

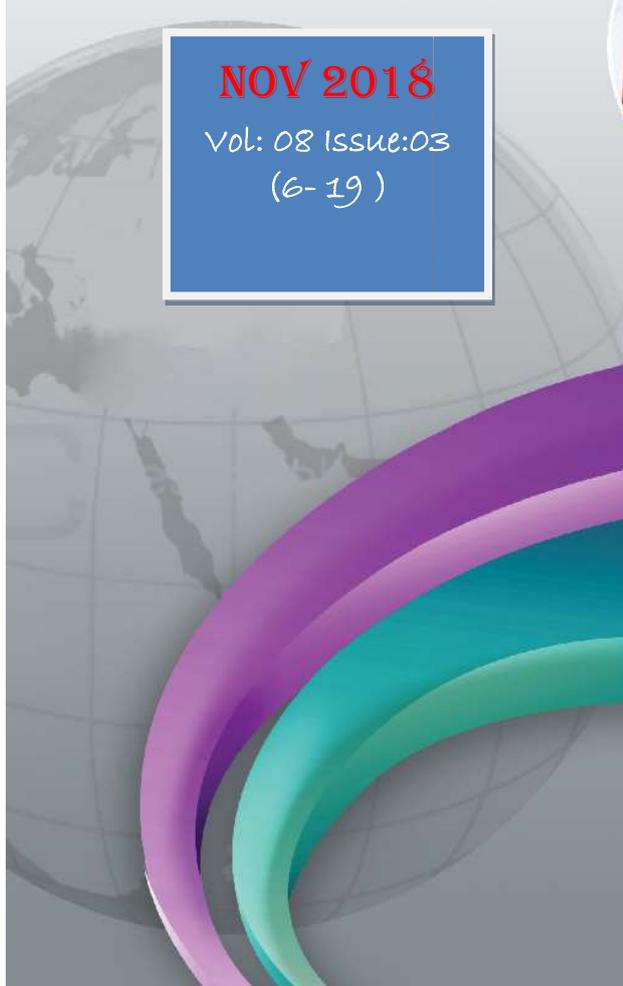


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Research Paper

PREPARATION AND EVALUATION OF SUSTAINED RELEASE TABLET BY USING NATURAL GUM AS RELEASE RETARDANT

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The objective of this study was to preparation and evaluation of sustained release tablet of Salbutamol sulphate using lepidium sativum natural gum, sustained release dosage form, for the treatment of Chronic Obstructive Pulmonary Disease (COPD). The tablets were prepared by wet granulation method using lepidim sativum gum. Powder blends were evaluated for loose bulk density, tapped bulk density, compressibility index and angle of repose, shows satisfactory results. The compressed tablets were then evaluated for various physical tests like diameter, thickness, uniformity of weight, hardness, friability, and drug content. The results of all these tests were found to be satisfactory. The in vitro dissolution study was carried out for 24 hours using type II dissolution apparatus. Among all the formulation, This finding reveals that above a particular concentration of lepidium sativum gum are capable of providing sustain release.

Key Words: Lactose, lepidium sativum gum, Salbutamol sulphate, sustained release tablets.

INTRODUCTION

Salbutamol sulphate is a sympathomimetic agent acting on the β_2 -adrenergic receptor shows site-specific absorption in the stomach and is used as a bronchodilator in the treatment of reversible bronchospasm. It can be specifically prescribed in case of acute asthma and also for symptom relief during maintenance therapy of asthma and other conditions with reversible airways obstruction (including COPD). The drug has plasma half-life range from 2 - 3 hr and the maximum plasma drug concentration occurs within 2.5 hr. It is given orally at a dose of 2-4 mg, three or four times a day.

The conventional tablet or capsule provides only a single and a transient burst of drug. A pharmaceutical effect is seen as long as the amount of drug is within therapeutic range. So it is selected to prepare a sustained release tablet of the drug.

Sustained release drug delivery system a release of the drug a period of time or the drug is absorbed over a longer period of time. Sustained release dosage form initially releases an adequate amount of drug to bring about the necessary blood concentration (loading dose, DL) for the desired therapeutic response and therefore, further amount of drug is released at a controlled rate (maintenance dose, DM) to maintain the said blood levels for some desirable period of time. Sustained release drug delivery system (SRDDS) have emerged as an effective mean of enhancing the bioavailability and controlled delivery of many drugs. SRDDS play an important role in reducing the dosing frequency as well as by enhancing the biological half life of specific certain drugs. Scholar Research Library Present study concerns with the preparation and evaluation of Salbutamol sulphate sustained release tablet for prolong drug release



leading to minimization of incidences of nocturnal and early morning asthmatic attacks, better patient convenience and a pharmaco-economic novel drug delivery system, for effective treatment for COPD.

