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Development and Characterization Salbutamol Sulphate Mouth Disintegrating Tablet

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Abstract

An orodispersible dosage form has been developed as a user-friendly formulation that disintegrates in the mouth immediately. Thus an attempt was made to improve the onset of action of bronchodilator used commonly in the treatment of asthma. Formulation was optimized for type of disintegrant used and method of formulation. Disintegrants such as CCS (Croscarmellose Sodium), SSG (Sodium Starch Glycolate), L-HPC (Low-substituted Hydroxy Propyl Cellulose), and Crospovidone XL-10 were used and tablets were prepared by direct compression method and wet granulation. Wet granulation formulation were again sub-divided where disintegrant was added intragranularly in one type and was added both in intra and extra granulation in the other. Mint flavor was added to give good mouth feel. Out of all formulations prepared, the one prepared with Crospovidone XL-10 added both intra and extra granulation showed least disintegrating time (9 sec) with good flow property. Direct compression blends had poor flow. Tablets were also evaluated for various physicochemical parameters. All the tablets showed burst release of drug. Hence, it was concluded that out of all formulations, the one prepared with Crospovidone XL-10 added both intra and extra granulation was the best formulation as it showed the least disintegration time.

Keywords: Crospovidone XL-10; Intra and extra granular addition; Asthma; Mouth feel; Wetting time; Water absorption ratio

Abbreviations: L.O.D: Loss On Drying; MCC: Micro Crystalline Cellulose

Introduction

Convenience of administration and patient compliance are gaining significant importance in the design of dosage forms. Recently more stress is laid down on the development of organoleptically elegant and patient friendly drug delivery system for pediatric and geriatric patients [1,2]. One important innovation in this direction is the development of fast dissolving/disintegrating oral dosage forms that dissolve or disintegrate instantly upon contact with recipient's tongue or buccal mucosa [3,4]. A tablet which can rapidly disintegrate in saliva is an attractive dosage form and a patient-oriented pharmaceutical preparation [5].

Superdisintegrants are added in formulation to increase the dissolution characteristics thus increasing bioavailability of drug [6]. There are three methods of addition of disintegrant into the formulation, intragranular (Internal addition), extragranular (External addition), partly intragranular and extragranular addition [7]. The time for disintegration of orally disintegrating tablets is generally considered to be less than one minute [8,9,10,11] although patients can experience actual oral disintegration times that typically range from 5-30 sec. Many companies have developed various types of fast-disintegrating dosage forms. A freeze-dried porous wafer known as Zydis [12, 13], a molding tablet known as EMP [13], an effervescent tablet known as OraSolve [13], and a disintegrant addition [13] have all been developed.

Asthma is a chronic inflammatory disease, which affects over 5-10% of population in industrialized countries [14]. It affects approx. 53 million people across world mostly in United States, France, Germany, Italy, Spain, United Kingdom, and Japan [14,15]. Thus, an attempt was made for preparation of fast dissolving tablets of a model bronchodilator, salbutamol sulphate with an aim of reducing lag time and providing faster onset of action to relieve immediately acute asthmatic attack.

Material and Methods

Salbutamol sulphate was provided as a gift sample by Lincoln pharmaceuticals, Ahmedabad, Lactose was obtained from Ranbaxy Fine-Chem. Ltd, Delhi, MCC PH 101 and Magnesium Stearate were obtained from Loba chemicals Pvt. Ltd., Mumbai, CCS, SSG, Crospovidone XL-10 and L-HPC were obtained from Microlabs, Bangalore and Aerosil was obtained from Eonik Degussa, Mumbai. All other chemicals were of analytical grade.

Equipment used

UV Spectrophotometer: Systronic 2201 UV/Vis double beam Spectrophotometer.

Tablet Compression Machine: Rimek 10 Station Press, Cadmach Machinery Co. Pvt. Ltd., Ahmedabad, India.

Dissolution test apparatus: Dissolution test apparatus-TDT-06T, Electrolab, Mumbai, India.

Roche friabilator: Camp-bell Electronics, Mumbai, India

Hardness tester: Validated dial type, Model: 1101, Shivani Scientific Industries Pvt. Ltd., Mumbai.

Sartorious electronic balance: Model CP- 224 S, Labtronic.

The amount of disintegrant, lactose and MCC PH 101 was previously optimized and hence kept constant in all the formulations.

