RESEARCH PAPER

Development and Characterization of a Spray-Dried Directly Compressible Co-Processed Excipient for Targeted Delivery of Mesalamine

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ABSTRACT

This study's main goal was to develop a colon-targeted drug delivery system by combining excipients made using the spray drying method, like binders and fillers, into a single powder blend with better tableting qualities. The study investigates the co-processing of excipients with various functions using spray drying. Particle size, density, flowability, and compressibility were among the physicochemical and tableting characteristics of the excipient that were evaluated. Mesalamine, the master medication, was immediately compressed using spray-dried co-excipient. For the in vitro drug release studies, a pH 7.4 phosphate buffer and simulated intestinal and stomach contents were utilized. The formulation's release profile showed a sustained drug release in the intestinal fluid, indicating that the drug was delivered to the colon. Overall, the co-processed excipient-based formulation created utilizing the spray drying technique showed promising results in terms of its physicochemical properties and colon-targeted drug delivery. This work lays the groundwork for the creation of innovative drug delivery methods to treat a range of inflammatory diseases that impact the colon.

Keywords: Spray dryer, Co-excipient, Colon targets, Ulcerative colitis, pH dependent polymers.

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INTRODUCTION:

The development of instantly compressible co-processed excipients is one emerging field of research in the pharmaceutical sector. Coexcipient polymers are a novel class of polymers that have attracted attention for colontargeted drug administration. By controlling the erosion and swelling of the polymer matrix, coexcipient polymers function as a drug's matrix or carrier and can modify the drug's release characteristics[1, 2]. To improve their functionality and compatibility, two or more excipients that have undergone collaborative spray drying processing are combined to create co-processed excipients. The co-processing technique aims to combine the positive properties of several excipients into a single blend in order to enhance tableting qualities, reduce production costs, and improve product performance. Spray drying is a popular method for producing powders with controlled particle size and improved flow capacity. By atomizing a liquid input into a spray of droplets that are rapidly dried in a hot gas stream, the process produces a dry powder. Spray drying different excipients together to create a single blend can improve their compatibility and functionality[3,4].

The medication used in the research was mesalamine, a non-steroidal anti-inflammatory drug (NSAID) often used to treat a range of inflammatory conditions. For colon-focused release, a variety of polymers were used in the formulation. Overall, the results of the study may contribute to the development of successful CTDDS formulations using the spray drying technique, which may enhance therapeutic results and reduce premature drug release. In order to construct a matrix that can control drug release by modifying the drug's diffusion through the matrix, co-excipients are typically polymers that are mixed with the drug[5, 6]. In this study, we developed a colon-targeted drug delivery system for the master drug mesalamine using a co-excipient polymer created by spray-drying. The co-excipients used in the formulation included Eudragit RSPO, hydroxypropyl methylcellulose K15 (HPMC), PVP K 30, and MCC[7].

Mesalamine and the co-excipient were directly crushed into tablets in a single operation.

2. MATERIALS AND METHODS

A. Mesalamine is procured from the Lupin Pharma. Aurangabad, India as a gift sample. All other chemicals were of analytical grade purchased from local suppliers.

B. Creation of a spray-dried, immediately compressible co-processed excipient Three steps were used in the formulation of the spray-dried co-excipient[8,9], includes;

1. Select the feed suspension and optimize spray drying settings in order to create a tablet that will be utilized to make co-excipient for control release. The spray drying conditions may optimized for suitable spray drying parameters.
2. Co-excipient preparation employing optimum spray drying conditions for control release. Lab Ultima Lu 222 Advanced Lab Spray Dryers were used for the spray drying processes. In order to achieve the required properties of the coexcipient that is generated, it is essential to exploit optimized operating spray drying conditions simultaneously with the choice of appropriate excipients in their suitable concentrations.

Preparation of co-excipient:

Using preset ratios of Eudragit, HPMC, PVP, and MCC, the co-excipient was created by spray drying. In an appropriate solvent system made up of acetone and water, the materials were thoroughly combined and dissolved. The solution was then sprayed using Labultima spray dryer that had an exit temperature of 40 °C and an intake temperature of 60 °C. The resulting powdered co-excipient was kept for later usage in an airtight container[10]. Preparation of Mesalamine tablets:

A tablet compression machine was used to directly compress the optimum co-excipient with mesalamine powder in an appropriate ratio. After that, the pills were put through the hardness test. tests and friability tests to confirm its durability and mechanical strength is known as validation[11]. Mesalamine tablets coating:

The customized tablets had been coated with an enteric coating made using Instacoat EEN, a dry powder that reconstitutes methacrylic acid copolymer in a hydroalcoholic solvent solution, in order to facilitate colon-specific medicine distribution. The coating was applied using a spray gun that had an exit temperature of 30°C and an input temperature of 50°C[12].

In-vitro dissolution studies:

In vitro dissolution tests were carried out using dissolution apparatus in pH 7.4 phosphate buffer, simulated intestinal fluid (pH 6.8), and simulated stomach fluid (pH 1.2). The tablets' dissolving profile was spectrophotometrically analyzed at 320 nm using a UV-visible spectrophotometer. Samples were collected often throughout the 24-hour investigation[13].

