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FORMULATION AND EVALUATION OF EXTENDED-RELEASE MATRIX TABLETS OF SALBUTAMOL SULPHATE USING NATURAL POLYMERS

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Abstract:

The present study involves the formulation and evaluation of extended release matrix tablets of Salbutamol Sulphate using natural polymers such as Guar Gum, Locust Bean Gum, and Gum Damar. The primary objective was to develop a sustained release formulation that could maintain therapeutic drug levels over an extended period, thereby reducing dosing frequency and improving patient compliance. A total of nine formulations were prepared using varying concentrations of the selected natural polymers. All formulations were subjected to pre-compression and post-compression evaluations, and the results were found to be within the acceptable limits as per IP standards. Among all, formulation F6 was identified as the optimized batch, as it exhibited the most desirable drug release profile, achieving 99.08% drug release over 12 hours. The study concludes that natural polymers can effectively be used in the formulation of extended release tablets of Salbutamol Sulphate, offering a promising and sustainable alternative to synthetic polymers in controlled drug delivery systems.

Keywords: *Salbutamol Sulphate, Locust Bean Gum, Guar Gum and Gum Damar*

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INTRODUCTION [1-9]

Extended release tablets are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect. The advantage of administering a single dose of a drug that is released over an extended period of time to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use.

The first Extended release tablets were made by Howard Press in New Jersy in the early 1950's. The first tablets released under his process patent were called 'Nitroglyn' and made under license by Key Corp. in Florida.

Extended release, prolonged release, modified release, extended release or depot formulations are terms used to identify drug delivery systems that are designed to achieve or extend therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose.

The goal in designing Extended or Extended delivery systems is to reduce the frequency of the dosing or to increase effectiveness of the drug by localization at the site of action, reducing the dose required or providing uniform drug delivery. So, Extended release dosage form is a dosage form that release one or more drugs continuously in predetermined pattern for a fixed period of time, either systemically or to a specified target organ.

Extended release dosage forms provide a better control of plasma drug levels, less dosage frequency, less side effect, increased efficacy and constant delivery. There are certain considerations for the preparation of extended release formulations:

- If the active compound has a long half-life, it is Extended on its own,
- If the pharmacological activity of the active is not directly related to its blood levels,
- If the absorption of the drug involves an active transport and
- If the active compound has very short half-life then it would require a large amount of drug to maintain a prolonged effective dose.

The above factors need serious review prior to design.

Introduction of matrix tablet as Extended release (SR) has given a new breakthrough for novel drug delivery system in the field of Pharmaceutical technology. It excludes complex production procedures such as coating and Pelletization during manufacturing and drug release rate from the dosage form is controlled mainly by the type and proportion of polymer used in the preparations. Hydrophilic polymer matrix is widely used for formulating an SR dosage form. Because of increased complication and expense involved in marketing of new drug entities, has focused greater attention on development of Extended release or controlled release drug delivery systems. Matrix systems are widely used for the purpose of Extended release. It is the release system which prolongs and controls the release of the drug that is dissolved or dispersed.

In fact, a matrix is defined as a well-mixed composite of one or more drugs with gelling agent i.e. hydrophilic polymers. By the Extended release method therapeutically effective concentration can be achieved in the systemic circulation over an extended period of time, thus achieving better compliance of patients. Numerous SR oral dosage forms such as membrane controlled system, matrices with water soluble/insoluble polymers or waxes and osmotic systems have been developed, intense research has recently focused on the designation of SR systems for poorly water soluble drugs.

Rationale For Extended Release Dosage Forms[10-12]:

Some drugs are inherently long lasting and require only once-a-day oral dosing to sustain adequate drug blood levels and the desired therapeutic effect. These drugs are formulated in the conventional manner in immediate release dosage forms. However, many other drugs are not inherently long lasting and require multiple daily dosing to achieve the desired therapeutic results. Multiple daily dosing is inconvenient for the patient and can result in missed doses, made up doses, and noncompliance with the regimen. When conventional immediate-release dosage forms are taken on schedule and more than once daily, they cause sequential therapeutic blood level peaks and valleys (troughs) associated with the taking of each dose . However, when doses are not administered on schedule, the resulting peaks and valleys reflect less than optimum drug therapy. For example, if doses are administered too frequently, minimum toxic concentrations of drug may be reached, with toxic side effects resulting. If doses are missed, periods of sub therapeutic drug blood levels or those below the minimum effective concentration may result, with no benefit to the patient. Extended-release tablets and capsules are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to be taken three or four times daily to achieve the same therapeutic effect. Typically, extended-release products provide an immediate release of drug that promptly produces the desired therapeutic effect, followed by gradual release of additional amounts of drug to maintain this effect over a predetermined period .

