ISSN: 2456-043X
International Journal of Engineering Science and Generic Research (IJESAR)
Available Online at www.ijesar.in
Journal Index In ICI World of Journals - ICV 2016 – 68.35
Volume 10; Issue 2; 2024; Page No. 42-50

Formulation Development and Evaluation of Fast Disintegrating Tablets of Salbutamol Sulphate for Respiratory Disorders: A Review

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Abstract

Recent advances in rapidly dissolving formulations have increased dosing for children and elderly patients who have difficulty swallowing chemotherapeutic agents currently aims to prepare rapidly dissolving salbutamol sulfate tablets for respiratory problems for pediatric treatment. While accurate dosing and patient compliance will be important prerequisites for long-term therapy, it is important to develop pharmacological interventions that address swallowing disorder, easy transportation, patient acceptance etc. The present study was therefore conducted with the intention of providing a readily soluble salbutamol sulfate with suitable alternatives. Highly corrosive compounds such as sodium starch glycolate were successfully developed. Binders were optimized with an optimal amount of hyperseparator. Tablets were prepared using direct compression technique. The tablets were evaluated for hardness, brittleness, weight change, wetting time, cracking time, and uniformity. The optimized formulations were evaluated by in vitro dissolution testing, pharmaco-excipient compatibility, and rapid stability studies. The conclusion was that a fast-dissolving solution of salbutamol sulfate with desirable fast-dissolving properties was successfully developed; provided a quick start to the process; and increased patient convenience and compliance.

Keywords: disintegration, treatment, drug evaluation, polyvinylpyrrolidone, microcrystalline, salbutamol sulfate.

Introduction

Despite significant innovations in drug delivery, the oral route remains the preferred route of therapeutic drug delivery due to dose accuracy, treatment costs study, due to its self-healing properties, non-invasive techniques, and ease of administration that result in high patient compliance.

[1]. The most popular applications are traditional medicine and hard gelatin capsules. The main disadvantage of such regimens is the “dysphagia” or difficulty swallowing experienced by many patients; About 50% of the population is affected by this type of problem. Thus, patients do not adhere to their prescriptions, resulting in nonadherence and less effective treatment

[2]. Recently, disintegration formulations have begun to gain popularity and acceptance as alternative medications, because of their ease of administration and good patient compliance.

[3]. In some conditions like motion sickness, sudden onset of nausea or vomiting, and dehydration, swallowing of traditional medicines. can be difficult especially in pediatric patients and elderly patients Drug breakdown rapid or oral breakthroughs have emerged as new dosages to address such problems

[4]. Recent advances in novel drug delivery systems (NDDS) aim to enhance the safety of a drug molecule and maintain therapeutic benefit in order to improve patient compliance

[5]. U.S. The Food and Drug Administration Center for Drug Evaluation and Evaluation (CDER) defines ODT in the "Orange Book" as "a stable quantity of a chemical compound, which breaks down rapidly, usually in seconds in a few cases, when the tongue is placed on it". The European Pharmacopoeia describes an ODT as "an uncoated tablet designed to be placed in the mouth where it dissolves rapidly before swallowing" and is a tablet that should disintegrate within 3 minutes

[6]. Fast dissolving drugs(FDTs) "fast dissolving", "fast dissolving", "fast dissolving", "fast dissolving", "oral disintegration", "fast dissolving", "fast dissolving", "oral dissolution", "chewing in the mouth ", "easily decomposable ", "porous", "EFVDAS", or "emergent drug absorption".

[7]. Drug concentrations may be increased due to oral absorption of drugs and salivary flow of dissolved drugs prior to gastric absorption Also, the amount of drugs absorbed into primary metabolic systems decreases when compared with the standard treatment

[8]. In general, the target populations for these new rapid/dispersible agents have been pediatrics, the elderly, and bedridden or cognitively impaired patients Patients with epilepsy, persistent nausea or vomiting, traveling, or having little or no fluids also affect FDT . It has a good selection of candidates

[9]. The drugs of choice for the treatment of asthma and other respiratory problems are available in the market in conventional tablet and liquid dosages Liquid dosages have their own limitations in terms of stability and dose measurement. Pediatric patients are resistant to oral medications, and patient compliance with such medications is questionable. Thus, they are not adherent to their prescriptions, leading to high compliance and ineffective treatment. The rapidly burst dosing provides a delivery route for children and other patients who have had difficulty swallowing the drug and for those with migraine salbutamol sulfate is a time-of-acting ß2-adrenergic receptor agonist short for relieving nasal congestion in conditions such as asthma and (chronic obstructive pulmonary disease). Discharge: COPD) .