Characterization of the Formulation:

Numerous characteristics, including hardness, thickness, weight fluctuation, friability, and dissolution research, were used to characterize the optimized formulation. Stability tests were conducted under conditions of increased humidity and temperature to confirm the formulation's stability throughout a six-month period.

Overall, a colon-targeted drug delivery system utilizing a co-excipient polymer made by spray drying was developed and characterized using the above-described methods. The study's findings serve as a foundation for the creation of innovative drug delivery methods for the management of numerous inflammatory diseases that impact the colon [14, 15].

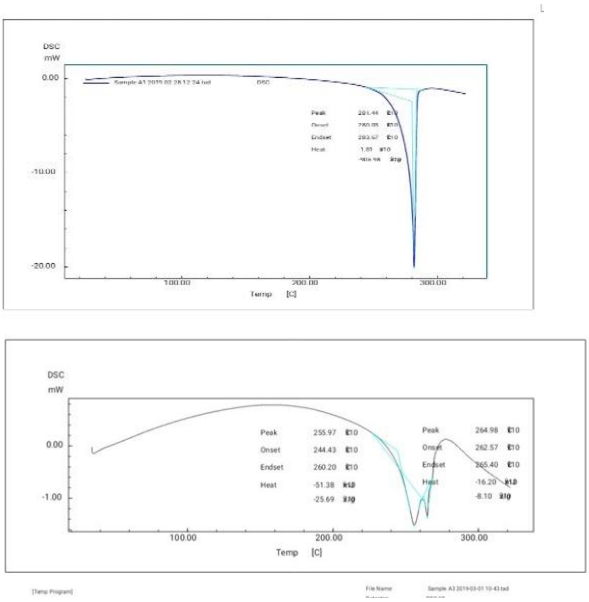

Fig. 1: DSC thermograms of **A**: Pure Mesalamine and **B**: Drug: Polymer physical mixture Design expert software determined the spray-dried parameters for the optimal batch, such as 1. Inlet temperature of 100 °C 2. Two bars of atomization pressure 3. 5 rpm feed rate 4. 22.35% output from spray drying 5. Content of moisture: 1.576% 6. Carr's index (13.49%) 7. Desirability (0.982).

3. RESULTS AND DISCUSSION

Study of drug-excipient compatibility:

The drug excipient interaction investigation was conducted utilizing DSC, FTIR spectroscopy, and physical observation.

Formulation of prototype formulation of Mesalamine control release matrix tablets using co-excipient for Colonic delivery:

Table 1: Formulation of prototype formulation of Mesalamine control release matrix tablets

Sr. No.	Ingredients (mg)	Formulation Code							
		B1	B2	B3	B4	B5	B6	B7	B8
1	Mesalamine	400	400	400	400	400	400	400	400
2	**Co-excipient**								
	Eudragit RSPO	100	100	100	100	200	200	200	200
	HPMC K5M	20	40	60	80	20	40	60	80
	HPMC K15M	-	-	-	-	-	-	-	-
	PVP K30	20	20	20	20	20	20	20	20
	MCC	259	239	219	199	159	139	119	99
3	Talc	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

4	Mg. stearate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Total weight	800	800	800	800	800	800	800	800

***In- vitro* drug release study of Prototype Formulation B1-B16**

To verify drug release behaviour and attain control release from co-excipient, *in-vitro* drug release research of preliminary trial batches B1 to B16 was carried out. Figure 2 displayed the percentage cumulative medication release result and its graphical depiction.

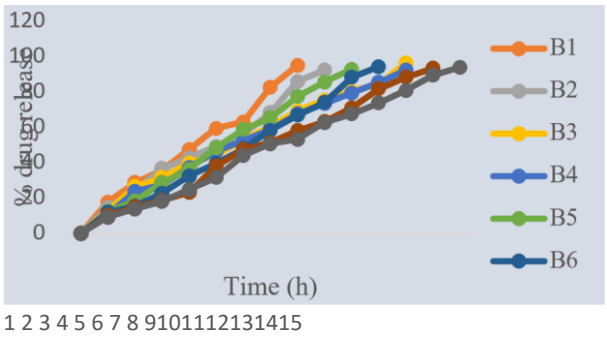

Fig. 2: % Drug release of mesalamine from Prototype formulation batches (B1-B8)

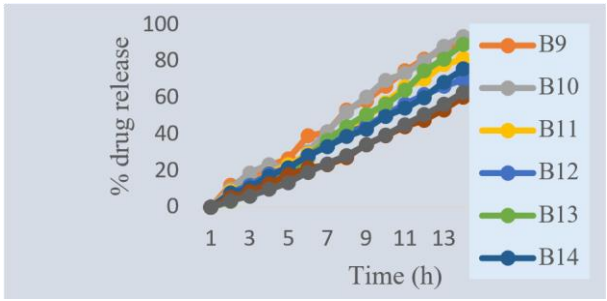

Fig. 3: % Drug release of mesalamine from Prototype formulation batches (B9-B16)