MATERIALS AND METHODS

Material The drug Salbutamol sulphate was obtained as a gift sample from friends. All other chemicals and reagents used were obtained from commercial sources and were of analytical grade.

Isolation of *lepidium sativum* gum

Gum was extracted by soaking the seeds of *Lepidium sativum* with 10 times its weight of distilled water and kept for 24 hours.



The viscous solution obtained was passed through the muslin cloth



Then it was poured in petri dish and it was put into the dessicator using charged silica gel for 1 day.



Then reddish brown mass was collected and was dried in hot air oven at 40-45 °C for 10 minutes and was powdered by passing it through sieve no. 60 and stored in air tight container.

Physicochemical characterization of the gum

Identification test

- The isolated gum was treated with 95% v/v ethanol.
- The isolated gum was treated with ruthenium red and iodine blue.

Solubility test The separated gum was evaluated for the solubility in water, ethanol, acetone and
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Chloroform in accordance with the specifications given in the Indian pharmacopoeia.

pH determination

pH was determined by shaking a 1% w/v solution of the sample in water for 5 minutes and reading was noted by digital pH meter.

Swelling index

1 gm gum was poured in 50 ml measuring cylinder for swelling index studies, and 25 ml of distilled water was added. The solution was shaken after every 10 minutes for 1 hr and it was kept for 2 hrs. The volume occupied by the gum after hydration was noted.

Preformulation studies of Salbutamol sulphate.

Preformulation studies were performed on the drug which included melting point determination, solubility studies and determination of

Melting point determination

Melting point of Salbutamol was determined by capillary melting method. Fine powder of Salbutamol was filled in the capillary tube (previously sealed on one end) which was placed on the bottom of the thermometer. Then it was placed in Thiel's tube filled with mineral oil. the tube was warmed to the melting temperature and the melting range was recorded.

Solubility determination

Solubility of salbutamol was determined in ethanol and distilled water. Solubility studies were performed by taking excess amount of salbutamol in different beakers containing different solvents. The mixtures were shaken at regular intervals for 24 hrs. The solutions were filtered through



Whatmanns filter paper grade no. 41. The filtered solutions were analysed spectrophotometrically at 276 nm.

Determination of λ_{max}

A solution of Salbutamol containing 10 $\mu\text{g/ml}$ was prepared in distilled water and UV spectrum was recorded using Shimadzu 1600 UV/Vis double beam spectrophotometer. The solution was scanned in the range of 200 nm- 400 nm and wavelength of maximum absorbance (λ_{max}) was noted.

Calibration curve of Salbutamol sulphate.

- **In 0.1 N HCl-**100 mg of Salbutamol was accurately weighed and transferred into 100 ml volumetric flask. It was dissolved and the volume was made up to 100 ml with 0.1 N HCl to give stock solution of concentration 1000 $\mu\text{g/ml}$. Then from the standard stock solution, 10 ml of the solution was diluted up to 100 ml with 0.1 N HCl to obtain a concentration of 100 $\mu\text{g/ml}$. Appropriate aliquots were taken into different volumetric flasks and the volume was made up to 10 ml with 0.1 N HCl so as to get different concentrations of range 2-20 $\mu\text{g/ml}$. The UV absorbance reading was noted at 276 nm using UV/Visible double beam spectrophotometer.

- **In phosphate buffer pH 6.8-** 100 mg of Salbutamol was accurately weighed and transferred into 100 ml volumetric flask. It was dissolved and the volume was made up to 100 ml with phosphate buffer to give stock solution of concentration 1000 $\mu\text{g/ml}$. Then from the standard stock solution, 10 ml of the solution was diluted up

to 100 ml with phosphate buffer to obtain a concentration of 100 $\mu\text{g/ml}$. Appropriate aliquots were taken into different volumetric flasks and the volume was made up to 10 ml with phosphate buffer so as to get different concentrations of range 2-20 $\mu\text{g/ml}$. The UV absorbance reading was noted at 276 nm using UV/Visible double beam spectrophotometer.

Compatibility studies

Compatibility studies did with the excipients and drug in different condition to observe the physicochemical property and It was carried out in stability chamber and Room temperature and observing the physical changes in compound.

Formulation of sustained release tablets of Salbutamol sulphate using lepidium sativum gum.

