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Research

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: Extended Release Tablets of Salbutamol Sulphate.

1. INTRODUCTION:

Out of the many routes of administration available, the oral route remains the most popular dosage form among patients as it is easy to administer, carry around, formulation design flexibility, cost-effectiveness, causes minimal discomfort for many patients, and least sterility restrictions during manufacturing. Most of the newly discovered drugs are lipophilic in nature and have poor aqueous solubility, thereby posing problems in their formulation into delivery systems[1].

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.[2-5]

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.[6-9]

1.1. RATIONALE FOR EXTENDED RELEASE DOSAGE FORMS[10]:

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.

List of Materials Used

Salbutamol Sulfate- Procured from Cipla provided by SURA LABS

Guar Gum- Merck Specialities Pvt Ltd, Mumbai, India

Locust Bean gum - Merck Specialities Pvt Ltd, Mumbai, India

Gum Damar- Merck Specialities Pvt Ltd, Mumbai, India

PVP K 30- Merck Specialities Pvt Ltd, Mumbai, India

MCC102- Merck Specialities Pvt Ltd, Mumbai, India

Mg. stearate- Merck Specialities Pvt Ltd, Mumbai, India

Talc - Merck Specialities Pvt Ltd, Mumbai, India

List of Equipment's used

Weighing Balance Sartorius

Tablet Compression Machine (Mult station) Lab Press

Limited, India.

Hardness tester Monsanto, Mumbai, India.

Vernier callipers Mitutoyo, Japan.

Roche Friabilator Labindia, Mumbai, India

Dissolution Apparatus Labindia, Mumbai, India

UV-Visible Spectrophotometer- Labindia, Mumbai, India

pH meter- Labindia, Mumbai, India

FT-IR Spectrophotometer Bruker, Germany

METHODOLOGY

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 Sulfate.

Procedure:

1) Salbutamol Sulfate 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 Sulfate	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

1 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[47] 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. 14

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

Where, θ is the angle of repose

h is the height in cm

r is the radius in cm

Flow property

Table 2: The flow property of powder blend

Flow property	Angle of repose	Compressibility index (%)	Hausner's ratio
Excellent	25-30	<10	1.00-1.11
Good	31-35	11-15	1.12-1.18
Fair	36-40	16-20	1.19-1.25
Passable	41-45	21-25	1.26-1.34
Poor	46-55	26-31	1.35-1.45
Very poor	56-65	32-37	1.46-1.59
Very very poor	>66	>38	>1.60

***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.

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 Sulfate using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release

studies.

1. Analytical Method

1.1 Standard graph of Salbutamol Sulfate in 0.1N HCl:

The scanning of the 10µg/ml solution of Salbutamol Sulfate in the ultraviolet range (200-400 nm) against 0.1 N HCl blank gave the λ_{max} as 282 nm. The standard concentrations of Salbutamol Sulfate (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 1: Standard curve of Salbutamol Sulfate 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

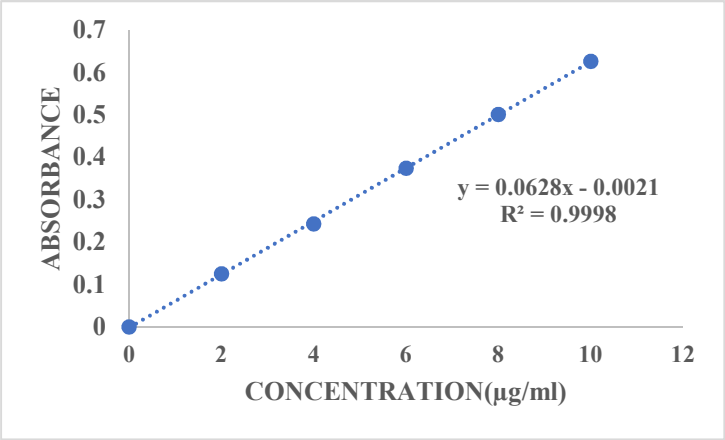

Fig. 1: Calibration curve of Salbutamol Sulfate in 0.1 N HCl at 282 nm

1.2 Standard Curve of Salbutamol Sulfate in Phosphate buffer pH 6.8

The scanning of the 10µg/ml solution of Salbutamol Sulfate in the ultraviolet range (200-400nm) against 6.8 pH phosphate buffer as blank gave the λ_{max} as 282 nm. The standard concentrations of Salbutamol Sulfate (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 2: Standard curve of Salbutamol Sulfate 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