According to the data, formulations that combined Eudragit RSPO with HPMC Trial batches B9, B10, B11, and B13 demonstrated good release for up to 14 hours. For 16, 15, 17, and 18 hours, respectively, B12, B14, B15, and B16 demonstrated satisfactory controlled release of the medication. The combination of the hydrophilic polymer HPMC K15M and the release-retardant pH-independent polymer Eudragit RSPO may be the cause of this. Diffusion and erosion may be linked to the drug release process. Batch B15 demonstrated 90% drug release in 17 hours based on in vitro drug release results. However, within the first five hours, over 20% of the medication was released. Batch B15 was chosen for additional research based on the aforementioned findings.

Preparation of Coated tablets:

Table 2: Formulation of prototype formulation of Mesalamine coated tablets

Sr. No.	Ingredients	C1	C2	C3	C4	C5
A	**Matrix Tablet Formulation**					
1	Mesalamine	400	400	400	400	400
2	Co-excipient (B15) (1:1)	400	400	400	400	400
3	Talc	0.5	0.5	0.5	0.5	0.5
4	Mg. stearate	0.5	0.5	0.5	0.5	0.5
5	Total weight (mg)	801	801	801	801	801
B	**Coating Formulation**					
1	Instacoat EEN (% weight gain)	1	2	3	4	5
2	IPA: Purified Water (70:30)	q.s.	q.s.	q.s.	q.s.	q.s.

According to the aforementioned findings from the C1–C5 batches, formulation C5, which contained 400 mg of co-excipient and 5% weight gain of Instacoat EEN coating, demonstrated sustained release with a desired lag time. As a result, it was chosen for additional factorial studies to maximize the impact of variables on formulation. The study employed a full factorial design with 3^2 randomization. In this design, two factors were chosen at three levels each, and experimental batches with codes D1–D9 were made utilizing all nine conceivable combinations that the software produced.

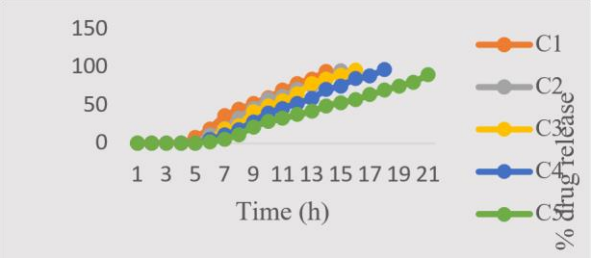

Fig. 4: Percent drug release

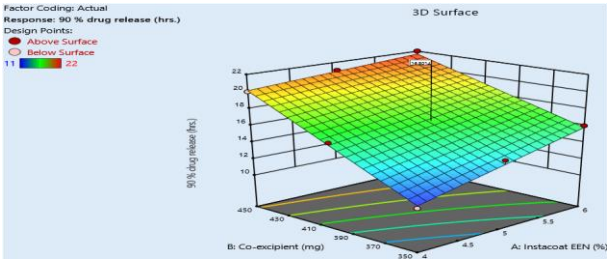

Fig. 5: Q_{90} 3D Surface Response Curve

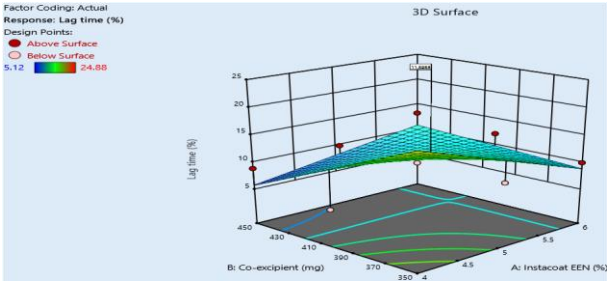

Fig. 6: Q_5 3D Surface Response Curve

Software-generated checkpoint for formulations of coexcipient-based mesalamine-coated tablets.

Table 3: Formulation generated by software for Mesalamine coated tablets

Ingredients	Quantity per Tablet (mg)
	E1
A	Matrix Tablet Formulation
Mesalamine	400
Co-excipient	393.55
Spray dried MCC	56.45
Magnesium stearate	0.5
Talc	0.5
Total weight	851
B	Coating Formulation
Instacoat EEN (% weight gain)	5.023
IPA: Purified Water (70:30)	q.s.

4. CONCLUSION:

In vitro drug release profiles are compared between the optimized batch (E1) and commercially available mesalamine control release tablets, such as Asaclol 400 mg (produced by Sun Pharma and contains 400 mg of mesalamine). In comparison to the marketed formulation, it was discovered that the optimized batch produced the required values for a lag time of about 5 hours with less than 10% drug release and a percentage cumulative drug released at 18 hours, or 93.65%. So, it was concluded that, the colon-targeted drug delivery system made using Co-excipient polymer made by spray drying process had better drug release and bioavailability.

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Conflict of Interests: There are no conflicts of interest.

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