Sustained release matrix tablets of salbutamol sulphate were prepared by wet granulation method using lepidium sativum gum as release retardant as per the formula shown in table 6.1. All ingredients except magnesium stearate and talc was mixed in mortar and pestle to obtain uniform mixture. Sufficient quantity of isopropyl alcohol was added to wet the mass which was then passed through sieve no. 22 to obtain the granules. Granules obtained was dried in oven at 40°C and stored in air tight container until further use. Before compression, granules were mixed with magnesium stearate and talc and compressed by single punch machine to obtain tablets.

Pre-compression evaluation of granules.

Determination of angle of repose

**Table 1: Salbutamol sulphate formulation containing *lepidium sativum* as release retardant.**

s.no	Ingredients	F1 (in mg)	F2 (in mg)	F3 (in mg)
1.	Salubtamol sulphate	6	6	6
2	<i>Lepidium sativum</i>	60	60	100
3	Lactose	126	106	66
4	Magnesium stearate	2	2	2
5	Talc	4	4	4
6	Isopropyl alcohol	q.s	q.s	q.s

The frictional forces in a loose powder can be measured by the angle of repose. It is an indicative properties of the powder. The accurately weight granules were taken in the funnel. The height of the funnel was adjust in such a way that the tip of the funnel just touch Apex of the granules. The granules were allow to flow through the funnel freely on the surface. The diameter of the granules was measured and angle of repose was Calculated using the following equation:

$$\theta = \tan^{-1} \left(\frac{h}{r} \right) \quad (6)$$

Where θ = angle of repose

h = hight of granules

r = radius of granules.

Table 2: Flow property and corresponding angle of repose

Flow property	Angle of repose
Excellent	25-30
Good	31-35
Fair –aid not added	36-40
Passable-may hang up	41-45
Poor must agitate , vibrate	46-55



- **Bulk density**

Bulk density is the ratio between a mass of granules and its bulk volume. It is expressed in gm/cc. bulk density is determined by pouring perceived bulk drug in to a graduated cylinder through a large funnel and measuring the volume and weight.

$$\text{Bulk density (V}_b) = \frac{\text{Mass}}{\text{Bulk Volume}}$$

- **Tapped density**

Tapped density is the ratio between mass of granules and volume of the granules after tapping. It is expressed by gm/cc. tapped density is determined by placing a graduated cylinder containing a known mass of drug or formulation on a mechanical tapper apparatus, which is operated for a fixed number of taps (500) until the powder bed volume reached a minimum.

$$\text{Tapped density (V}_t) = \frac{\text{Mass}}{\text{Tapped Volume}}$$

- **Carr's Index**

This was measured for the property of a powder to be compressed as such they measured for relative importance of interparticulate interactions. Carr's index was calculated by following equation:

$$\text{Carr's index (I)} = \frac{V_T - V_B}{V_T} \times 100$$

Where V_t = tapped volume

V_b = bulk volume

- **Hausner's ratio**

Hausner's ratio was calculated by following equation:

$$\text{Hausner's ratio(H)} = \frac{V_t}{V_b}$$

Where V_t = Tapped volume

V_b = Bulk volume

- **Post compression evaluation of Salbutamol sulphate tablets**

Tablet description

The general appearance of a tablet, its visual identity and overall elegance is essential for consumer acceptance.

Thickness

The thickness of the tablets was determined by using vernier callipers. Five tablets were used, and average values were calculated.

Weight uniformity test

To study weight variation twenty tablets of the formulation were weighed using in electronic balance and the test was performed according to the official method. Twenty tablets were selected randomly from each batch and weighed individually for weight variation.

Table 3: Specification for weight variation of tablets as per IP.

Average weight of tablets (in mg)	Percent difference
80 or less	10
More than 80 but less than 250	7.5
More than 250	5



Hardness

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Pfizer hardness tester. It is expressed in kg/cm². Three tablets were randomly picked and hardness of the tablets was determined.

Friability

The friability of the tablets was measured in a Roche friabilator. It is expressed in percentage (%). Ten tablets were initially weighed and transferred into friabilator. The friabilator was operated at 25rpm for 4 min or run up to 100 revolutions. The tablets weighed again. The % friability was then calculated by following equation:

$$F(\%) = \frac{(W_{\text{initial}}) - (W_{\text{final}})}{(W_{\text{initial}})} \times 100$$

Where W_i = initial weight of tablet

W_f = final weight of tablet

Determination of drug content.

20 tablets were weighed and powdered. Powder equivalent 6 mg equi of Salbutamol sulphate was accurately weighted and transferred into a 100ml volumetric flask. Initially, 10 ml of phosphate buffer (pH 6.6) was added and shaken for 10 min. then volume was made up up to 100 ml with buffer. subsequently, the solution was filtered and analysed at 276nm using UV-visible spectrophotometer.