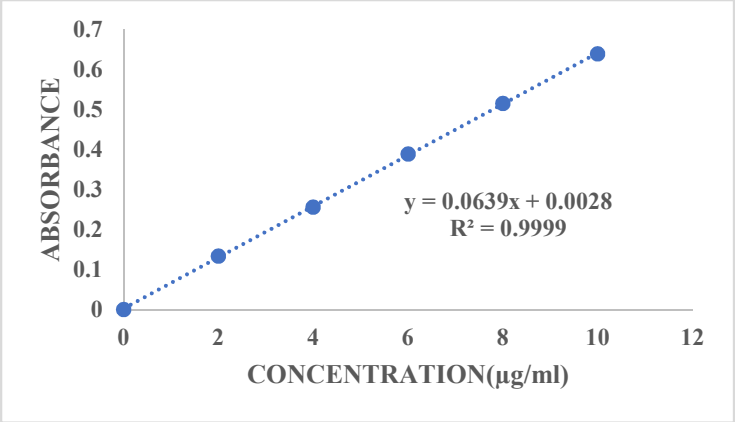

Fig 2: Calibration of Salbutamol Sulfate in Phosphate buffer pH 6.8

2 Drug and Excipient Compatibility Studies

2.1 FTIR study

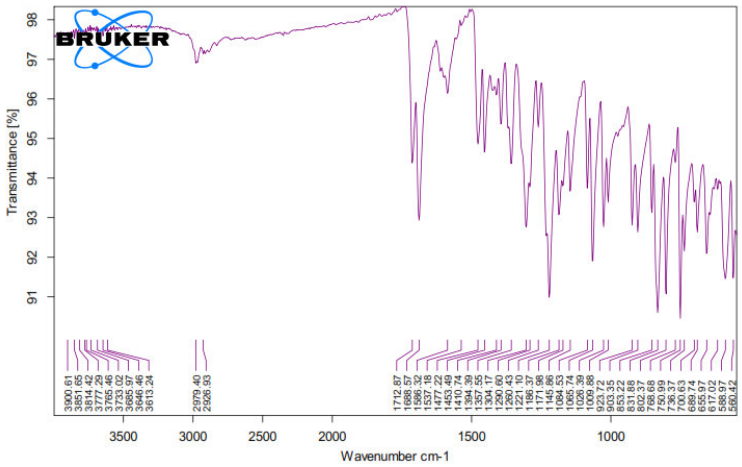

Fig : Ftir Graph Of Pure Drug Of Salbutamol Sulfate

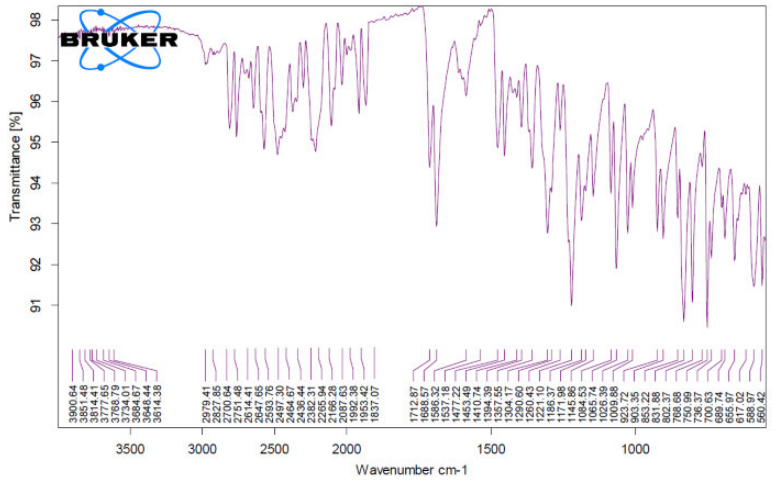

Fig : Ftir Graph Of Pure Drug Of Salbutamol Sulfate Optimised Graph

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

3 EVALUATION PARAMETERS

3.1 Pre-compression parameters

Table 3: 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.

3.2 Post Compression Parameters For tablets

Table 4: Post Compression Parameters of 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

***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 5: Dissolution Data of Salbutamol Sulfate 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

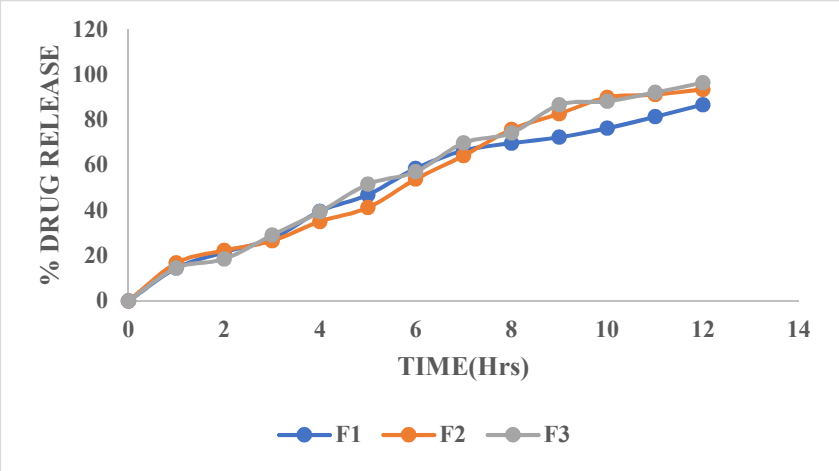

Figure 3: Dissolution study of Salbutamol Sulfate Extended tablets (F1 to F3)