The Extended plasma drug levels provided by extended-release products oftentimes eliminate the need for night dosing, which benefits not only the patient but the care giver as well.

Drawbacks of Conventional Dosage Forms[13]:

- Poor patient compliance, increased chances of missing the dose of a drug with short half-life for which frequent administration is necessary.
- A typical peak-valley plasma concentration time profile is obtained which makes attainment of steady-state condition difficult.
- The fluctuations in drug levels may lead to precipitation of adverse effects especially of a drug with small Therapeutic Index (TI) whenever over medication occur.

TERMINOLOGY[14,15]:

Modified release delivery systems may be divided conveniently in to four categories.

A) Delayed release

B) Extended release

- Controlled release
- Extended release

C) Site specific targeting

D) Receptor targeting

DESIGN AND FORMULATION OF ORAL SUATAINED RELEASE DRUG DELIVERY SYSTEM[16, 17, 18, 19]:

The oral route of administration is the most preferred route due to flexibility in dosage form, design and patient compliance. But here one has to take into consideration, the various pH that the dosage form would encounter during its transit, the gastrointestinal motility, the enzyme system and its influence on the drug and the dosage form. The majority of oral Extended release systems rely on dissolution, diffusion or a combination of both mechanisms, to generate slow release of drug to the gastrointestinal milieu. Theoretically and desirably a Extended release delivery device, should release the drug by a zero-order process which would result in a blood level time profile similar to that after intravenous constant rate infusion.

Extended (zero-order) drug release has been attempted to be achieved with various classes of Extended drug delivery system: A) Diffusion Extended system.

i) Reservoir type.

ii) Matrix type

B) Dissolution Extended system.

i) Reservoir type.

ii) Matrix type

C) Methods using Ion-exchange.

D) Methods using osmotic pressure.

E) pH independent formulations.

F) Altered density formulations.

AIM AND OBJECTIVE

Aim of the Work

The aim of the study is to formulate and evaluate Salbutamol Sulphate extended release tablets by using natural polymers such as Guar Gum, Locust Bean gum and Gum Damar.

Objective of the Study:

- To Formulate extended release tablets of Salbutamol Sulphate for the treatments of broncho spasm (due to any cause—allergic asthma or exercise-induced), as well as chronic obstructive pulmonary disease.
- The objective of this present study is to reduce the dosing frequency of Salbutamol Sulphate so prepared extended release dosage form for prolong its duration of action and reduced side effects.
- The present work is aimed at preparing and evaluating extended release tablets of Salbutamol Sulphate using natural polymers.
- To study the effect of nature of the polymer and drug: polymer ratio on the rate of drug release.
- To evaluate pre and post compression evaluation parameters
- To perform drug and excipient compatibility studies (FTIR)
- To optimize the formula.

METHODOLOGY [20-29]

Analytical method development:

Buffer Preparation:

Preparation of 0.2M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000mL of distilled water and mixed.

Preparation of 0.2M sodium hydroxide solution: Accurately weighed 8 gm sodium hydroxide pellets were dissolved 1000ml of distilled water and mixed.

Preparation of pH 6.8 Phosphate buffer: Accurately measured 250ml of 0.2M potassium Dihydrogenortho phosphate and 112.5 ml 0.2M NaOH was taken into the 1000ml volumetric flask. Volume was made up to 1000ml with distilled water.

a) Determination of absorption maxima:

100mg of Salbutamol Sulphate pure drug was dissolved in 100ml of 0.1N HCL (stock solution- 1). 10ml of above solution was taken and make up with 100 ml by using 0.1 N HCL (stock solution-2 i.e. 100µg/ml). From this 10ml was taken and make up with 100 ml of 0.1 N HCL (10µg/ml). Scan the 10µg/ml using Double beam UV/VIS spectrophotometer in the range of 200 – 400 nm.

b) Preparation calibration curve:

100mg of Salbutamol Sulphate pure drug was dissolved in 15ml of Methanol and volume make up to 100ml with 0.1N HCL (stock solution-1). 10ml of above solution was taken and make up with100ml by using 0.1 N HCl (stock solution-2 i.e 100µg/ml). From this take 0.2, 0.4, 0.6, 0.8 and 1 ml of solution and make up to 10ml with 0.1N HCL to obtain 2, 4, 6, 8 and 10 µg/ml of Salbutamol Sulphate per ml of solution. The absorbance of the above dilutions was measured at 282nm by using UV-Spectrophotometer taking 0.1N HCl as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis. The above procedure was repeated by using pH 6.8 phosphate buffer solutions.

Formulation development of Extended-release Tablets:

All the formulations were prepared by direct compression method. The compositions of different formulations are given in Table 7.1. The tablets were prepared as per the procedure given below and aim is to prolong the release of Salbutamol Sulphate.

