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Formulation and Evaluation of Orodispersible Tablet for Anti-Asthamatic Drug

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Objective of the present work is to develop orodispersible tablets of Salbutamol to improve bioavailability, disintegration time, dissolution efficacy and patient compliance. Orodispersible tablets are the fast growing and highly accepted drug delivery system in now days mainly to improve patient compliance. Orodispersible tablets have number of advantages over conventional dosage forms, because of that Orodispersible tablets have emerged as an alternative to conventional dosage forms. Orodispersible tablets dissolve or disintegrates instantly on the patient tongue or buccal mucosa. Orodispersible tablets of solbutamol were prepared using superdisintegrants, Crospovidone,Mannitol (Pearlitol SD-200), as diluents by direct compression method. Nine formulations were prepared using the superdisintegrants at lower, intermediate & higher concentration. Mannitol is used to enhance the organoleptic properties of tablets. Tablets were evaluated for uniformity of weight, hardness, friability,

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water absorption ratio, dispersion time, disintegration time and in vitro drug release. All the formulations showed disintegration time less than 33 mins and drug release by dissolution (100% at the end of 10 mins).

Keywords: Salbutamol; orodispersible tablets; crospovidone; mannitol (Pearlitol SD-200).

1. INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. DDS has made a significant contribution to global pharmaceutical sales through market segmentation, and are moving rapidly. Orodispersible tablets (ODT) are oral solid dosage forms that disintegrate in the oral cavity in easy swallow residue. Orodispersible tablets are also known as Mouth dissolving tablets, Orally disintegrating tablets, Melt- in- mouth, Fast dissolving drug delivery, Rapimelts tablets, Porous tablets, Quick dissolving tablets etc. Recently ODT terminology has been approved by United States Pharmacopoeia, British Pharmacopoeia, and Centre for Drug Evaluation and Research (CDER). US FDA defined ODT tablets as “A solid dosage form containing medicinal substances which disintegrates rapidly usually within a matter of seconds, when placed upon the tongue”. European pharmacopoeia also adopted the term “orodispersible tablet” as a tablet that is to be placed in the mouth where it disperses, rapidly before swallowing despite various terminologies used. Recently, ODT have started gaining popularity and acceptance as new drug delivery systems, because they are easy to administer and lead to better patient compliance especially in elderly and children. In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous and soft- moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, which are difficult to handle, often requiring specialized peel off blister packaging. Along with the rapid market growth of ODT products, the technologies, too, have advanced considerably over the years. The newest generation of ODTs can produce more robust, versatile tablets that overcome some of the limitations of earlier ODTs. Companies such as Eurand can produce pleasant tasting tablets, overcoming the common problem of poor drug taste compromising the benefits of an ODT. In addition, some companies is developing controlled release ODTs, significantly broadening the applications of this dosage form. A key reason that companies choose an ODT over other delivery technologies is that it is a relatively easy and often less risky delivery option to develop. Since the route of administration remains the same, ODTs that are formulated as bioequivalent line extensions or generic versions of an existing oral dosage form have minimal clinical requirements to gain approval. Some of the common applications of ODTs are listed in table 1 [1].

2. FORMULATION OF ODT [2]

2.1 Excipients

Excipients balance the properties of the actives in ODTS. This demands a thorough understanding of the chemistry of these excipients to prevent interaction with the actives. Determining the cost of these ingredients is another issue that needs to be addressed by formulators. The role of excipients is important in the formulation of fastmelting tablets.

2.2 Bulking Materials

Bulking materials are significant in the formulation of ODTs. The material contributes functions of a diluent, filler and cost reducer. Bulking agents improve the textural characteristics that in turn enhance the disintegration in the mouth, besides; adding bulk also reduces the concentration of the active in the composition. The recommended bulking agents for this delivery system should be more sugar-based such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose) and starch hydrolystate for higher aqueous solubility and good sensory perception. Mannitol in particular has high aqueous solubility and good sensory perception. Bulking agents are added in the range of 10 percent to about 90 percent by weight of the final composition.