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Preparation of the mouth disintegrating tablet of salbutamol sulphate by direct compression method: Accurately weighed quantities of salbutamol sulphate, Lactose, MCC PH 101 and disintegrant, were mixed for 10 minutes and passed through sieve no. 40. The blend was mixed with mint flavor and Aerosil passed through sieve no. 40 for 5 minutes. Finally Magnesium Stearate passed from sieve no. 60 was mixed in above blend and was mixed for 3 minutes. The homogenized mixture was subjected for direct compression to produce 100 mg tablets by using Rimek 10 Station Press. The tablets obtained contained 4.8 mg of salbutamol sulphate. (equivalent to 4mg of salbutamol) The drug and composition of the ingredients are shown in Table 1.

Preparation of the mouth disintegrating tablet of salbutamol sulphate by wet granulation method where disintegrant is added intragranularly: Accurately weighed quantities of salbutamol sulphate, Lactose, MCC PH 101 and disintegrant, were mixed for 10 minutes and passed through sieve no. 40. The blend was subjected to granulation with the help of water as a granulating solvent. The granules were dried at 60°C till L.O.D reaches 2-2.5%. The dried granules were passed through sieve no. 16 and then mixed with mint flavor and Aerosil passed through sieve no. 40 for 5 minutes. Finally Magnesium Stearate passed from sieve no. 60 was mixed in above blend and was mixed for 3 minutes. The homogenized mixture was subjected for compression to produce 100 mg tablets by using Rimek 10 Station Press. The drug and composition of the ingredients are shown in Table 2.

Preparation of the mouth disintegrating tablet of salbutamol sulphate by wet granulation method where disintegrant is added both intragranular and extragranular: Accurately weighed quantities of salbutamol sulphate, Lactose, MCC PH 101 and disintegrant, were mixed for 10 minutes and passed through sieve no. 40. The blend was subjected to granulation with the help of water as a granulating solvent. The granules were dried at 60°C till L.O.D reaches 2-2.5%. The dried granules were passed through sieve no. 16 and then mixed with disintegrant, mint flavor and Aerosil passed through sieve no. 40 for 5 minutes. Finally Magnesium Stearate passed from sieve no. 60 was mixed in above blend and was mixed for 3 minutes. The homogenized mixture was subjected for compression to produce 100 mg tablets by using Rimek 10 Station Press. The drug and composition of the ingredients are shown in Table 3.

Ingredients	Batch Code			
	DC1	DC2	DC3	DC4
Salbutamol sulphate	4.8	4.8	4.8	4.8
Lactose Monohydrate	52.2	52.2	52.2	52.2
MCC PH 101*	35	35	35	35
CCS*	5	-	-	-
SSG*	-	5	-	-
Crospovidone XL-10	-	-	5	-
L-HPC*	-	-	-	5
Mint flavor	1	1	1	1
Aerosil	1	1	1	1
Magnesium Stearate	1	1	1	1

Salbutamol sulphate 4.8 mg is equivalent to 4 mg of salbutamol
*MCC – Microcrystalline Cellulose, CCS – Croscarmellose Sodium, SSG – Sodium Starch Glycolate, L-HPC – Low substituted Hydroxy Propyl Cellulos

Table 1: Composition of Direct Compression Tablets.

Ingredients	Batch Code			
	IG1	IG2	IG3	IG4
Salbutamol Sulphate	4.8	4.8	4.8	4.8
Lactose Monohydrate	52.2	52.2	52.2	52.2
MCC PH 101*	35	35	35	35
CCS*	5	-	-	-
SSG*	-	5	-	-
Crospovidone XL-10	-	-	5	-
L-HPC*	-	-	-	5
Water	Q.S.	Q.S.	Q.S.	Q.S.
Mint flavor	1	1	1	1
Aerosil	1	1	1	1
Magnesium Stearate	1	1	1	1

Salbutamol sulphate 4.8 mg is equivalent to 4 mg of salbutamol
*MCC – Microcrystalline Cellulose, CCS – Croscarmellose Sodium, SSG – Sodium Starch Glycolate, L-HPC – Low substituted Hydroxy Propyl Cellulose

Table 2: Composition of Tablet Prepared by Wet Granulation Method where Disintegrant was added Intragranularly.