Procedure:

1) Salbutamol Sulphate and all other ingredients were individually passed through sieve no # 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

Table 1: Formulation of Extended-release tablets

Ingredients (mg)	Formulation Codes								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Salbutamol Sulphate	4	4	4	4	4	4	4	4	4
Guar Gum	20	40	60	-	-	-	-	-	-
Locust Bean gum	-	-	-	20	40	60	-	-	-
Gum Damar	-	-	-	-	-	-	20	40	60
PVP K 30	15	15	15	15	15	15	15	15	15
MCC102	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Mg. stearate	6	6	6	6	6	6	6	6	6
Talc	5	5	5	5	5	5	5	5	5
Total weight (mg)	200	200	200	200	200	200	200	200	200

Evaluation Parameters:

Pre Compression parameters

Bulk density (D_B)

Bulk density is the ratio between a given mass of the powder and its bulk volume.

Bulk density = Mass of Powder / Bulk volume of the powder

Bulk density (D_B) = W /V_0

Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and measure the bulk volume.

Tapped Density (D_T)

Tapped density is the ratio between a given mass of powder (or) granules and the constant (or) fixed volume of powder or granules after tapping.

Procedure: An accurately weighed quantity of granules (w) (which was previously passed through sieve No: 40) was carefully transferred into 250 ml measuring cylinder and the cylinder was tapped on a wooden surface from the height of 2.5 cm at two second intervals. The tapping was continued until no further change in volume (until a constant volume) was obtained (V_f).

The tapped density was calculated by using the formula

Tapped density = mass of the powder/ tapped volume

Tapped density (D_T)=W/V_f

Hausner's ratio

Hausner's ratio is an indirect index of ease of powder flow and was calculated by the formula,

Hausner's ratio = D_T/D_B

Where, D_T is the tapped density

D_B is the bulk density

Compressibility index

Compressibility index (CI) was determined by measuring the initial volume (V_o) and final volume (V_f) after hundred tapping's of a sample in a measuring cylinder. It indicates the powder flow properties and expressed in terms of percentage and given in table no. 14 and calculated by using the formula.

% Compressibility index = V_o - V/V_o x 100

Angle of repose

Angle of repose was measured by fixed funnel method. It determines flow property of the powder. It is defined as maximum angle formed between the surface of the pile of powder and the horizontal plane.

The powder was allowed to flow through the funnel fixed to a stand at definite height (h). By measuring the height and radius of the heap of powder formed (r), angle of repose was calculated by using formula given below and the calculated values obtained was shown in table no. 4

$\theta = \tan^{-1}$ (h / r) Where, θ is the angle of repose

h is the height in cm

r is the radius in cm

Post Compression parameters

Weight variation test

Twenty tablets were randomly selected and weighed, to estimate the average weight and that were compared with individual tablet weight. The percentage weight variation was calculated as per Indian Pharmacopoeial Specification. Tablets with an average weight 250 mg so the % deviation was ±5 %.

Friability test

Twenty tablets were weighed and subjected to drum of friability test apparatus. The drum rotated at a speed of 25 rpm. The friabilator was operated for 4 minutes and reweighed the tablets. % loss (F) was calculated by the following formula.

F =100 (W0-W)/W0

Where W0 = Initial weight, W = Final weight

Hardness test

The hardness of tablets was measured by using Monsanto hardness tester. The results were complies with IP specification.

Thickness test

The rule of physical dimension of the tablets such as sizes and thickness is necessary for consumer acceptance and maintain tablet uniformity. The dimensional specifications were measured by using screw gauge. The thickness of the tablet is mostly related to the tablet hardness can be used as initial control parameter.

Drug content

The amount of drug in tablet was important for to monitor from tablet to tablet, and batch to batch is to evaluate for efficacy of tablets. For this test, take ten tablets from each batch were weighed and powdered. Weighed equivalent to the average weight of the tablet powder and transferred into a 100 ml volumetric flask and dissolved in a suitable quantity of media. The solution was made up to the mark and mixed well. Then filter the solution. A portion of the filtrate sample was analyzed by UV spectrophotometer.

***In vitro* drug release studies**

Apparatus	--	USP-II, Paddle
Method		
Dissolution Medium	--	0.1 N HCL, p H 6.8 Phosphate buffer
RPM	--	50
Sampling intervals (hrs)	--	1, 2, 3, 4, 5, 6, 7, 8, 9,10, 11 and 12
Temperature	--	37°c ± 0.5°c

Procedure:

900ml 0f 0.1 HCl was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The media was allowed to equilibrate to temp of 37°c ± 0.5°c. Tablet was placed in the vessel and apparatus was operated for 2 hours. Then 0.1 N HCl was replaced with pH 6.8 phosphate buffer and process was continued upto 12 hrs at 50 rpm. At specific time intervals, withdrawn 5 ml of sample and again 5ml media was added to maintain the sink condition. Withdrawn samples were analyzed at wavelength of drug using UV- spectrophotometer.