Table 1. Common reasons and conditions for using ODT

Medication type	Indication
Fast – acting	Pain, fever, heartburn, diarrhoea, migraine, anxiety, insomnia
Compliancecritical	Parkinson's disease, Alzheimer's disease, psychosis, Schizophrenia, Hypertension, Cholesterol, Transplantation
Paediatric	Cough/cold/allergy, Pain, fever, ADHD

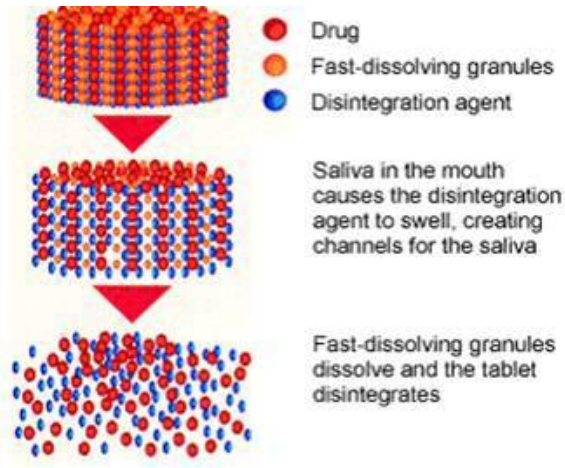

Fig. 1. Basic mechanism of super disintegrants

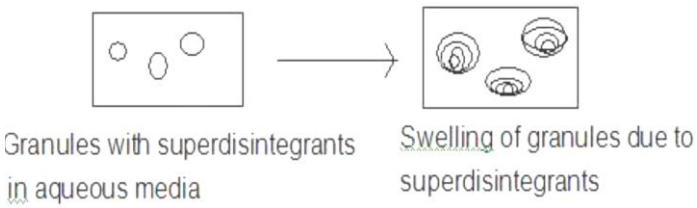

Fig. 2. Mechanism of superdisintegrants by swelling

Table 2. Relationship between % compressibility

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Very Poor

Table 3. Scale of Flowability by Hausner's Ratio

Limits of Hausner's Ratio	Category
1.2 – 1.3	Excellent
1.3 – 1.4	Good
1.4 – 1.5	Fair
1.5 -1.6	Poor

2.3 Emulsifying Agents

Emulsifying agents are important excipients for formulating fast-melting tablets they aid in rapid disintegration and drug release without chewing, swallowing or drinking water. In addition, incorporating emulsifying agents is useful in stabilizing the immiscible blends and enhancing bioavailability. A wide range of emulsifiers is recommended for fast tablet formulation, including alkyl sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agentscan be incorporated in the range of 0.05 percent to about 15 percent by weight of the final composition.

2.4 Lubricants

Lubricants, though not essential excipients, can further assist in making these tablets more palatable after they disintegrate in the

mouth. Lubricants remove grittiness and assist in the drug transport mechanism from the mouth down into the stomach.

2.5 Flavours and Sweeteners

Flavors and taste-masking agents make the products more palatable and pleasing for patients. The addition of these ingredients assists in overcoming bitterness and undesirable tastes of some active ingredients. Both natural and synthetic flavors can be used to improve the organoleptic characteristic of fast-melting tablets. Formulators can choose from a wide range of sweeteners including sugar, dextrose and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose. The addition of sweeteners contributes apleasant taste as well as bulk to the composition.

2.6 Evaluation of ODTs [2]

Evaluation parameters of tablets mentioned in the pharmacopoeias need to be assessed, along with some special tests are discussed here.

2.6.1 Hardness/crushing strength

A significant strength of ODT is difficult to achieve due to the specialized processes and ingredients used in the manufacturing. The limit of crushing strength for an ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The crushing strength of the tablet may be measured using conventional hardness testers.