[10] Due to sore throat, the patient finds it difficult to swallow tablet type dosage form. Thus rapidly dissolving drugs would be ideal doses for pediatric patients who have difficulty swallowing drugs

[11]. Therefore, efforts were made to develop a rapid disintegration formulation of salbutamol sulfate with the aim of improving/enhancing patient comfort and compliance, reducing shelf life, and speeding up the onset of the process though immediately relieved respiratory problems

2. Materials and Methods

2.1.The equipment used. Salbutamol sulfate was obtained as a gift sample from Trojan Pharma of Baddi, India. Microcrystalline cellulose (Avicel PH-102) was obtained as a gift sample from the NB staff in Nagpur, India. Sodium starch glycolate (Primogel, Explotab) and direct compressible Mannitol (DMannitol) were purchased from Qualikems Fine Chem Pvt. Ltd. Ltd. Ltd. Ltd. Sodium stearyl fumarate was purchased from Himedia. Sodium saccharin was purchased from Loba Chemie, Mumbai, and talc from Nice Chemicals Private Limited, Hyderabad, India. All other chemicals and reagents that were of analytical grade were used.

2.2. Methods

2.2.1. Optimizing the selection and quantification of excipients. The most important parameter to be optimized in the development of rapid spherical degradation is the degradation time. Fast disintegration tablets were first prepared using different excipients (binders and super disintegrants) and then analyzed for various parameters such as friability, hardness, disintegration time etc. to select the best combination for making fast disintegration tablets.

(1) Preparation of highly degradable sodium starch glycolate (Primogel, Explotab). For tablets and capsules that require rapid dissolution, the addition of a suitable superdisintegrant in its optimum concentration is a prerequisite before optimal bioavailability Super disintegrants reduce the dissolution time which in turn leads to rapid drug dissolution. Thus, proper selection of super desigrant and its effectiveness and stability are important for fast disintegrating dosage form Formulations F1–F6 were prepared to study the effect of type and concentration of super disintegrating agent in Table 1. By direct compression method so it fixed the tablets. Weighed amounts of salbutamol sulfate along with various amounts of super disintegrant and excipients were mixed in geometric progression in a dry clean mortar and then the mixture was passed through a number 60 sieve to straighten it. The powder mixture was then pressed into tablets with an 8 mm punch in a multipunch tablet compaction machine (Dheeman Industries, India).

(2) Preparation of polyvinylpyrrolidone (PVP K-30) or microcrystalline cellulose (Avicel PH-102) as a binder with an excellent super disintegration agent. Tablets were prepared using direct compression technique. The composition of the rapid disintegration formulation is shown in Table 2. Weighted amount of salbutamol sulfate with appropriate amount of sodium starch glycolate with different amount of binder (PVP K-30, MCC) with excipients in sludge formation dry and clean inside . The mixture was then concentrated directly through a number 60 sieve. The powder mixture was then pressed into tablets with an 8 mm punch in a multipunch tablet compaction machine (Dheeman Industries, India).

2.3. Finally, salbutamol sulfate rapid disintegration tablets by direct compression method. Rapid disintegration tablets of salbutamol sulfate were prepared by direct compression method according to formula given in Table 3. Weighed amount of salbutamol sulfate was mixed in dry clean mortar in geometric progression with excipients and optimized concentration of superdisintegrant and binder. The mixture was then concentrated directly through a number 60 sieve. The powder mixture was then pressed into tablets with an 8 mm punch in a multipunch pellet compression machine. They examined that chorus.

2.4. Evaluation Parameters

2.4.1. Weight Variation. Twenty tablets were selected and weighed on digital weighting balance (Ohaus, USA), and

Table 1: Formula for 1 tablet (200 mg) of different concentrations of sodium starch glycolate (data in mg)

Sr no	Ingredients	F1	F2	F3	F4	F5	F6
1	Salbutamol sulphate	2	2	2	2	2	2
2	Sodium starch glycolate	2 (1%)	4 (2%)	8 (4%)	12 (6%)	16 (8%)	20 (10%)
3	Polyvinylpyrrolidone K-30	4	4	4	4	4	4
4	Sodium stearyl fumarate	3	3	3	3	3	3
5	Talc	3	3	3	3	3	3
6	Sodium saccharin	5	5	5	5	5	5
7	Mannitol	181	179	175	171	167	163

Table 2: Formula for 1 tablet (200 mg) for the optimization of polyvinylpyrrolidone K-30 or microcrystalline cellulose with optimized concentration of sodium starch glycolate.