In vitro dissolution studies.

The in vitro dissolution was carried out using IP dissolution apparatus type-I. The matrix tablets were placed in the 0.1N HCL for first 2 hours and pH 6.6 phosphate buffers for next 6 hrs respectively. the study was performed at 37°C and rotating speed of 50 rpm in a 900ml dissolution medium. The 5ml aliquots were withdrawn at intervals of 1,2,3,4,5,6,7,6,9,10hrs and replacement was done with equal volume of fresh

Table 4: physicochemical properties of *lepidium sativum* gum

Parametrs	Results
Description	Brownish white powder
Solubility	Forms colloidal solution, soluble in luck warm water, practically insoluble in ethanol, acetone, ether and chloroform.
Appearance	Lustrous
Identification	Transparent angular masses.
<ul style="list-style-type: none"> • Mounted in 75% ethanol. • Mounted in ruthenium red and in iodine solution. 	Particles stained red Particles stained blue
pH (1%w/v)	Neutral
Swelling Index	18



dissolution medium maintained at same temperature. The absorbance of collected samples was measured at 276nm using UV-visible spectrophotometer. Drug concentration in the sample was determined from calibration curve.

RESULT AND DISCUSSION

Extraction and characterization of *lepidium sativum* gum.

Percentage yield.

The percentage yield of crude *lepidium sativum* gum found to be 0.50%.

Physicochemical characterization of the gum

Preformulation studies of Salbutamol sulphate.

Melting point.

Melting point of Salbutamol sulphate was found to be 148°C which complies with the reference values.

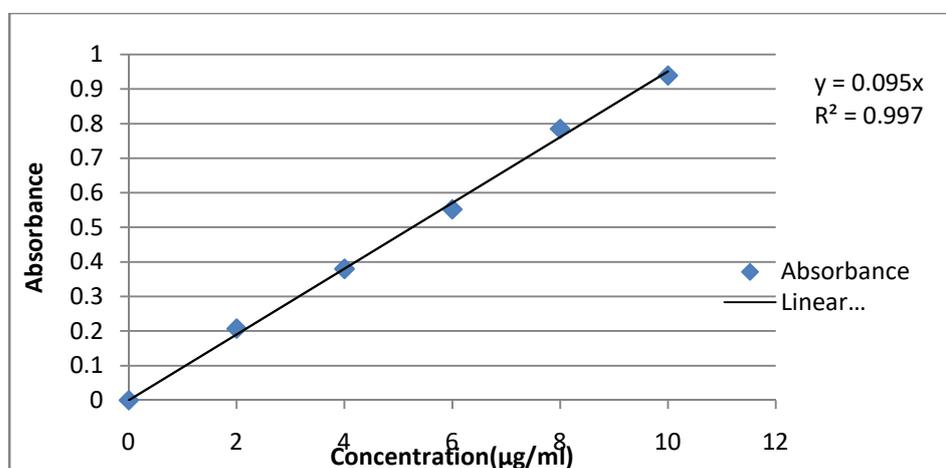


Figure 1: Calibration curve of Salbutamol sulphate in 0.1N HCl.

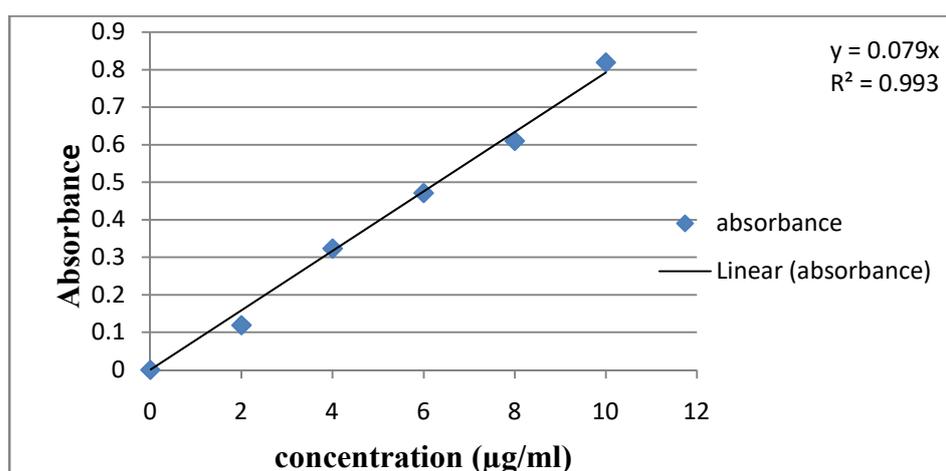


Figure 2: standard calibration curve of Salbutamol sulphate in phosphate buffer pH 6.8.