2.6.2 Friability

To achieve % friability within limits for an ODT is a challenge to the formulator since all methods of manufacturing of ODT are responsible for increasing the % friability values. Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%).

2.6.3 Moisture uptake studies

Moisture uptake studies for ODT should be conducted to assess the stability of the formulation. Ten tablets from each formulation were kept in a desiccator over calcium chloride at 37°C for 24 h. The tablets were then weighed and exposed to 75% relative humidity, at room temperature for 2 weeks. Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the desiccator for 3 days. One tablet as control (without superdisintegrant) was kept to assess the moisture uptake due to other excipients. Tablets were weighed and the percentage increase in weight was recorded.

2.6.4 Disintegration test

The time for disintegration of ODTs is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration test for ODT should mimic disintegration in mouth with in salivary contents.

2.6.5 Dissolution test

The development of dissolution methods for ODTs is comparable to the approach taken for conventional tablets and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1 N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as conventional tablets. USP dissolution apparatus 1 and 2 can be used. USP 1 Basket apparatus may have certain applications, but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. USP 2 Paddle apparatus, which is the most suitable and common choice for ODTs, with a paddle speed of 50 rpm commonly used. Typically, the dissolution of ODT is very fast when using USP monograph conditions; hence, slower paddle speeds may be utilized to obtain a profile. The USP 2 Paddle apparatus at 50-100 rpm is suitable for dissolution testing of taste-masked drug as well. The media used for the taste-masked drug should match that of the finished product to maximize the value of the test. High performance liquid chromatography

(HPLC) is often required to analyze dissolution aliquots due to presence of UV absorbing components, specifically flavors and sweetener. Excipient to drug ratio may be higher since the formulation isdesigned to have good taste and mouth feel, decreasing the detection of the drug to background (excipient) in the UV spectrophotometer.

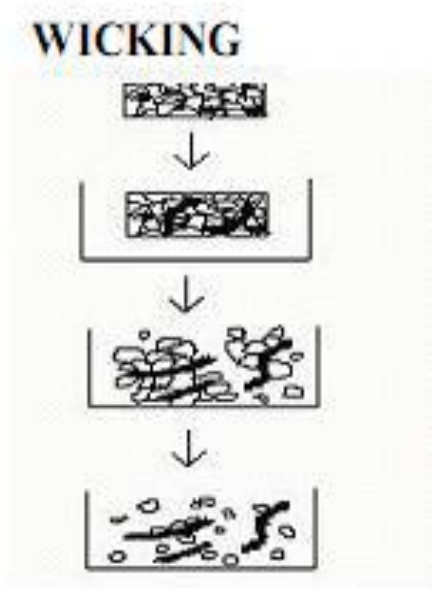

Fig. 3. Mechanism of superdisintegrants by Porosity and capillary action (wicking)

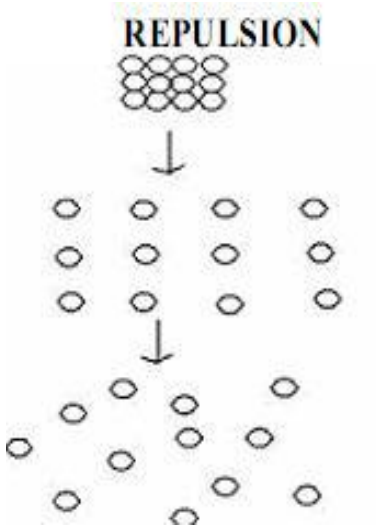

Fig. 4. Mechanism of superdisintegrants due to particleparticle Repulsive forces

Table 4. Angle of repose as an indication of powder flow properties

Sr. No.	Angle of Repose (°)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

Table 5. Formulation of orodispersible tablets

Ingredients(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Salbutamol	8	8	8	8	8	8	8	8	8
MCC (PH-102)	39	39	39	39	39	39	39	39	39
Crosscarmellose sodium	9	13.5	18	-	-	-	-	-	-
Crosspovidone	-	-	-	9	13.5	18	-	-	-
Indion 414	-	-	-	-	-	-	9	13.5	18
Povidone	1	1	1	1	1	1	1	1	1
Pearlitol SD200	91	86.5	82	91	86.5	82	91	86.5	82
Aspartame	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Talcum powder	1%	1%	1%	1%	1%	1%	1%	1%	1%
Mg. Stearate	1%	1%	1%	1%	1%	1%	1%	1%	1%