Contents Formula no.	Salbutamol sulphate (mg)	SSG (mg)	PVK-30 (mg)	MCC (mg)	Sodium stearyl fumarate (mg)	Talc (mg)	Sodium saccharin (mg)	Mannitol (mg)
F1	2	8	2	_	2	2	5	179
F2	2	8	4	–	2	2	5	177
F3	2	8	6	–	2	2	5	175
F4	2	8	8	–	2	2	5	173
F5	2	8	10	–	2	2	5	171
F6	2	8	12	–	2	2	5	169
F7	2	8	14		2	2	5	167
F8	2	8	_	2	2	2	5	169
F9	2	8	_	4	2	2	5	177
F10	2	8	_	6	2	2	5	175
F11	2	8	_	8	2	2	5	173
F12	2	8	_	10	2	2	5	171
F13	2	8	_	12	2	2	5	169
F14	2	8	_	14	2	2	5	167

average weight was determined. Then individual tablets were weighed, and the individual weight was compared with an average weight [12] (see Table 4).

2.4.2. obesity. Tablet thickness was determined using a vernier caliper (Indian Caliper Industries, Ambala, India). Three tablets from each group were used, and an average value was calculated

[12] .2.4.3. The difficult things. The crushing strength of the pellets was measured using a Monsanto hardness tester (Perfit). Three compounds from each chemical group were randomly tested, and the average reading was noted. Hardness is expressed in kg/cm

[13].2.4.4. Moderate friability. Ten tablets were weighed and placed in a Roche friabilator (Veego, India) and the apparatus was rotated at 25 rpm for 4 min. The percentage of crispiness of tablets was measured using the following solution

[14]:

$$\text{Percentage friability} = \frac{\text{Initial weight- Final weight}}{\text{Initial weight}} \times 100. \quad (1)$$

2.4.5. In vitro water dispersion studies. Experiments were carried out on 6 tablets using a digital tablet dissolution tester (Vigo, India). Distilled water at a temperature of 37∘ C ± 2∘ C was used as the dispersion medium, and the time taken for the solution to dissolve completely without any tangible residue in the tube was measured in seconds

[15].2.4.6. Humidification time. A Petri dish containing 6 mL of distilled water was taken. A few amaranth-colored tablets were placed inside. The time required for the surface of the slabs to completely turn yellow was noted

[16].2.4.7. Drug Content Uniformity. Ten tablets (200 mg) were powdered in mortar pestle, and the blend equivalent to

Table 3: Formula of salbutamol sulphate FDT prepared by direct compression method (data in mg).

Sr. no.	Ingredients	Formula for 1 tablet (200 mg)	Formula for 110 tablets (200 mg)
1	Salbutamol sulphate	2	220
2	Sodium starch glycolate	8	880
3	Microcrystalline cellulose	2	220
4	Sodium stearyl fumarate	5	550
5	Talc	3	330
6	Sodium saccharin	5	550
7	Mannitol	175	19250

Table 4: Weight variation specification as per IP.

Average weight of tablet	% Deviation
80 mg or less	±10
More than 80 mg but less than 250 mg	±7.5
250 mg or more	±5

2 mg of salbutamol sulfate was weighed and dissolved in 100 mL of 6.8 pH phosphate buffer solution. The solution was sonicated, filtered through whatman filter paper, and suitably diluted with 6.8 pH phosphate buffer, and the solution was analyzed by double beam UV spectrophotometer (UV-1800 Shimadzu) at 276 nm each. Each sample was analyzed in triplicate. [17]2.4.8. In vitro dispersion studies. The release of the synthesized FDT was determined using USP eight step solution test apparatus 2 (paddle method) (Lab, India). Wetting tests were conducted using 500 mL of phosphate buffer solution, pH 6.8 at 37 ± 0.5∘ C and 50 rpm. Samples of the product (5 mL) were withdrawn from the infusion tube at a specified time interval, the samples were exchanged with fresh distilled water and the samples were filtered through Whatman filter paper. The absorbance of these solutions was measured at 276 nm using a double beam UV spectrophotometer (UV-1800 Shimadzu). Cumulative percent (%) drug release was calculated using standard salbutamol sulfate [18] .2.4.9. Pharmaceutical compatibility studies. These studies were conducted to confirm the chemical and pharmacodynamic interactions. These studies are mainly FTIR spectroscopy. The FTIR spectra of pure and FDT-treated compounds were recorded on an FTIR spectrophotometer (Bruker, USA). The scanning range was from 4000 to 600 cm−1, and the resolution was 1 cm−1. Scanning was checked for the presence of main drug peaks, variable and overlapping drug peaks, and the presence of additional peaks due to excipient interactions This spectral analysis was used to assess the compatibility of drugs with applied excipients [19]2.4.10. A rapid stability check. Rapid stability tests are carried out at 40 ± 2∘ C (oven) temperature and ambient humidity and room temperature (Desiccator) The tablets were withdrawn on the 15th and 30th day and analyzed for hardness, crispness, chemical composition only, in vitro dissolution time while for fast disintegrating tablets Important features are [19]

