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FORMULATION AND EVALUATION OF SALBUTAMOL SULPHATE MATRIX TABLETS USING DIFFERENT POLYMERS

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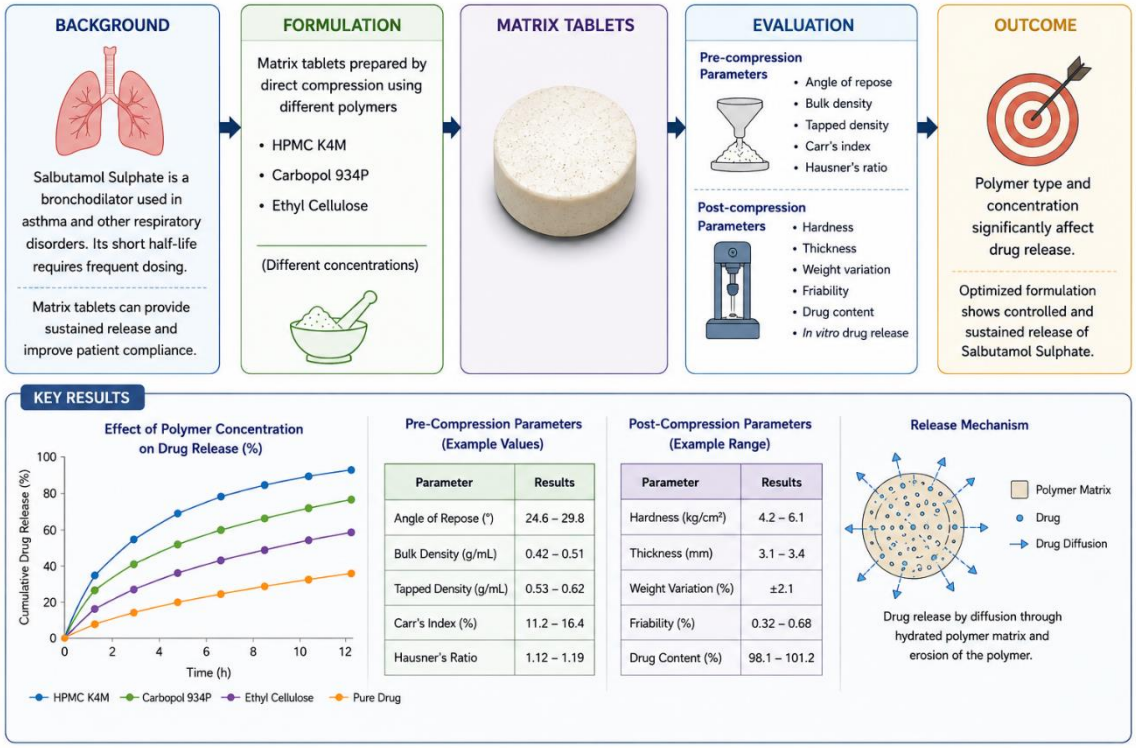
ABSTRACT

The present study was aimed at the formulation and evaluation of matrix tablets of Salbutamol Sulphate using different polymers to develop a sustained-release drug delivery system. Salbutamol Sulphate is a bronchodilator widely used in the treatment of asthma and other respiratory disorders; however, its short biological half-life necessitates frequent dosing. To overcome this limitation, matrix tablets were prepared by the direct compression method using various polymers such as Hydroxypropyl Methylcellulose (HPMC), Carbopol, and Ethyl Cellulose at different concentrations.The prepared formulations were evaluated for pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. Post-compression studies were carried out for hardness, thickness, weight variation, friability, drug content uniformity, and in vitro drug release. All formulations showed satisfactory physical characteristics and complied with pharmacopeial limits. The drug release profiles demonstrated that polymer type and concentration significantly influenced the release rate of Salbutamol Sulphate. An increase in polymer concentration resulted in a slower and more controlled drug release pattern.The optimized formulation exhibited satisfactory physicochemical properties and sustained drug release for an extended period. The study concluded that matrix tablets prepared with suitable polymers can effectively control the release of Salbutamol Sulphate, thereby improving therapeutic efficacy, reducing dosing frequency, and enhancing patient compliance.