Ingredients	Batch Code			
	IG1	IG2	IG3	IG4
Salbutamol Sulphate	4.8	4.8	4.8	4.8
Lactose	52.2	52.2	52.2	52.2
MCC PH 101*	35	35	35	35
CCS*	2.5	-	-	-
SSG*	-	2.5	-	-
Crospovidone XL-10	-	-	2.5	-
L-HPC*	-	-	-	2.5
Water	Q.S.	Q.S.	Q.S.	Q.S.
CCS*	2.5	-	-	-
SSG*	-	2.5	-	-
Crospovidone XL-10	-	-	2.5	-
L-HPC*	-	-	-	2.5
Mint flavor	1	1	1	1
Aerosil	1	1	1	1
Magnesium Stearate	1	1	1	1

Salbutamol sulphate 4.8 mg is equivalent to 4 mg of salbutamol
*MCC – Microcrystalline Cellulose, CCS – Croscarmellose Sodium, SSG – Sodium Starch Glycolate, L-HPC – Low substituted Hydroxy Propyl Cellulose

Table 3: Composition of Tablet Prepared by Wet Granulation Method where Disintegrant was added both Intra and Extragranularly.

Evaluation of tablets

Pre-compressional evaluation [16]:

a) Angle of repose (θ)

Angle of repose (θ) was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. The radius of the heap (r) was measured and angle of repose was calculated.

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

b) Bulk density

Apparent bulk density (δb) was determined by placing presieved drug excipients blend into a graduated cylinder and measuring the volume (Vb) and weight (M) "as it is".

$$\delta b = M/Vb$$

c) Tapped density

The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the

cylinder and the weight (M) of the blend was measured. The taped density was calculated using following formula.

$\delta t = M/Vt$

d) Compressibility index

The simplest way of measurement of free flow property of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by % compressibility which is calculated as follows:

$C = (\delta t - \delta b) / \delta t * 100$

e) Hausner's ratio

Hausner's ratio is an index of ease of powder flow, it is calculated by following formula. Hausner's ratio = $\delta t / \delta b$

Post compression parameters

a) Measurement of the tablet tensile strength and friability [16]

Six tablets of each formulation were picked randomly and dimensions were determined. Hardness of tablets was examined using a hardness tester to measure the crushing strength of the tablets (Validated dial type). The mean hardness was calculated and expressed as Kg/cm^2. The friability of tablets was determined using Roche Friabilator (USP) at 25rpm for 4 minutes. It is expressed in percentage (%).

b) Drug content uniformity [17]

Tablets containing 4.8 mg of drug is dissolved in 100 ml of simulated gastric fluid (SGF) pH 1.2. The drug is allowed to dissolve in the solvent, the solution was filtered, and 1ml of filtrate was suitably diluted with simulated gastric fluid pH 1.2 and analyzed spectrophotometrically at 276 nm. The amount of salbutamol sulphate was estimated by using standard calibration curve of the drug. Drug content studies were carried out in triplicate for each batch of formulation.

c) In vitro disintegration time [17]

Tablet disintegration was carried out by placing one tablet in each tube of the basket and top portion of the each tube was closed with a disc. The apparatus was run with pH 1.2 SGF (simulated gastric fluid) maintained at 37 ± 2^0C as the immersion liquid. The assembly was raised and lowered upto 30 cycles per minute. The time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded. The experiment was carried out in triplicate.

d) Wetting time and Water absorption ratio [18]

The tablet was placed in a Petri dish having a 6.5 cm in diameter, containing 10 ml of water and the time for complete wetting was recorded. The experiment was carried out in triplicate at room temperature. Water absorption ratio was calculated by keeping the tablet on a piece of tissue paper folded twice in a small Petri dish containing 6ml of distilled water. Time for complete wetting of tablet was recorded. The wetted tablet was then weighed. Water absorption ratio R, was determined using equation, $R = 10 \times [(W_a - W_b) \div W_b]$, Where, W_b = weight of the tablet before water absorption and W_a = weight of the tablet after water absorption.

e) Mouth feel and in vivo disintegration time

To know the mouth feel, taste and disintegration of the tablets, formulations were given to six healthy human volunteers. The mouth feel, taste and in vivo disintegration was evaluated.