Application of release rate kinetics to dissolution data

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Zero order release rate kinetics:

To study the zero–order release kinetics the release rate data ar e fitted to the following equation.

$$F = K_o t$$

Where, 'F' is the drug release at time't', and 'K_o' is the zero order release rate constant. The plot of % drug release versus time is linear.

First order release rate kinetics: The release rate data are fitted to the following equation

$$Log (100-F) = kt$$

A plot of log cumulative percent of drug remaining to be released vs. time is plotted then it gives first order release.

Higuchi release model: To study the Higuchi release kinetics, the release rate data were fitted to the following equation.

$$F = k\ t1/2$$

Where, 'k' is the Higuchi constant.

In higuchi model, a plot of % drug release versus square root of time is linear.

Korsmeyer and Peppas release model:

The mechanism of drug release was evaluated by plotting the log percentage of drug released versus log time according to Korsmeyer- Peppas equation. The exponent 'n' indicates the mechanism of drug

release calculated through the slope of the straight Line.

$$M_t / M_\infty = K t^n$$

Where, M_t / M_∞ is fraction of drug released at time 't', k represents a constant, and 'n' is the diffusional exponent, which characterizes the type of release mechanism during the dissolution process. For non-Fickian release, the value of n falls between 0.5 and 1.0; while in case of Fickian diffusion, n = 0.5; for zero-order release (case I I transport), n=1; and for super case II transport, n > 1. In this model, a plot of log (M_t / M_∞) versus log (time) is linear.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

Drug excipient interaction studies are significant for the successful formulation of every dosage form. Fourier Transform Infrared (FTIR) Spectroscopy studies were used for the assessment of physicochemical compatibility and interactions, which helps in the prediction of interaction between drug and other excipients. In the current study 1:1 ratio was used for preparation of physical mixtures used for analyzing of compatibility studies. FT-IR studies were carried out with a Bruker FTIR facility.

RESULTS AND DISCUSSION:

The present work was designed to developing Extended tablets of Salbutamol Sulphate using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Analytical Method

Standard graph of Salbutamol Sulphate in 0.1N HCl:

The scanning of the 10µg/ml solution of Salbutamol Sulphate in the ultraviolet range (200- 400 nm) against 0.1 N HCl blank gave the lamda $_{max}$ as 282 nm. The standard concentrations of Salbutamol Sulphate (2-10 µg/mL) prepared in 0.1N HCl showed good linearity with R^2 value of 0.9998, which suggests that it obeys the Beer-Lamberts law.

Table 2: Standard curve of Salbutamol Sulphate in 0.1N HCl

Concentration (µg/ ml)	Absorbance
0	0
2	0.125
4	0.243
6	0.375
8	0.502
10	0.627

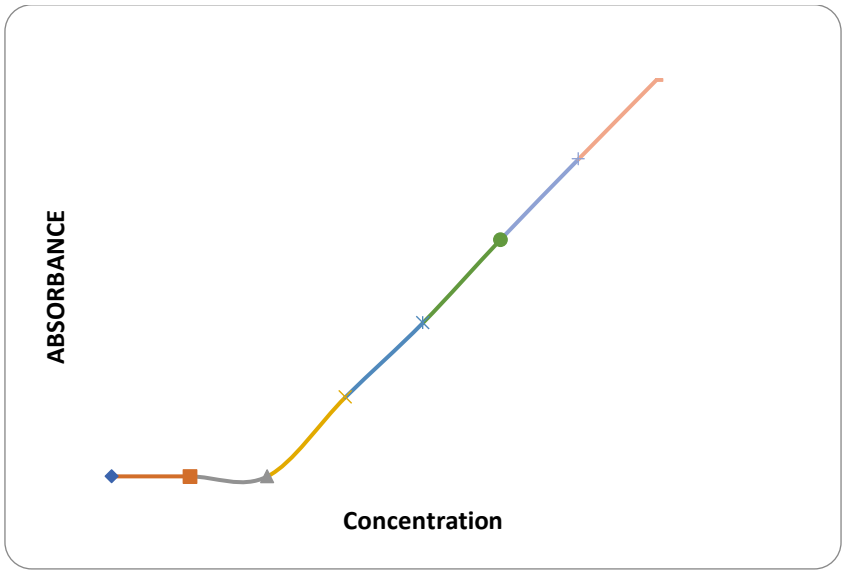

Fig. 1: Calibration curve of Salbutamol Sulphate in 0.1 N HCl at 282 nm

Standard Curve of Salbutamol Sulphate in Phosphate buffer pH 6.8

The scanning of the 10µg/ml solution of Salbutamol Sulphate in the ultraviolet range (200- 400nm) against 6.8 pH phosphate buffers as blank gave the lamda $_{max}$ as 282 nm. The standard concentrations of Salbutamol Sulphate (2-10µg/ml) prepared in 6.8 pH phosphate buffer showed good linearity with R^2 value of 0.999, which suggests that it obeys the Beer-Lamberts law.