Solubility

The solubility of pure drug in solvent was carried out and found to be freely soluble in distill water, www.pharmaerudition.org Nov 2018, 8(3), 6-19

sparingly soluble in ethanol and slightly soluble in dichloromethane.



Estimation of Salbutamol sulphate by UV spectroscopy

The λ_{\max} of salbutamol sulphate was found to be 276 nm.

- **Compatibility studies:** - It was carried out in stability chamber and Room temperature and observing the physical changes in compound and it was given in Table 5 .

Table 5: Compatibility study of drug and excipients

S/No.	Compound	75% RH,40°C Stability Chamber			
		15 days	30 days	45 days	R.T
1	Drug + <i>lepidium sativum</i> (1:1)	No change	No change	No change	No change
2.	Drug + lactose (1:1)	No change	No change	No change	No change

Pre-compression evaluation of Salbutamol sulphate tablets

Table 6: Evaluation of Pre-compression parameters of granules.

Formulation code	Angle of repose	Bulk density	Tapped density	Carr's index	Hausner ratio
F1	25.4	0.46	0.51	9.58	1.106
F2	26.8	0.48	0.54	9.89	1.118
F3	28.4	0.52	0.57	11.35	1.123

Post-compression evaluation of Salbutamol sulphate tablets.

Table 7: Evaluation of Post-compression of Salbutamol sulphate tablets.

Formulation code	Thickness (nm)	Weight variation (mg)	Hardness (kg/cm ²)	Friability (%)	Drug content (%)	Disintegration Time (sec)
F1	4.34	200.3	5.7	0.45	94.08	145
F2	4.23	200.7	5.5	0.55	94.71	177
F3	4.17	200.8	5.7	0.64	94.82	243



Table 8: *In vitro* drug release data of Salbutamol sulphate in different formulation

Time (in min)	F1	F2	F3	M
15	5.60	7.30	3.2	3.3
30	7.0	11.25	6.1	5
45	12.30	15.20	7.5	7.1
60	25.10	22.50	17.17	11.05
90	28.40	28.70	20.20	15.91
120	37.70	34.20	24.20	22.18
150	45.50	41.30	27.70	29.04
180	58.05	47.30	35.40	34.08
240	61.70	53.21	41.60	42.48
300	68.70	57.60	47.70	53.73
360	76.70	68.40	55.64	57.86
420	83.20	77.40	68.03	66.10
480	87.37	86.30	78.45	77.45
540	91.26	88.10	85.44	81.79
600	94.02	93.80	88.80	85.68
660	-	-	91.20	90.80

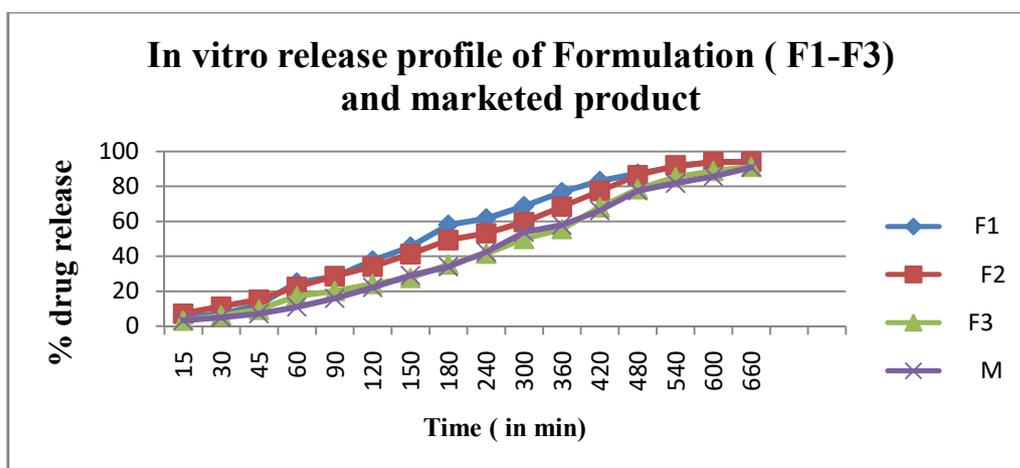


Figure 3: Comparative *In vitro* release profile of formulation F1-F3.