Results and Discussion

Precompression parameters

Granules ready for compression containing drug and various excipients was subjected for pre-compression parameters (Micromeritic properties) to study the flow properties of granules, to achieve uniformity of tablet weight. The data obtained for angle of repose for all the formulations were tabulated in Table 4 and the values were found to be in the range of 19° to 33°. The formulations of direct compression revealed poor flow property and formulations of wet granulation had good flow property. Loose bulk density (LBD) and tapped bulk density (TBD) for the blend is shown in Table 4. The loose bulk density and tapped bulk density for all the formulations blend varied from 0.56 gm/cm^3 to 0.76 gm/cm^3 and 0.73 gm/cm^3 to 0.89 gm/cm^3 respectively. The results of Carr's consolidation index or compressibility index (%) for all the formulations blend ranged from 9.52 to 24.32. The results for all the formulations were recorded in Table 4.

Post-compression parameters

The tablets prepared were subjected for evaluation according to various official specifications and other parameters. Hardness, friability, weight variation, wetting time, *in vitro* water absorption ratio, drug content, disintegration time, *in vivo* taste, mouth feel and disintegration were performed. Formulations prepared were randomly picked from

FMC*	Angle of Repose (θ)	Loose Bulk Density (gm/cm^3)	Tapped Bulk Density (gm/cm^3)	% Compressibility	Hausner's ratio
DC1	33	0.58	0.75	22.66	1.29
DC2	31	0.56	0.74	24.32	1.32
DC3	31	0.56	0.73	23.28	1.3
DC4	32	0.57	0.74	22.97	1.29
IG1	24	0.73	0.86	15.11	1.17
IG2	22	0.76	0.84	9.52	1.10
IG3	22	0.72	0.89	13.25	1.23
IG4	24	0.75	0.84	10.71	1.12
IEG1	21	0.69	0.80	13.75	1.15
IEG2	19	0.71	0.82	13.41	1.15
IEG3	20	0.72	0.84	14.28	1.16
IEG4	20	0.71	0.81	12.34	1.14

FMC*- Formulation code.

Table 4: Angle of repose, loose bulk density, tapped bulk density, Carr's Compressibility Index, Hausner's ratio.

FMC*	Weight Variation	Drug content (%)	Hardness (Kg/cm^2)	Friability (%)
DC1	99±0.002	98.32±.860	4.5±0.246	0.84
DC2	99±0.001	97.39±0.124	4.8±0.131	0.83
DC3	100±0.002	98.36±0.679	4.6±0.346	0.75
DC4	98±0.002	99.00±0.374	4.5±0.456	0.73
IG1	100±0.002	102.13±0.659	4.3±0.283	0.63
IG2	101±0.002	99.36±0.980	4.2±0.546	0.59
IG3	101±0.001	98.33±0.618	4.2±0.244	0.56
IG4	99±0.001	98.66±0.231	4.2±0.224	0.59
IEG1	100±0.002	98.79±0.679	4.3±0.248	0.63
IEG2	100±0.002	99.03±0.776	4.3±0.218	0.69
IEG3	101±0.001	99.64±0.235	4.4±0.216	0.66
IEG4	101±0.002	101.33±0.577	4.5±0.212	0.67

*FMC- Formulation code.
All values are indicated as Mean ± S.D (n=3).

Table 5: Characterization of salbutamol sulphate Tablets.

each batch examined under lens for shape and in presence of light for color. Tablets showed flat, circular shape and were white in color. The hardness of the tablets was found in the range of 4.2±0.224 to 4.8±0.131 Kg/cm^2, respectively. The mean hardness test results are tabulated in Table 4.Friability of the all the formulation was in the range of 0.56% to 0.84%. The obtained results were found to be well within the approved range (<1%) in all designed formulations. The results are shown in Table 4.The content uniformity was performed for all the formulations and results are tabulated in Table 5. The drug content was found to be 97.39±0.124% to 102.13±0.659%. The results were within the range and that indicated uniformity of mixing of the drug with excipients in the developed formulations. The weight variation for all the formulations is shown in Table 5. All the tablets passed the weight variation test; average percentage weight variation was found within the pharmacopoeial limits of ±7.5%. The obtained results were found to be 98±0.002mg to 101±0.002mg.

In vitro disintegration time: The disintegration time recorded of all the formulation found in the range of 7.01±0.04 to 18.15±0.05 seconds. The results are shown in Table 6 and Figure 1.