Table 3: Standard curve of Salbutamol Sulphate in Phosphate buffer pH 6.8

Concentration (µg / ml)	Absorbance
0	0
2	0.134
4	0.256
6	0.389
8	0.515
10	0.639

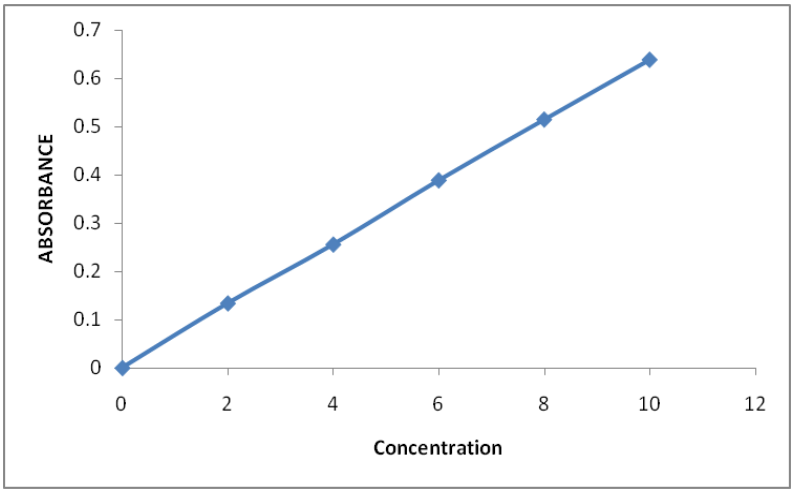

Fig.2: Calibration of Salbutamol Sulphate in Phosphate buffer pH 6.8

Drug and Excipient Compatibility Studies

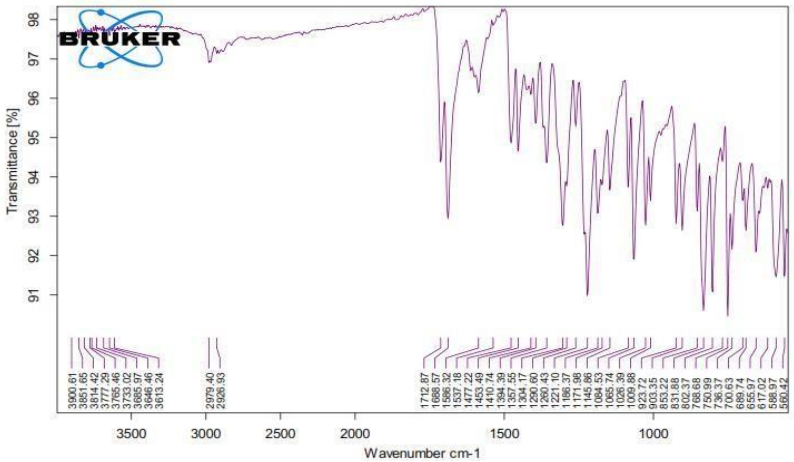

Fig 3 : FTIR Graph Of Pure Drug Of Salbutamol Sulphate

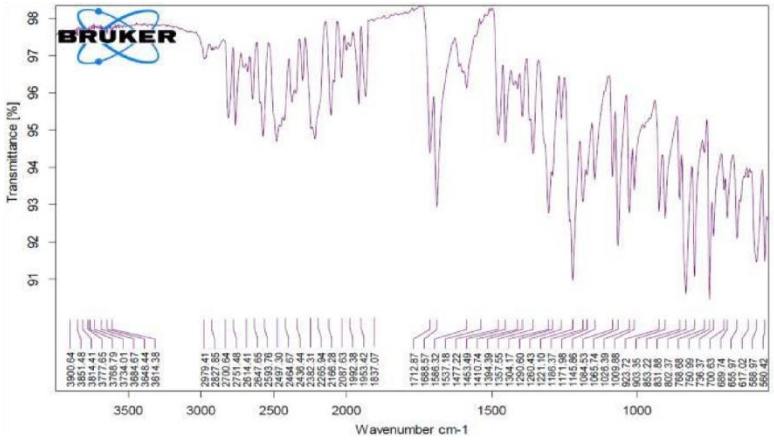

Fig 4: FTIR Graph Of Pure Drug Of Salbutamol Sulphate Optimised Graph

There is no incompatibility of pure drug and excipients. There is no disappearance of peaks of pure drug and in optimised formulation.