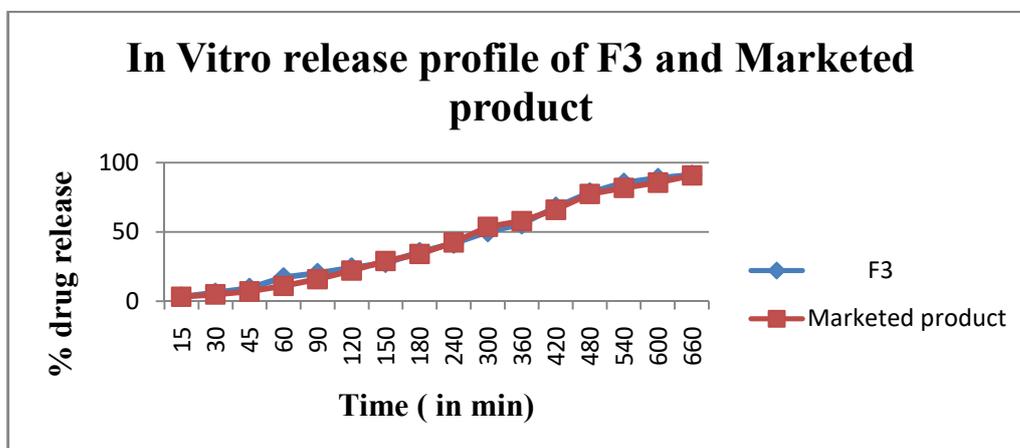


Figure 4: Comparative *In vitro* release profile of F3 and Marketed product.

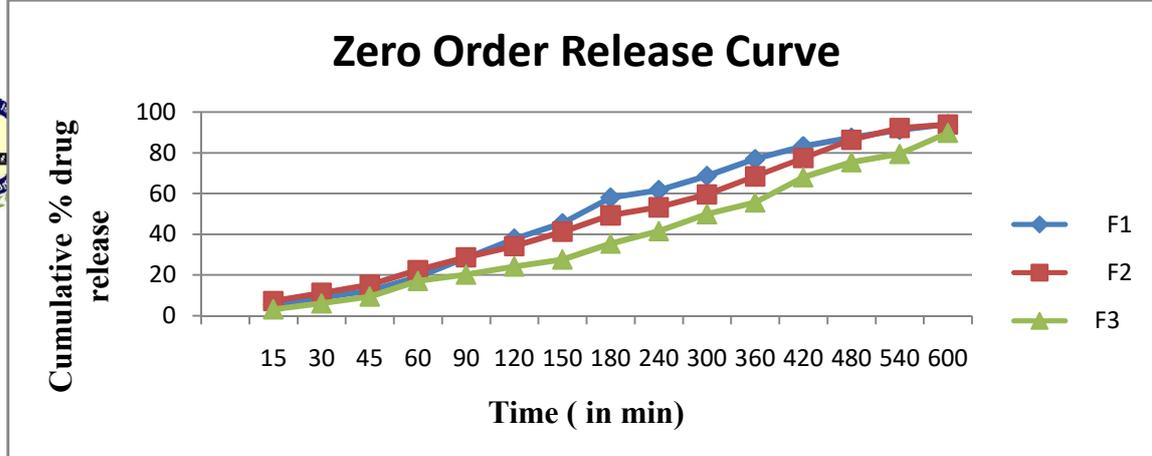


Figure 6: Release Kinetics Profile of Salbutamol SR tablets according to Zero order.

Table 9: Kinetic values obtained from In-vitro release data of Salbutamol SR tablets (F1 to F3)

Formulation code	Zero order R ²	First order R ²	Higuchi R ²	Korsmeyer-peppas R ²	Hixson-Crowell R ²
F1	0.96	0.88	0.98	0.88	0.93
F2	0.97	0.92	0.99	0.92	0.97
F3	0.91	0.91	0.98	0.91	0.97

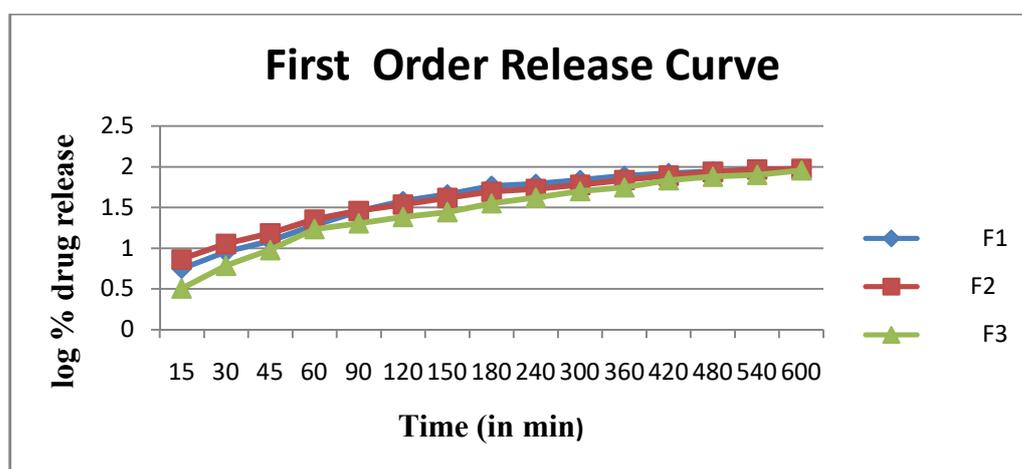


Figure 5: Release Kinetics Profile of Salbutamol SR tablets according to first order.