3. Results and Discussion

The present study was to prepare and test the fast soluble solution of salbutamol sulfate by direct compression method using sodium starch glycolate as super disintegrant and mannitol as direct compressible diluent, and sodium saccharin was used to provide palatability was enhanced Avicel pH 102 and included in formulation as a disintegrant and binder for packaging. This microcrystalline cellulose grade is granular and therefore exhibits excellent flowability. Sodium saccharin was added as a sweetener to improve mouthfeel and mouthfeel. Sodium stearyl fumarate has been used in

preference to magnesium stearate not only because of the metallic taste of the latter, but also because of its water solubility and direct pressing characteristics

3.1. Preparation of highly degradable sodium starch glycolate (Primogel, Explotab). Pharmaceutical scientists often use superdistentants to develop FDTs or to improve drug solubility. The main requirement for such dosages is rapid dissolution. The amount of superdistentant was optimized in the development of FDT. To study the effect on dissolution time, a total of 6 formulations (F1–F6) were prepared with different concentrations of sodium starch glycolate. The results of optimal superdissolution concentration in FDTs by direct compression method are shown in Table 5. From the experimental parameters, it was found that 4% sodium starch glycolate is the optimum concentration based on fast tablet dissolution time of dissolution the lowest time at which F3 compounds were detected. The more aggressive action of SSG results in mucous taste and cough which in turn leads to rapid dissolution. It absorbs water rapidly, swells to 200–300% moisture, and disintegrates rapidly. Sodium starch glycolate is used as a hyperdissolving agent in tablet manufacture at a concentration of 4–6%. Disintegration times greater than 8% may actually increase due to gelling and its subsequent effect on viscosity production.

Table 5: Evaluation parameters for the optimization of sodium starch glycolate

Sr. no	Evaluation parameters	F1 (1%)	F2 (2%)	F3 (4%)	F4 (6%)	F5 (8%)	F6 (10%)
1	Weight variation (IP)	Passed	Passed	Passed	Passed	Passed	Passed
2	Friability (%)	0.8	0.8	0.3	0.1	0.1	0.1
3	∗Hardness (Kg/cm2) ± S.D	2.2 ± 0.57	1.6 ± 0.28	1.5 ± 0.28	1.5 ± 0.32	2.0 ± 0.57	1.8 ± 0.28
4	∗∗Disintegration time (sec) ± S.D	80 ± 2.34	59 ± 6.67	34 ± 2.63	48 ± 6.38	78 ± 7.39	95 ± 6.97

∗Average of three determinations.
∗∗Average of six determinations.

3.2. Preparation of polyvinylpyrrolidone (PVP K-30) or microcrystalline cellulose (Avicel PH-102) as a binder with an excellent super disintegration agent. Binders such as polyvinylpyrrolidone (PVP K-30) or microcrystalline cellulose were optimized in super dissolution concentration to further study the effect of binder on dissolution time and hardness and friability of formulation tablets by a total of 14 formulations(F1–F14) were.Table 6 shows the results of optimization of different binders in FDTs by direct compression method.

From the experimental parameters it was observed that the disintegration time of the alloy decreased further and the tablet hardness and brittleness were within IP limits The lowest disintegration time was observed in the F8 alloy ie. 1% MCC, i.e. 2% compared to PVP K-30. Liquid materials such as PVP K-30 tend to fracture rather than fracture, while insoluble materials such as MCC tend to form a rapidly Presence of porous morphology liquid is drawn or “bad” by capillary action and tears interparticle bonds causing tablet to disintegrate hence last of salbutamol sulfate FDT 1 as the optimum amount of binder selected for formulation % microcrystalline cellulose was selected