EVALUATION PARAMETERS

Pre-compression parameters

Table 4: Pre-compression parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/cm^3)	Tapped density (gm/ cm^3)	Carr's index (%)	Hausner's Ratio
F1	26.12 ± 0.1	0.44 ± 0.03	0.50± 0.061	12 ± 0.58	1.13 ± 0.012
F2	28.53 ± 0.57	0.48 ± 0.06	0.56 ± 0.08	14.28 ± 0.47	1.16 ± 0.032
F3	25.46 ± 0.57	0.55 ± 0.08	0.62 ± 0.011	11.29 ± 0.57	1.12 ± 0.015
F4	27.61 ± 0.63	0.53 ± 0.09	0.61 ± 0.071	13.1 ± 0.15	1.15 ± 0.021
F5	25.15 ± 0.58	0.49 ± 0.01	0.56 ± 0.08	12.5 ± 0.21	1.14 ± 0.012
F6	26.08 ± 0.51	0.55 ± 0.011	0.62 ± 0.06	11.29 ± 0.35	1.12 ± 0.023
F7	28.38 ± 0.56	0.47 ± 0.08	0.54 ± 0.01	12.96 ± 0.42	1.14 ± 0.031
F8	27.26 ± 0.56	0.52 ± 0.055	0.59 ± 0.08	11.86 ± 0.57	1.13 ± 0.026
F9	26.43 ±1 0.62	0.56 ± 0.07	0.63 ± 0.012	11.11 ± 0.12	1.12 ± 0.056

Tablet powder blend was subjected to various pre-compression parameters. The angle of repose values was showed from 25 to 30; it indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.44±0.03 to 0.56 ± 0.07 (gm/cm^3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.50± 0.061to 0.63 ± 0.012 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging from 11 to 14.28 which showed that the powder has good flow properties. All the formulations were showed the Hausner ratio ranging from 0 to 1.25 indicating the powder has good flow properties.

Post Compression Parameters For tablets

Table no 5: Post Compression Parameters of Salbutamol Sulphate ER Tablets

Formulation codes	Weight variation (mg)	Hardness (kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	199.95 ±1.22	4.8±0.01	0.45±0.05	4.0 ±0.05	98.8 ± 0.14
F2	199.15 ± 1.31	4.7±0.05	0.54±0.07	3.9 ±0.04	99.3 ± 0.13
F3	201.26 ± 0.81	4.5±0.07	0.55±0.02	3.8 ±0.06	98.2 ± 0.15
F4	203.36 ± 1.17	4.7±0.04	0.56±0.04	4.1±0.08	99.8 ± 0.17
F5	197.25 ± 2.02	4.6±0.09	0.48±0.08	3.8 ±0.09	99.3 ± 012
F6	200.5 ± 1.25	4.7±0.01	0.45±0.02	3.8 ±0.05	97.2 ± 0.19
F7	198.26 ± 0.95	4.8±0.04	0.51±0.04	4.0 ±0.03	102.3 ± 0.21
F8	203.63 ± 1.04	4.8±0.03	0.52±0.03	4.1±0.04	103.5 ± 0.14
F9	199.53 ± 0.53	4.5 ± 0.02	0.561 ±0.03	3.9 ±0.02	99.56 ± 0.22

Weight variation and thickness: All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown in table 7.4. The average tablet weight of all the formulations was found to be between 197.25 ± 2.02 to 203.63 ± 1.04**.** The maximum allowed percentage weight variation for tablets weighing >80-200 mg is 7.5% and no formulations are not exceeding this limit. Thus all the formulations were found to comply with the standards given in I.P. And thickness of all the formulations was also complying with the standards that were found to be between 3.8 ±0.06 to 4.1±0.08.

Hardness and friability: All the formulations were evaluated for their hardness, using Monsanto hardness tester and the results are shown in table 7.4. The average hardness for all the formulations was found to be between **(**4.5 ± 0.07 to 4.8±0.04**)** Kg/cm^2 which was found to be acceptable.

Friability was determined to estimate the ability of the tablets to withstand the abrasion during packing, handling and transporting. All the formulations were evaluated for their percentage friability using Roche friabilator and the results were shown in table 7.4. The average percentage friability for all the formulations was between 0.45±0.04 and 0.56±0.04, which was found to be within the limit.