KEYWORDS: Salbutamol Sulphate, Matrix Tablets, Sustained Release, Polymers, HPMC, Carbopol, Ethyl Cellulose, Drug Release.

Graphical Abstract



INTRODUCTION

Oral drug delivery remains the most preferred and convenient route of administration due to its ease of use, patient acceptance, cost-effectiveness, and flexibility in formulation design. However, conventional immediate-release dosage forms often require frequent administration to maintain effective plasma drug concentration, which may lead to fluctuations in drug levels and reduced patient compliance.**[1]** To overcome these limitations, sustained-release drug delivery systems have been developed to provide controlled release of the drug over an extended period, thereby reducing dosing frequency and improving therapeutic efficacy.**[2]**Matrix tablets represent one of the most widely used sustained-release oral dosage forms because of their simple manufacturing process, good stability, and ability to control the drug release profile.**[3]** In matrix systems, the active pharmaceutical ingredient is uniformly dispersed within a polymeric network that regulates the release of the drug through mechanisms such as diffusion, swelling, and erosion of the polymer matrix.**[4]** The selection of a suitable polymer and its concentration plays a vital role in determining the rate and extent of drug release from matrix tablets.Salbutamol Sulphate is a selective β_2-adrenergic receptor agonist widely used as a bronchodilator in the management of bronchial asthma, chronic obstructive pulmonary disease (COPD), and other respiratory disorders associated with reversible airway obstruction. It acts by relaxing the smooth muscles of the bronchial

passages, resulting in improved airflow and relief from symptoms such as wheezing and shortness of breath. Although Salbutamol Sulphate is highly effective, it possesses a relatively short biological half-life of approximately 3–6 hours, which necessitates repeated administration to maintain therapeutic drug levels.**[5,6]** Frequent dosing may decrease patient adherence and may increase the possibility of side effects associated with fluctuations in plasma drug concentration.The development of sustained-release matrix tablets of Salbutamol Sulphate offers an effective approach to prolong drug release, maintain a consistent therapeutic concentration, and reduce the frequency of administration. **[7]**The performance of such formulations is largely influenced by the type and amount of polymer incorporated into the matrix system. Various hydrophilic and hydrophobic polymers, including Hydroxypropyl Methylcellulose (HPMC), Carbopol, and Ethyl Cellulose, have been extensively investigated for their ability to modify drug release characteristics.**[8]** Hydrophilic polymers generally swell in the presence of gastrointestinal fluids and form a gel barrier that controls the diffusion of the drug, whereas hydrophobic polymers retard drug release by creating a less permeable matrix structure.The formulation of matrix tablets involves careful selection of excipients, optimization of polymer concentration, and evaluation of various pre-compression and post-compression parameters to ensure the quality and performance of the final dosage form.**[9]** Pre-compression studies such as angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio provide information regarding the flow properties of the powder blend. Post-compression evaluation, including hardness, thickness, weight variation, friability, drug content uniformity, and in vitro drug release studies, is essential to assess the mechanical strength, uniformity, and release behavior of the prepared tablets.**[10]**Therefore, the present study was designed to formulate and evaluate sustained-release matrix tablets of Salbutamol Sulphate using different polymers and to investigate their influence on the physicochemical properties and drug release profile of the prepared formulations.**[11]** The optimized polymer combination is expected to provide prolonged drug release, improved therapeutic effectiveness, reduced dosing frequency, and enhanced patient compliance. The findings of this study may contribute to the development of an efficient sustained-release oral dosage system for the effective management of respiratory disorders.**[12]**

MATERIALS AND METHODS

Materials

Salbutamol Sulphate was obtained as a gift sample from a reputed pharmaceutical company and used as the active pharmaceutical ingredient. Hydroxypropyl Methylcellulose (HPMC

K4M), Carbopol 934P, and Ethyl Cellulose were selected as release-retarding polymers. Microcrystalline Cellulose (MCC) was used as a diluent, Magnesium Stearate as a lubricant, and Talc as a glidant. All chemicals and reagents used in the study were of analytical grade.