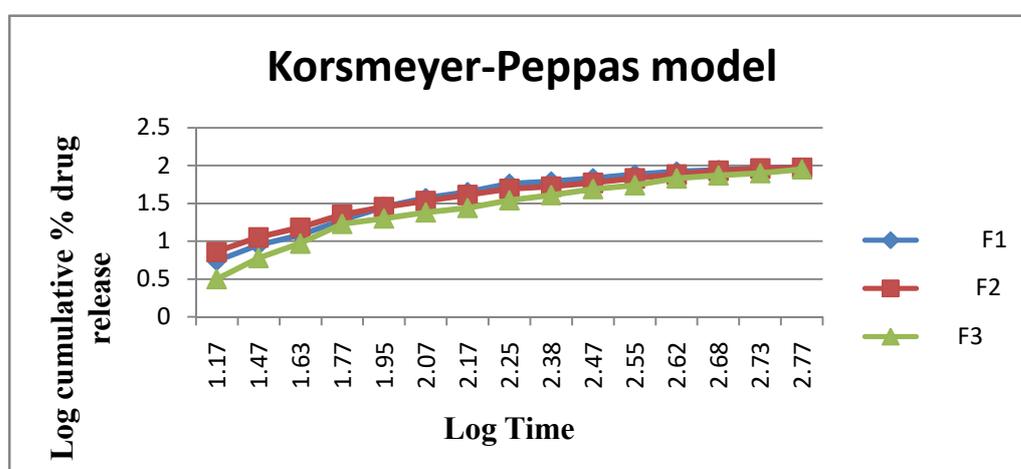


Figure 7: Release Kinetics Profile of Salbutamol SR tablets according to Korsmeyer-Peppas model.

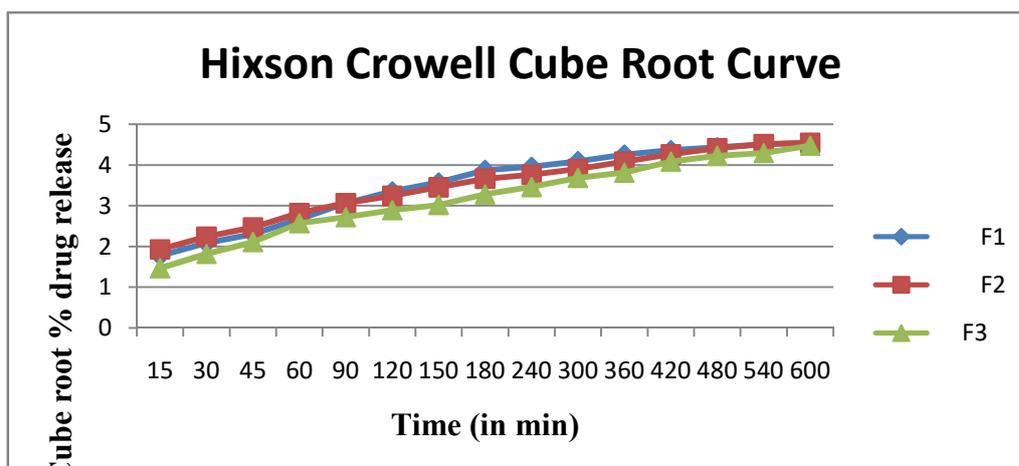


Figure 8: Release Kinetics Profile of Salbutamol SR tablets according to Hixson Crowell.