Drug content: All the formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown in table 7.4. The drug content values for all the formulations were found to be in the range of **(**97.2±0.19 to 103.5±0.14**).** According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the FDT formulations comply with the standards given in IP.

***In Vitro* Drug Release Studies**

The formulations prepared with different natural polymers by wet granulation method. The tablets dissolution study was carried out in paddle dissolution apparatus using 0.1N HCl for 2 hours and 6.8 pH phosphate buffers for remaining hours as a dissolution medium.

Table 6: Dissolution Data of Salbutamol Sulphate Tablets Prepared With Guar Gum In Different Concentrations

Time (hr)	Cumulative Percent Drug Released		
	F1	F2	F3
0	0	0	0
1	14.57	16.81	14.61
2	21.58	22.32	18.59
3	27.57	26.61	29.12
4	39.69	35.15	39.45
5	46.97	41.29	51.61
6	58.62	53.84	57.18
7	66.48	64.26	69.92
8	69.74	75.82	74.29
9	72.38	82.81	86.72
10	76.35	89.96	88.24
11	81.42	91.21	92.17
12	86.75	93.55	96.54

Fig. 5: Dissolution study of Salbutamol Sulphate Extended tablets (F1 to F3)

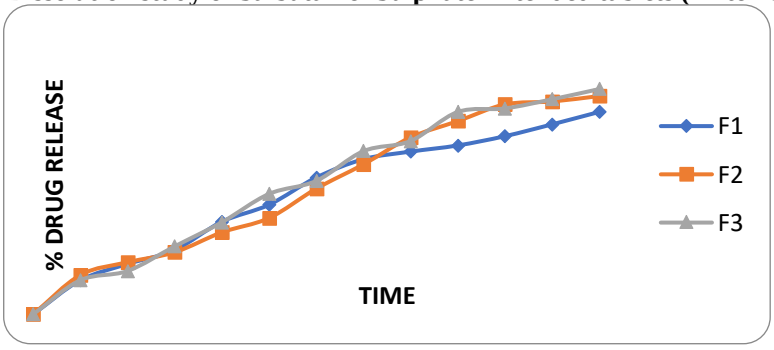

Table 7: Dissolution Data of Salbutamol Sulphate Tablets Prepared With Locust Bean gum in Different Concentrations

Time (hr)	Cumulative Percent Drug Released		
	F4	F5	F6
0	0	0	0
1	25.28	19.93	29.28
2	33.47	23.66	36.15
3	39.59	41.31	43.55
4	48.26	46.69	49.47
5	55.12	58.74	53.82
6	61.63	63.98	69.83
7	67.81	69.82	73.02
8	73.27	76.21	87.52
9	79.44	83.84	91.91
10	84.11	91.23	94.11
11	89.75	94.52	97.22
12	92.81	98.99	99.08

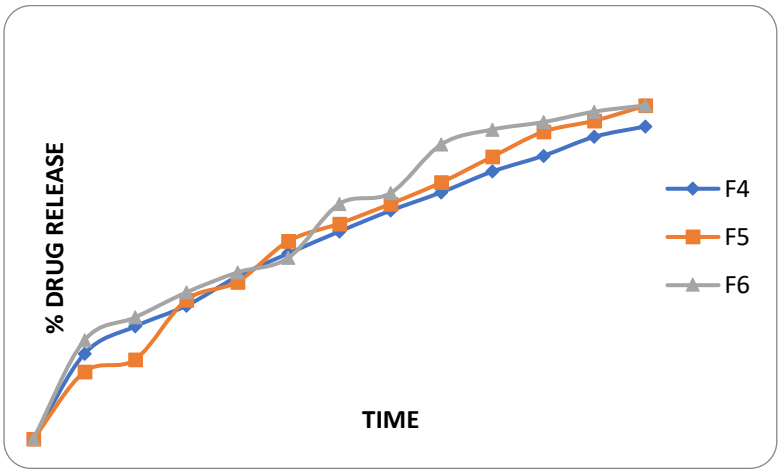

Fig. 6: Dissolution study of Salbutamol Sulphate tablets (F4 to F6)

Table 8: Dissolution Data of Salbutamol Sulphate Tablets Prepared Wit Gum Damar in Different Concentrations

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED		
	F7	F8	F9
0	0	0	0
1	9.28	11.97	13.40
2	13.26	15.22	19.75
3	19.62	22.35	26.05
4	25.72	28.10	30.58
5	31.73	32.34	36.57
6	36.48	39.23	40.04
7	42.29	45.76	47.96
8	49.68	50.38	58.45
9	57.30	69.45	76.11
10	68.74	74.56	82.74
11	77.19	78.15	86.04
12	87.56	98.74	92.12