FMC*	In Vitro DT (sec)*	Wetting Time (Sec)	Water Absorption Ratio	In Vivo DT (Sec)*	Mouth feel
DC1	8.02±0.06	11.23±2.13	71.6±2.14	14.56±3.19	+
DC2	8.52±0.02	12.34±3.15	73.45±2.54	15.65±2.14	+
DC3	7.01±0.04	10.24±2.16	76.25±2.14	13.52±1.65	+
DC4	7.21±0.03	10.98±3.15	73.25±1.65	13.65±2.58	+
IG1	18.15±0.05	22.42±3.12	74.35±2.30	25.46±2.65	+
IG2	17.53±0.04	23.12±1.32	71.26±2.89	26.41±2.24	+
IG3	14.89±0.01	18.35±3.32	78.52±3.45	22.41±3.31	+
IG4	16.14±0.04	19.25±2.35	76.54±3.68	25.12±2.16	+
IEG1	12.02±0.05	15.25±1.35	77.0±2.46	19.25±1.95	+
IEG2	11.54±0.03	15.62±3.45	76.4±2.09	18.8±2.89	+
IEG3	9.06±0.05	12.42±1.45	78.2±3.15	13.25±1.56	+
IEG4	13.02±0.08	13.10±3.15	77.2±3.54	15.06±2.78	+

*FMC-Formulation code, DT- Disintegration, '+' good palatable mouth feel, '-' poor palatable mouth feel
All values are indicated as Mean ± S.D (n=3).

Table 6: Characterization of salbutamol sulphate Tablets.

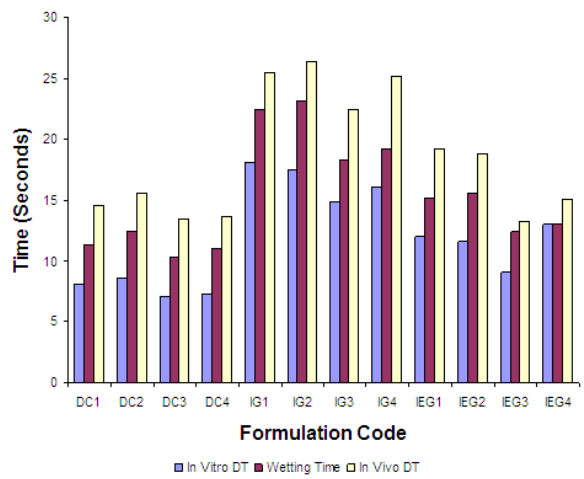

Figure 1: Bar graph showing In Vitro disintegration time, In Vivo disintegration time and wetting time.

Wetting time and Water absorption ratio: Wetting time of all the formulations recorded was found to be 10.24±2.16 to 23.12±1.32 seconds. The result of wetting time is shown in Table 5. Wetting time is closely related to the inner structure of the tablet. The obtained results mimic the action of saliva in contact with the tablet to illustrate the water uptake and subsequent wetting of the tablet. The wetting process was very rapid in all the formulations. The hydration studies demonstrated that all tablets were characterized by very similar hydration profiles. They hydrated quickly and showed high hydration percentage 71.26±2.89 to 78.52±3.45. Tablet hydration capacity is a very important parameter in the design of a new drug fast disintegrable dosage forms because of a strict relationship between water absorption and the drug release mechanism. The obtained results are shown in Table 5 and Figure 1.

Mouth feel and in-vivo disintegration: In the formulations, mint flavor and lactose were added to improve the mouth feel and taste of salbutamol sulphate tablets. . Volunteers felt that the tablets had a good taste and good palatable mouth feel. In-vivo disintegration times of tablet were found to be 13.25±1.56 to 26.41±2.24 seconds. The results are shown in Table 6.

Conclusion

From the present study, it can be concluded that orodispersible/ mouth disintegrating tablets can be prepared using different techniques such as direct compression method, wet granulation where disintegrant is added intragranularly and wet granulation method where disintegrant is added both intra and extragranularly. However, the direct compression method shows some problems of poor flow. Thus, wet granulation method where disintegrant is added both intra and extragranularly can be considered as the most promising technique as it overcomes the poor flow problem and shows short disintegration time. Out of all the disintegrants used Crospovidone XL-10 showed the least disintegration time in all formulation techniques, hence it can be concluded to be the best superdisintegrant.

Declaration of Interest

The authors report no declarations of interest.

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