3.3. Evaluation of Salbutamol Sulphate Fast Disintegrating Tablet. The final FDT of salbutamol sulfate was tested in all official tests for the product and found to be within limits as

shown in Table 7. The weight percent change is within acceptable limits acceptable for uncovered medicine as per Indian Pharmacy. Pharmaceutical scientists are well aware that higher concentrations of pharmaceutical compounds mean longer breakdown times. Since mechanical integrity is of great importance in the optimization of FDTs, the hardness of the pellets was determined. Salbutamol sulfate FDT yields were less than 1% acceptable according to IP standards. The homogeneity of the prepared salbutamol sulfate FDT matched the IP description. None of the ten compounds exceeded 85–115% labeling. These results indicated equal dose distribution and adequate amounts of active ingredient. The wetting and drying times were almost ideal for the formulations. According to the IP, the dissolved solution should disintegrate within 3 minutes, but the FDT formulation has shown a low DT indicating that the solution is suitable for oral suspension

3.4. In vitro dispersion studies. In vitro dissolution studies showed that more than 50% of the drug was dissolved from the solution within 5 min. Fast chemical dispersion can result from easy dissociation of a particle by a super disruptive process. It was observed from the in vitro dissolution data that salbutamol sulfate release at 12 min was 96.75 ± 2.42% indicating that the tablet complied with the IP specification, ie. 85%–110% (see Figure 1).

3.5. Pharmaceutical compatibility studies. The results of the IR analysis showed that there was no interaction between the drug used in the solution and other excipients. FTIR of salbutamol sulfate shows intense band at 1386.68 cm−1, 1612.60 cm−1, 1386.68 cm−1 corresponding to functional groups like Tri-methyl group, secondary amine group, phenol group FTIR of salbutamol sulfate FDT medically matches. The intense bands at 1610.35 cm−1, and 1388.41 cm−1 showed no change in reactive groups such as Tri-methyl group, secondary amine group, and phenol group and happened Salbutamol Sulphate structure a does not disturb emphasis, which as shown in Fig. 2 . There is no indication of contact.

3.6. A rapid stability check. In the present study, the performance of fabricated FDTs (three specialized designs) bonded with aluminum foil for aluminum packaging i.e. was studied. pharmaceutical stability testing in airtight containers with tight air and water tightness , under the following conditions for a period of one month in accordance with the ICH guidelines for study conduct quickly about the shows him. For stability analysis, the material is exposed to appropriate conditions of temperature and humidity. However, the analysis would be more time consuming, so it would be easier to carry out a rapid stability analysis, where the product is stored under extreme conditions of hot and humidity as given are the same as the stability data shown in Tables 8 and 9 .

The results of the stability analysis showed that no significant differences were observed in terms of hardness, disintegration time, chemical homogeneity and economic stability before and during room storage internal temperature and ambient temperature, but the hardness increased with time at 40∘C ± 2∘ temperature C and ambient water f The tablet was dehydrated, but in the cases overall the DT is within the specified IP limits (within 3 minutes) This indicates that the product is stable under both conditions.

Statistical analysis (ANOVA) was also performed using the GraphPad InStat 3 statistical program for Windows. The stability data shown in the tables for the three main groups of formulations were observed before and after stability testing Statistical significance of differences represented the mean ± standard deviation (SD) of three or six determinations bet

4.Conclusion

The rapid tablet disintegration is a promising strategy in terms of rapid pharmacokinetics and would be advantageous in comparison with the conventional dosages currently available. The dose of FDT was well balanced in terms of burst

time and mechanical strength. The primary objective of the study was to develop a rapidly disintegrating formulation of salbutamol sulfate using commonly available excipients

FIGURE 2: FTIR spectra of salbutamol sulphate versus salbutamol sulphate FDT.

TABLE 8: Stability data of salbutamol sulphate FDT at room temperature and at ambient humidity and traditional technology. It was concluded from the study that a fast disintegrating salbutamol sulfate tablet can be marketed with commonly available drugs such as super disintegrating, hydrophilic and inflammatory excipients and appropriate supplementation.

Conflict of Interests

The author declares that he has no financial and personal relationships with other persons or entities that could inappropriately influence this research

TABLE 9: Stability data of salbutamol sulphate FDT at temperature (40°± 2°C) and at ambient humidity.

Acknowledgments

The author is highly thankfull of NB Entrepreneurs, Nagpur, and Trojan Pharma, Baddi, India, for providing gift samplesof Avicel PH-102 and drug and also to Dr. Mahendra Singh Rathore, HOD of Pharmaceutics Department, CT Institute of Pharmaceutical Sciences, Jalandhar, for his valuable sugges-tions, necessary help, and for his efforts to facilitate the use of the necessary instruments and materials required during the entire course of this research work.

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