Table (1) Chemicals used.

S. No.	Name	Manufacturer
1.	Salbutamol sulphate	Coax Bioremedies Pvt. Ltd., Hisar
2.	Ethyl cellulose	Coax Bioremedies Pvt. Ltd., Hisar
3.	Carbopol	Burzin and Leones Pvt. Ltd., Mumbai
4.	Xanthan Gum	Qualigens Fine Chemicals, Mumbai
5.	Micro crystalline cellulose	Qualigens Fine Chemicals, Mumbai.
6.	Potassium dihydrogen orthophosphate	Ranbaxy Fine Chemicals Ltd. Mohali
7.	Sodium hydroxide	Qualigens Fine Chemicals Mumbai.
8.	Hydrochloric acid	Qualigens Fine Chemicals, Mumbai.
9.	Magnesium Stearate	S. D Fine Chem Ltd., Mumbai.
10.	Talc	Nice Chemicals Pvt. Ltd., Cochin.

Table (2) - Equipment used.

Sr. no.	Name of Equipment	Manufacturer
1.	Weighing balance (HR-200)	AND company Ltd. Japan
2.	pH meter(L1-120)	Elico Ltd., Hyderabad .
3.	Pestle Mortar	Narang Scientific Works Pvt. Ltd., N. Delhi.
4.	Hot air oven	LABCO, Ambala.
5.	Tablet punching machine	Spinex Pvt. Ltd.
6.	Hardness tester	JSGW Pvt. Ltd. , Ambala
7.	Friability tester	Prolific Engg. Noida.
8.	U.V.-Vis-NIR spectrophotometer(Cary5000)	CARY VARIAN Pvt. Ltd. Australia
9.	Disintegrator	TA Instruments New castle DE, USA
10.	Dissolution apparatus	Hi-media Laboratories Pvt. Ltd.,Mumbai
11.	Thickness tester	Electrolab Pvt. Ltd., Mumbai
12.	Vernier caliper	Decibel Instruments, Chandigarh.
13.	Desicator	Water's ,Milford ,U. S. A.

Method of Preparation of Matrix Tablets

The sustained-release matrix tablets of Salbutamol Sulphate were prepared by the direct compression method using different concentrations of polymers. The accurately weighed quantities of Salbutamol Sulphate, selected polymers, and other excipients were passed through a suitable sieve and mixed thoroughly to obtain a uniform powder blend. The prepared blend was evaluated for pre-compression parameters to assess its flow properties.

After blending, Magnesium Stearate and Talc were added and mixed gently to avoid over-lubrication. The final powder mixture was compressed into tablets using a rotary tablet compression machine with suitable punches to obtain matrix tablets of desired weight and hardness.

Evaluation of Pre-compression Parameters

Angle of Repose

The angle of repose was determined by the fixed funnel method to evaluate the flow characteristics of the powder blend. The angle of repose (θ) was calculated using the relationship:

$\tan \theta = h/r$

where *h* is the height of the powder cone and *r* is the radius of the base of the cone.

Bulk Density and Tapped Density

The bulk density and tapped density of the powder blends were determined using a graduated measuring cylinder. The powder was carefully poured into the cylinder to measure bulk volume, followed by tapping until a constant volume was obtained to calculate tapped density.

Carr's Index and Hausner's Ratio

Carr's compressibility index and Hausner's ratio were calculated to evaluate the compressibility and flow behavior of the powder blends using standard equations.

Evaluation of Post-compression Parameters

Weight Variation Test

Twenty tablets from each formulation were randomly selected and individually weighed using an analytical balance. The average weight and percentage deviation were calculated to ensure uniformity of tablet weight.

Thickness and Hardness

The thickness of tablets was measured using a digital Vernier caliper, while hardness was determined using a Monsanto or digital hardness tester to assess the mechanical strength of the tablets.

Friability Test

The friability of the prepared tablets was evaluated using a Roche friabilator. A pre-weighed sample of tablets was rotated at 25 rpm for 4 minutes, and the percentage weight loss was calculated.

