14.48±0.29
10	F_{10}	28.48±2.09	14.85±0.24

*Each sample was analysed in triplicate (n=3)

Post-compression parameters: Microscopic examination of tablets from each formulation batch showed circular shape with no cracks. The dimensions determined for formulated tablets were almost uniform in all the ten formulations and were found to be in the range of 4.025 mm to 4.034 mm. The diameter of the tablet ranges between 13.50 mm to 13.60 mm. The measured hardness of tablets of each batch ranged between 4.20 to 4.80 kg/cm^2. The values of friability test were less than 1% in all the formulations ensuring that the tablets were mechanically stable. The percentage weight variations for all formulations were within the Pharmacopoeial limits of ±5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values. The percentage of drug content was found to be between 97.26±2.41% and 98.91±2.26% of Salbutamol sulphate, which was within acceptable limits. Tablet dimensions, Hardness, Friability, Weight variation and Drug content uniformity of the tablets are listed in **Table 4**.

TABLE 4: EVALUATION OF FLOATING TABLET

Formulation code	Diameter	Thickness	Hardness	Friability	*Weight of the tablet (%Deviation±)	*Drug content
F1	13.58	4.032	2.6	0.5	496±0.4542	98.14±2.92
F2	13.54	4.030	3.2	0.3	499±0.3212	97.26±2.41
F3	13.50	4.025	3.4	0.3	510±0.1021	98.41±2.48
F4	13.58	4.032	2.6	0.4	492±0.5201	97.37±1.89
F5	13.60	4.034	3.0	0.4	486±0.3257	98.91±2.26
F6	13.54	4.030	3.0	0.5	495±0.6544	97.51±2.15
F7	13.50	4.025	3.8	0.3	497±0.7782	97.74±2.01
F8	13.52	4.027	3.4	0.2	501±0.1323	97.63±1.77
F9	13.58	4.032	3.6	0.4	494±0.1432	97.82±2.22
F10	13.54	4.030	3.4	0.4	495±0.2432	97.52±3.01

*Each sample was analysed in triplicate (n=3)

To provide good floating behavior in the stomach, the density of the device should be less than that of the gastric contents (1.004g/cm^3). All the batches showed density below than that of gastric fluid (1.004). On immersion in 0.1N HCl solution (pH 1.2) at 37^{0}C, the tablets floated, and remained buoyant without disintegration. From the results it can be concluded that the batch containing HPMC polymers showed good buoyancy lag time (BLT) and total floating time (TFT). Formulation F7 containing Carbopol showed good BLT of 106 sec and TFT of more than 13 hrs. Carbopol was used as release retardant and it also provided an additional gelatinous layer to the formulation. Tablet density, Buoyancy lag time, Total floating time and Swelling Index is given in **Table 5.**

TABLE 5: TABLET DENSITY, BUOYANCY LAG TIME, TOTAL FLOATING TIME AND SWELLING INDEX

Formulation Code	Tablet Density (gm/cc)	Bouncy Lag Time (sec)	Total Floating Time (hrs)	Swelling Index (%)	
				Thickness	Diameter
F1	0.97	72	>10	34.42	08.54
F2	0.92	56	>8	26.05	03.84
F3	0.96	75	>11	15.77	01.78
F4	0.90	101	>12	30.95	06.04
F5	0.99	98	>11	27.42	03.82
F6	0.98	77	>10	16.63	02.81
F7	0.93	106	>13	55.03	16.15
F8	0.97	97	>10	12.74	04.44
F9	0.95	81	>12	44.84	13.55
F10	0.98	73	>8	16.13	04.87

Results of *in-vitro* drug release studies indicated that the F7 (Carbopol-200 mg, Sodium Alginate-50 mg) and F9 (Dextrin 20 mg, HPMC 130 mg) had good sustained release. From the in-vitro dissolution data it was found that formulation F1, F3, F4, F5 and F8 containing HPMC released 85%, 85%, 88.55%, 90% and 98% respectively of drug within 8 hr of the study indicating that the polymer amount is not sufficient to control the drug release. F7 containing Carbopol (200 mg) alone released 78.55% of drug within 8 hrs. It concludes F7 had better-sustained release than the other formulation (F1 to F9). The optimized formulation F7 had better control over release rate. Percentage cumulative drug release of various Formulations (F1-F10) is given in the **Table 6** and **Fig 2.**

TABLE 6: PERCENTAGE CUMULATIVE DRUG RELEASE FROM FORMULATIONS (F1-F10)

Sl. No.	Time in hrs	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
1.	1	22.85	31.40	22.85	28.60	28.60	30.00	22.85	32.85	22.85	38.55
2.	2	38.00	41.45	38.00	37.15	38.55	40.00	30.00	42.85	35.70	50.00
3.	3	41.45	51.45	41.45	44.30	45.70	51.45	38.55	52.85	44.30	61.40
4.	4	51.45	62.85	51.45	52.85	55.70	62.85	44.30	64.30	47.15	68.55
5.	5	62.85	71.45	62.85	64.30	67.15	71.45	52.85	72.85	55.70	74.30
6.	6	71.45	80.00	71.45	71.45	78.55	81.45	62.85	84.30	65.70	80.00
7.	7	80.00	85.70	80.00	84.30	85.70	85.70	68.55	90.00	72.85	92.85
8.	8	85.00	98.55	85.00	88.55	90.00	91.14	78.55	98.00	84.30	98.55

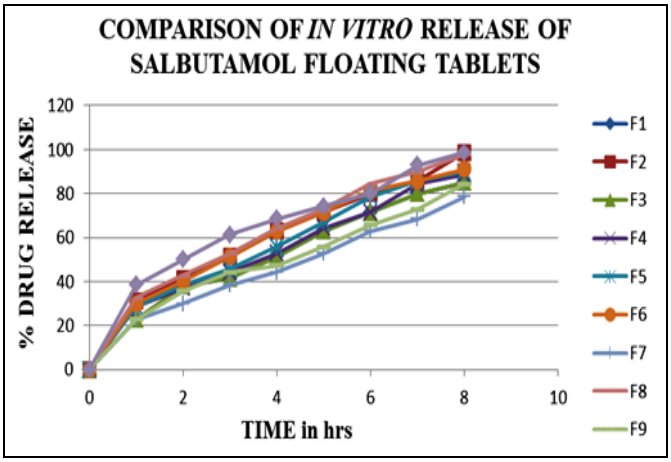

FIGURE 2: COMPARISON OF *IN VITRO* RELEASE OF SALBUTAMOL FLOATING TABLETS FORMULATION (F1-F10)

CONCLUSION: It was concluded that preformulation study was done initially and results directed the further course of formulation. The tablets were formulated using various concentrations of polymers such as HPMC, NaCMC, Sodium Alginate, Dextrin and Carbopol and effervescing agent (sodium bicarbonate).

Results of *in-vitro* drug release studies indicated that the F7 (Carbopol-200 mg, Sodium Alginate-50 mg) and F9 (Dextrin 20 mg, HPMC 130 mg) had good sustained release. From the in-vitro dissolution data it was found that formulation F1, F3, F4, F5 and F8 containing HPMC released 85%, 85%, 88.55%, 90% and 98% respectively of drug within 8 hr of the study indicating that the polymer amount is not sufficient to control the drug release. F7 containing Carbopol (200 mg) alone released 78.55% of drug within 8 hrs. It concludes F7 had better-sustained release than the other formulation (F1 to F9). The optimized formulation F7 had better control over release rate.

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