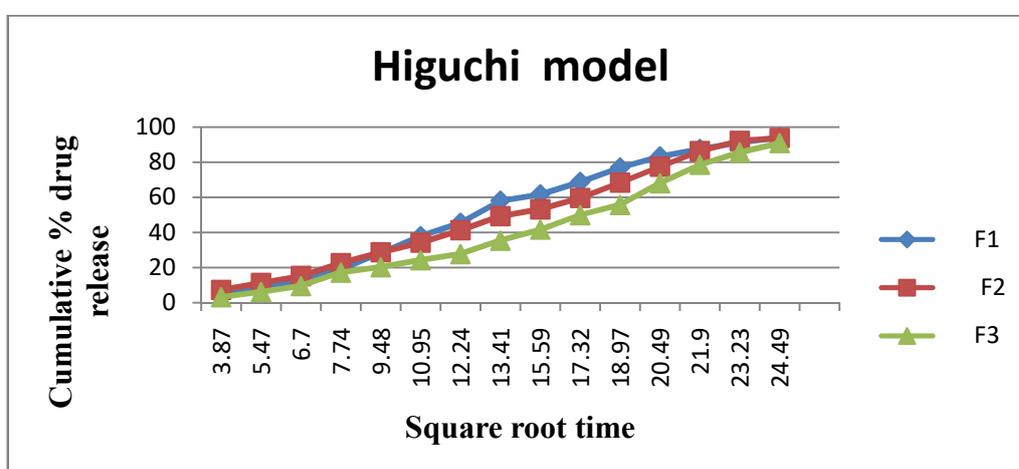


Figure 9: Release Kinetics of Salbutamol SR tablets according to Higuchi model.

DISCUSSION

The granules prepared for compression of Salbutamol sulphate sustained release matrix tablets were evaluated for their flow properties.

Angle of repose was in the range of $25^{\circ}.4$ to $28^{\circ}.4$ this result shows (<30) good flow properties of the granules. The bulk density of the granules in the range of 0.46 to 0.52g/ml; the tapped density was in the range of 0.51 to 0.57g/ml, which indicate that the powder was not bulky. The Carr's index was found to be in range of 9.34 to 11.35 and the Hausner ratio was found to be in the range of 1.106

to 1.128, indicating compressibility of the tablet blend is good.

All tablets formulations was subjected to various parameters and the result obtained were within the range. The Salbutamol sulphate sustained release matrix tablets were off-white, smooth, and flat shaped in appearance. The thickness of different matrix tablets (F1-F3) was found to be within limits of specifications. The weight uniformity and hardness of tablets (F1-F3) showing satisfactory results as per Indian pharmacopoeia (IP) limit. The friability was below 1% for the formulation (F1-F3),



which is an indication of good mechanical resistance of the tablet. The percentage of drug content for F1 to F3 was found between 90 to 100 of Salbutamol Sulphate which complies with official specification. It is clear from above said parameters evaluated for different formulation of tablets were within in the prescribed limits.

The result of *in vitro* dissolution studies of all formulations were shown in figure-3.

Of the three ratio of *lepidium sativum* gum used, F3 showed a drug release of about 17% after 1hr and 88.8% after 10th hr. this might be due to large concentration of gum and its property to form a thick gel layer, which retard the drug release from a tablet. Whereas, the F1 and F2 released the drug about 93% and 94%, after 10th hr this may be due to quick hydration of gum matrix.

It is expected that as the concentration of gum increases the release rate decreases. Formulation F3 met the needed theoretical drug release profile and has the sustain action i.e. retarding the drug release is for a long time and more bioavailability; for these reasons, F3 considered the best formulation among all three formulation.

Table no. 7.6 shows data analysis of release profiles according to different kinetics model. The kinetic treatment reflected that release profiles data of formulation that is F1, F2 & F3 showed higher r^2 values for Higuchi plot indicating drug release follow Higuchi model.

CONCLUSION

The present study shows that effect of *lepidium sativum* linn. Gum as release retardant in formulation development of Salbutamol sulphate tablets in comparison with standard polymers. From the results, it is concluded that www.pharmaerudition.org Nov 2018, 8(3), 6-19

lepidium sativum linn. has better retarding capacity like xanthum gum and guar gum. The gum used is having good swelling index, disintegration time fall within the standard limits, the mechanical properties were assessed using the crushing strength and friability of the tablet. Drug release properties of the tablet assessed using disintegration time and dissolution time as assessment parameters.

- Isolation and purification of *lepidium sativum* linn were completed.
- The preformulation studies like pH, solubility, melting point of gum were compiled with standards.
- Compatibility study showed that are no physicochemical changes in drug with excipient.
- Preformulation studies like angle of repose, bulk density, tapped density, carr's index and hausner's ratio of drug were compiled with standards.
- In vitro drug release of Salbutamol sulphate tablets shown that concentration of gum retard the *in vivo* release.

So it is concluded from the results that *lepidium sativum* linn. Gum can be an alternative release retardant for the pharmaceutical formulations. The gum found to be effective at low concentration and could able to retard the release of drug. Abundant availability, food grade status, economical feasibility, commercial suitability and reliability make the gum as an alternative for the existing toxic, synthetic and ineffective excipients.



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