Table 6: Dissolution Data of Salbutamol Sulfate 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

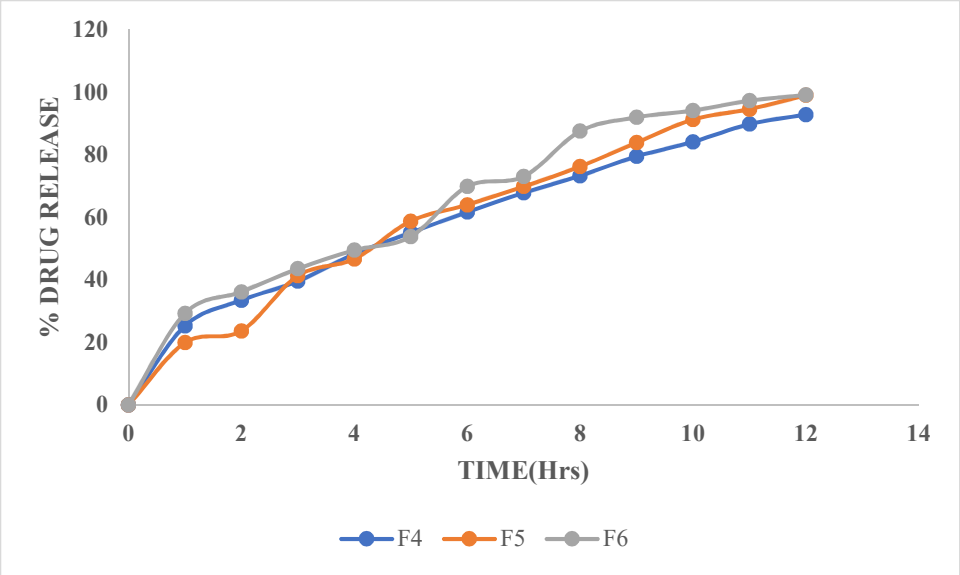

Figure 4: Dissolution study of Salbutamol Sulfate tablets (F4 to F6)

Table 6: Dissolution Data of Salbutamol Sulfate Tablets Prepared With 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

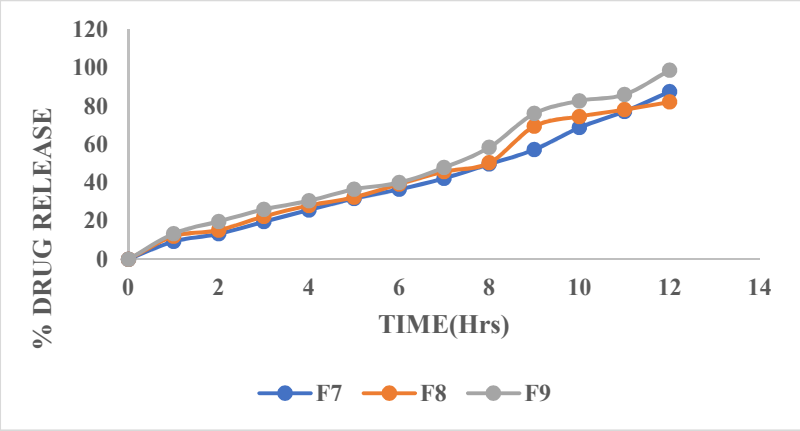

Figure 5: Dissolution study of Salbutamol Sulfate tablets (F7 to F9)

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.

8.4 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 Sulfate 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

Table 7: Release kinetics data for optimised formulation (F6)