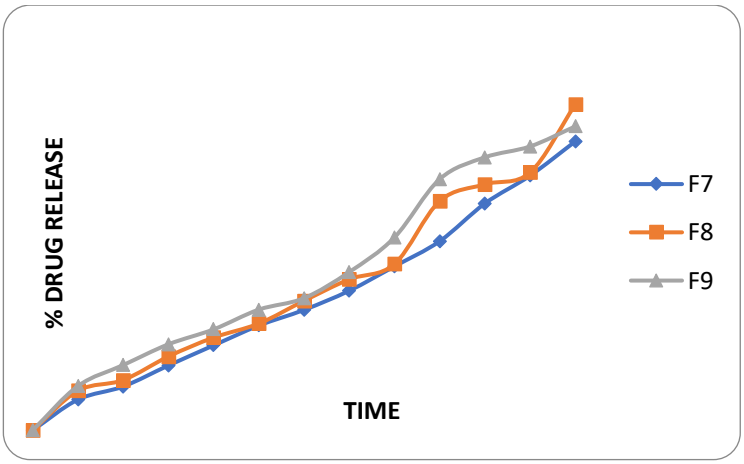

Fig. 7: Dissolution study of Salbutamol Sulphate tablets (F7 to F9)

Whereas the formulations prepared with Guar Gum retarded the drug release up to 12 hours in the concentration 60 mg % drug release was 96.54%.
Whereas the formulations prepared with Locust Bean gum retarded the drug release up to
12 hours in the concentration 60 mg % drug release was 99.08 %
Whereas the formulations prepared with Gum Damar retarded the drug release up to 12 hours in the concentration 40 mg % drug release was 98.74%
Hence from the above dissolution data it was concluded that F6 formulation was considered as optimised formulation because good drug release (99.08 %) in 12 hours.

Application of Release Rate Kinetics to Dissolution Data

Data of *in vitro* release studies of formulations which were showing better drug release were fit into different equations to explain the release kinetics of Salbutamol Sulphate release from Extended tablets. The data was fitted into various kinetic models such as Zero, first order kinetics; Higuchi and Korsmeyer papas mechanisms and the results were shown in below table

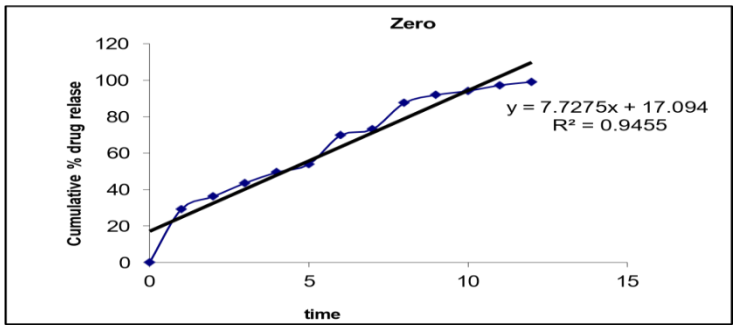

Figure 8: Graph of zero order kinetics

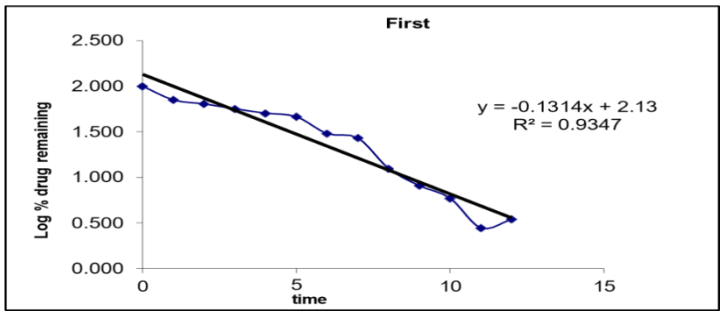

Figure 9: Graph of first order release kinetics

Optimised formulation F6 was kept for release kinetic studies. From the above graphs it was evident that the formulation F6 was followed Zero order release mechanism.

CONCLUSION:

The present study focused on the formulation and evaluation of extended-release matrix tablets of Salbutamol Sulphate using natural polymers. The tablets were successfully prepared using various natural polymers such as Guar Gum, Locust Bean gum and Gum Damar in different concentrations. All formulations were evaluated for pre-compression and post-compression parameters, which were found to be within acceptable limits as per IP standards. Among the formulations, the optimized batch demonstrated sustained drug release for up to 12 hours, maintaining consistent and controlled release profiles. The drug release followed a diffusion- controlled mechanism, indicating the efficiency of natural polymers in extending drug release. Thus, the use of natural polymers in extended-release formulations of Salbutamol Sulphate presents a cost-effective, safe, and eco-friendly alternative to synthetic polymers, showing promising potential for future pharmaceutical applications.

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