Table 6. Calibration curve data of Salbutamol in 0.1 N HCl

Sr. No.	Concentration (µg/mL)	Absorbance
1	0	0
2	5	0.114
3	10	0.229
4	15	0.334
5	20	0.439
6	25	0.544
7	30	0.654

Table 7. Drug release kinetic study of optimized batc

MODELS		F_8 (salbutamol)
Korsmeyer- peppas	n	0.987
Zero order	R	0.976
First order	R	0.846
Higuchi model	R	0.996
Best fit model		Higuchi

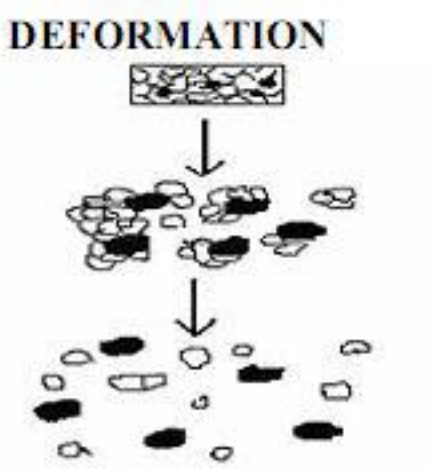

Fig. 5. Mechanism of superdisintegrant due to deformation

2.7 Techniques Used in Preparartion of ODTs [3]

2.7.1 Freeze drying/ lyophilization

Lyophilization means drying at low temperature under condition that involves the removal of water by sublimation. Drug in a water soluble matrix which is then freeze dried to give highly porous structure. The tablets prepared by lyophilization disintegrate rapidly in less than 5 seconds due to quick penetration of saliva in pores when placed in the oral cavity. Lyophilization is useful for heat sensitive drugs i.e. thermo-labile substances. Freeze drying process normally consists of three steps: Material is frozen to bring it below the eutectic point. primary drying to reduce the moisture around 4% w/w of dry product. Secondary drying to reduce the bound moisture up to required final volume.

2.7.2 Spray drying

This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This then mixed with active ingredients and compressed into tablets. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material (e.g. citric acid) and / or alkali material (e.g. sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

2.7.3 Molding

Tablets prepared by this method are solid dispersions. Molded tablets offer improved taste due to water soluble sugars present in dispersion matrix. Molding process is of two type's i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and posses a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30°C under vacuum.

2.7.4 Sublimation

In this method a subliming material like (Ammonium bicarbonate, Ammonium carbonate, Urea, Benzoic acid, Naphthalene, camphor) is removed by sublimation from compressed tablets and high porosity is achieved due to the formation of many pores. where camphor particles previously existed in the compressed tablets prior to sublimation of the camphor. A high porosity was achieved due to the formation of many pores where camphor particles previously existed in the compressed mannitol tablets prior to sublimation of the camphor. These compressed tablets which have high porosity (approximately 30%) rapidly dissolved within 15 seconds in saliva.

2.8 Mass Extrusion

This technology involves softening of the active blend using the solvent mixture of water soluble polyethylene glycol and methanol and expulsion of softened mass through the extruder or syringe to get a cylindrical shaped extrude which are finally cut into even segments using heated blade to form tablets. This process can also be used to coat granules of bitter drugs to mask their taste.

2.9 Direct Compression

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to.

2.9.1 Superdisintegrants

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble

excipients and effervescent agents further hastens the process of disintegration. For the success of fast dissolving tablet, the tablet having quick dissolving property which is achieved by using the super disintegrants.