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	%) REL	LOG (T	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
29.28	1	1.000	1.467	0.000	1.850	29.280	0.0342	-0.533	70.72	4.642	4.135	0.506
36.15	2	1.414	1.558	0.301	1.805	18.075	0.0277	-0.442	63.85	4.642	3.997	0.645
43.55	3	1.732	1.639	0.477	1.752	14.517	0.0230	-0.361	56.45	4.642	3.836	0.806
49.47	4	2.000	1.694	0.602	1.704	12.368	0.0202	-0.306	50.53	4.642	3.697	0.945
53.82	5	2.236	1.731	0.699	1.664	10.764	0.0186	-0.269	46.18	4.642	3.588	1.054
69.83	6	2.449	1.844	0.778	1.480	11.638	0.0143	-0.156	30.17	4.642	3.113	1.528
73.02	7	2.646	1.863	0.845	1.431	10.431	0.0137	-0.137	26.98	4.642	2.999	1.642
87.52	8	2.828	1.942	0.903	1.096	10.940	0.0114	-0.058	12.48	4.642	2.320	2.322
91.91	9	3.000	1.963	0.954	0.908	10.212	0.0109	-0.037	8.09	4.642	2.007	2.634
94.11	10	3.162	1.974	1.000	0.770	9.411	0.0106	-0.026	5.89	4.642	1.806	2.836
97.22	11	3.317	1.988	1.041	0.444	8.838	0.0103	-0.012	2.78	4.642	1.406	3.235
99.08	12	3.464	1.996	1.079	0.540	8.257	0.0101	-0.004	0.92	4.642	0.973	3.669

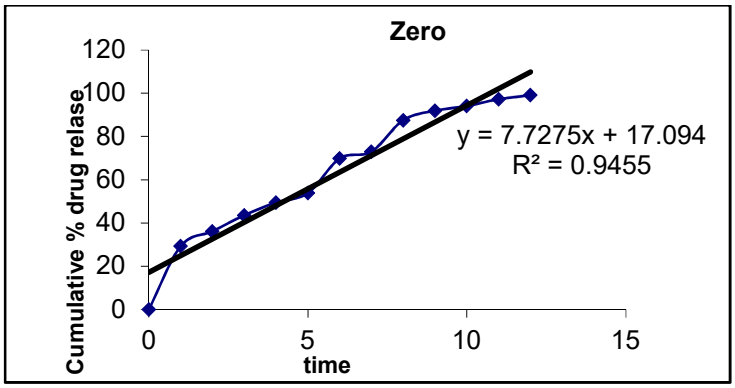

Figure 5: Graph of zero order kinetics

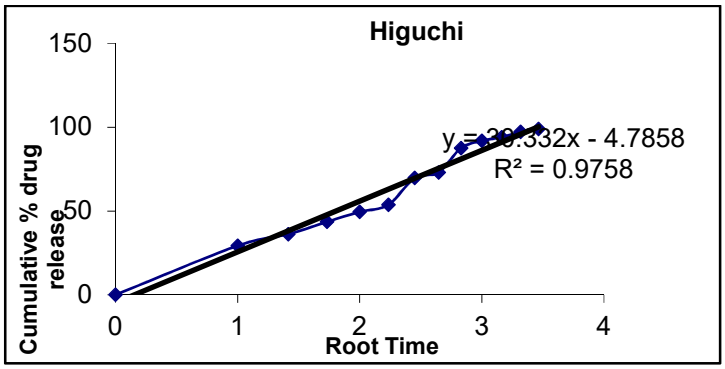

Figure 6: Graph of Higuchi release kinetics

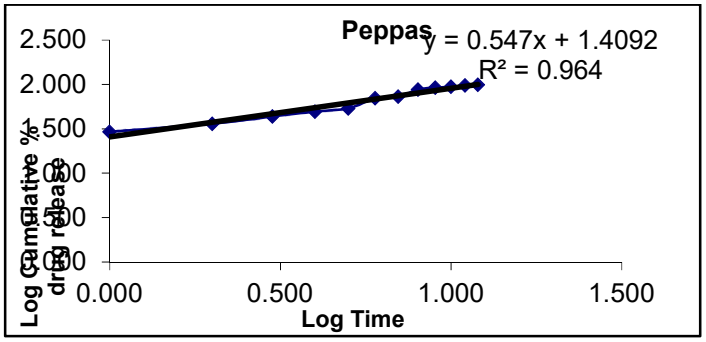

Figure 7: Graph of peppas release kinetics

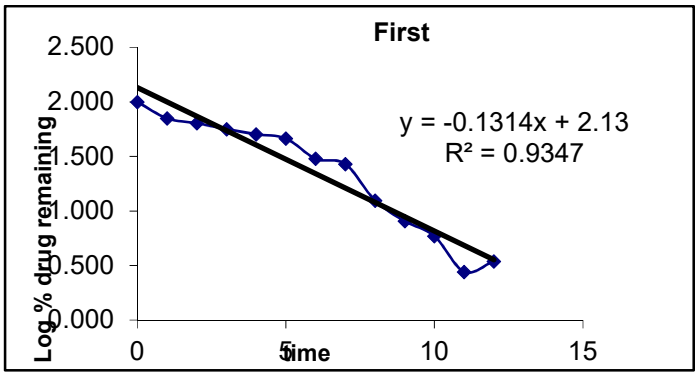

Figure 8: Graph of first order release kinetics

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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