Drug Content Uniformity

Ten tablets were powdered, and an amount equivalent to the required quantity of Salbutamol Sulphate was dissolved in a suitable solvent, filtered, and analyzed using a UV-visible spectrophotometer at the appropriate wavelength to determine the drug content.

Each quantity mentioned will be taken in mgs

Total weight of the tablet = 200mg

Each tablet contains = 4mg of the drug

In Vitro Drug Release Study

The in vitro drug release study of the prepared matrix tablets was carried out using the USP dissolution apparatus type II (paddle method). The dissolution medium was maintained at 37 ± 0.5°C with a paddle speed of 50–100 rpm. Samples were withdrawn at predetermined time intervals and replaced with fresh dissolution medium to maintain sink conditions. The collected samples were analyzed spectrophotometrically to determine the amount of drug released.

Table no. (3): Formulation of Salbutamol Matrix Tablet.

Batch > ingredients	**F.1**	**F 2**	**F3**	**F 4**	**F 5**	**F 6**	**F 7**	**F 8**	**F 9**	**F10**	**F11**	**F 12**
Drug	4	4	4	4	4	4	4	4	4	4	4	4
Ethyl cellulose	10	-	-	20	-	-	30	-	-	10	20	30
Carbopol 934P	-	10	-	-	20	-	-	30	-	10	20	30
Xanthan gum	-	-	10	-	-	20	-	-	30	10	20	30
Compressible Lactose	180	180	180	170	170	170	160	160	160	160	130	100
Magnesium Sterate	4	4	4	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2	2	2	2

Concentration(µg/ml)	**Absorbance**
0	0
5	0.127
10	0.231
15	0.327
20	0.439
25	0.533
30	0.645
35	0.756
40	0.846
45	0.959
50	1.046

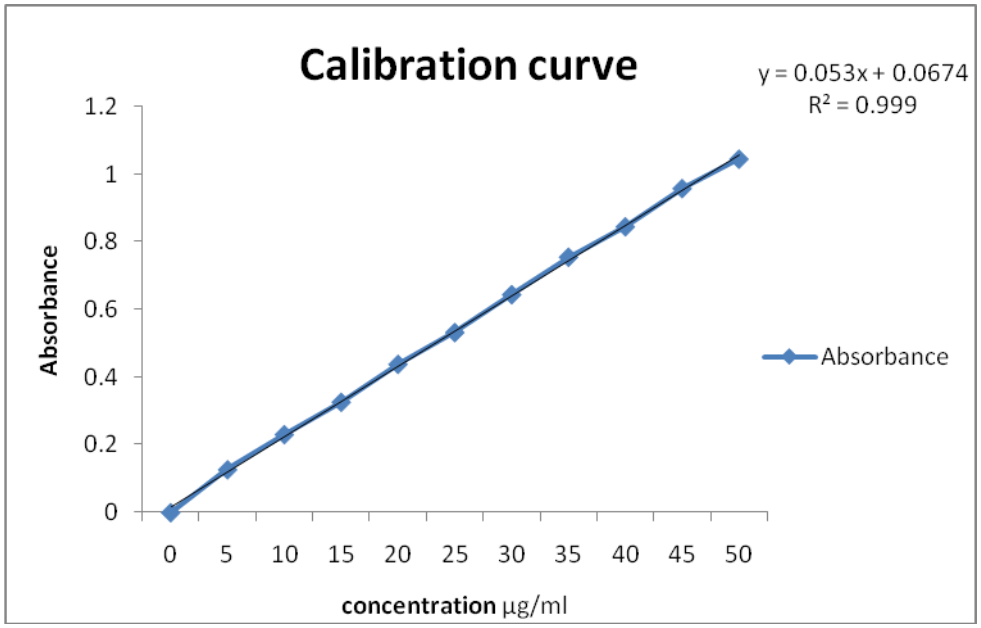


Fig 2: Calibration curve of Salbutamol in methanol.

RESULTS AND DISCUSSION

Pre-compression Evaluation

The powder blends prepared for the formulation of Salbutamol Sulphate matrix tablets were evaluated for their flow properties before compression. The angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were determined. The obtained results indicated satisfactory flow characteristics and good compressibility of all the formulations, which confirmed their suitability for the direct compression process. The values of Carr's index and Hausner's ratio were found within acceptable limits, indicating uniform flow behavior of the powder blends.

Post-compression Evaluation

The prepared matrix tablets were evaluated for various physical parameters including appearance, thickness, weight variation, hardness, friability, and drug content uniformity. All formulations showed smooth surface, acceptable appearance, and good mechanical strength. The tablet thickness and weight variation were found to be within the acceptable pharmacopoeial limits, indicating uniformity in tablet production.

The hardness of the tablets was found to be sufficient to withstand handling and transportation without breaking. The friability values of all formulations were less than 1%, demonstrating adequate resistance to abrasion. Drug content analysis revealed uniform distribution of Salbutamol Sulphate throughout the matrix tablets, with all formulations

showing drug content within acceptable limits, indicating good mixing and uniformity of the prepared formulations.

In Vitro Drug Release Study

The in vitro dissolution studies demonstrated that the type and concentration of polymer had a significant influence on the release behavior of Salbutamol Sulphate from the matrix tablets. Formulations containing higher concentrations of polymers exhibited a slower drug release rate due to the formation of a stronger and more viscous matrix barrier around the tablet.HPMC K4M, a hydrophilic polymer, absorbed dissolution medium and formed a gel layer around the tablet, which controlled the diffusion of the drug and provided a sustained-release effect. Carbopol 934P also showed a considerable retardation of drug release because of its high swelling capacity and gel-forming ability. Ethyl Cellulose, a hydrophobic polymer, reduced the penetration of dissolution medium into the matrix and further contributed to prolonged drug release.The comparison of different formulations indicated that the optimized polymer concentration produced a desirable sustained-release profile by maintaining controlled drug release over an extended period. The drug release pattern suggested that a balanced combination of polymer type and concentration plays an important role in achieving the required release characteristics.

CONCLUSION

The present study was successfully carried out to formulate and evaluate sustained-release matrix tablets of Salbutamol Sulphate using different polymers by the direct compression method. Salbutamol Sulphate is a selective β_2-adrenergic agonist widely used for the treatment of asthma and chronic obstructive pulmonary diseases (COPD). However, due to its short biological half-life of approximately 3–6 hours and the requirement of frequent dosing, there is a need to develop a sustained-release dosage form to maintain prolonged therapeutic action and improve patient compliance.Pre-formulation and pre-compression studies were performed to assess the suitability of the drug and powder blends for tablet preparation. The powder blends exhibited good flow properties with angle of repose, Carr's index, and Hausner's ratio values within acceptable limits, indicating their suitability for direct compression. The prepared matrix tablets were evaluated for post-compression parameters, and all formulations showed satisfactory physicochemical characteristics. The hardness of tablets was found to be in the range of 5–7 kg/cm², friability was less than 1%, weight variation complied with pharmacopoeial limits, and drug content uniformity was found in the

range of 98–102%, indicating uniform distribution of Salbutamol Sulphate in the formulations.The in vitro dissolution study demonstrated that the type and concentration of polymers significantly influenced the drug release pattern. Formulations containing HPMC K4M, Carbopol 934P, and Ethyl Cellulose successfully controlled the release of Salbutamol Sulphate by forming a matrix barrier that regulated drug diffusion and erosion. An increase in polymer concentration resulted in a slower and more prolonged drug release profile. The optimized formulation exhibited controlled drug release for up to 12 hours with satisfactory tablet properties and desired sustained-release behavior.Therefore, the study concluded that polymer-based matrix tablets of Salbutamol Sulphate can be considered an effective sustained-release drug delivery approach. The developed formulation may reduce dosing frequency, maintain therapeutic plasma concentration for a longer duration, improve patient compliance, and enhance the overall effectiveness of Salbutamol therapy in the management of respiratory disorders.

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Conflict of Interest

The authors announce that there is no disagreement of interest associated with this research work.

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