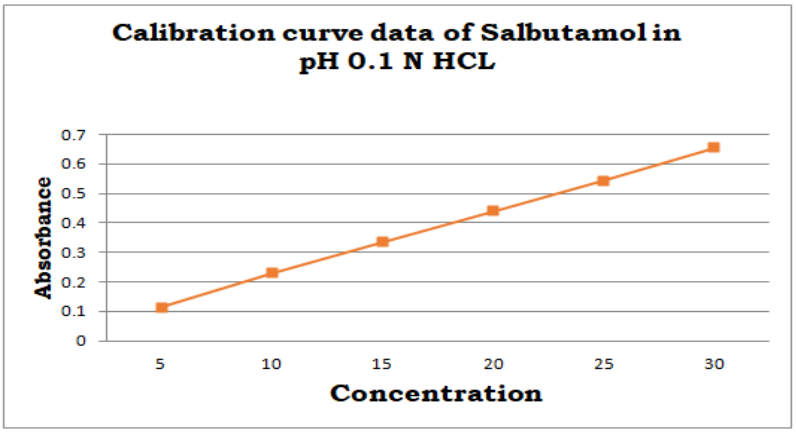

Fig. 6. Calibration curve data of salbutamol in 0.1 N HCl

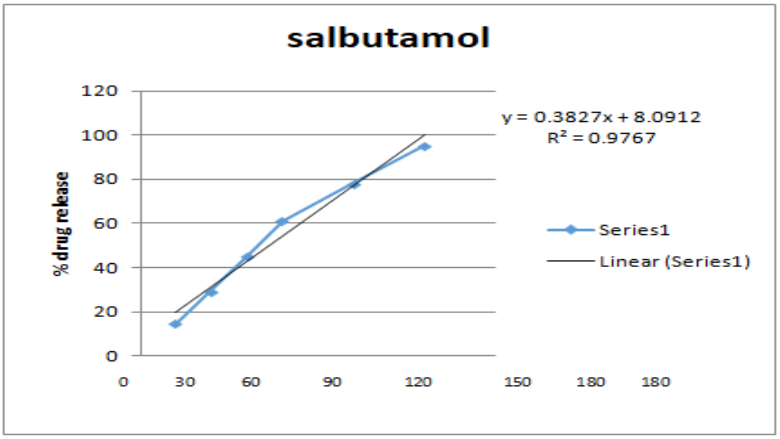

Fig. 7. Curve fitting data of the release rate profile of zero order

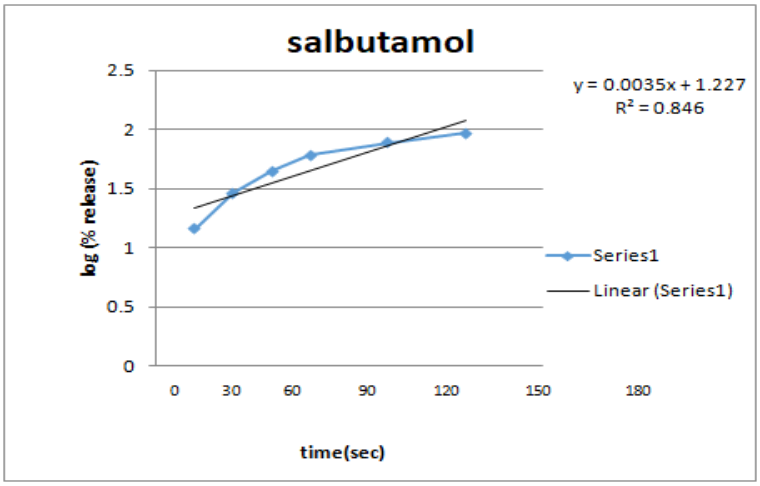

Fig. 8. Curve fitting data of the release rate profile of first order

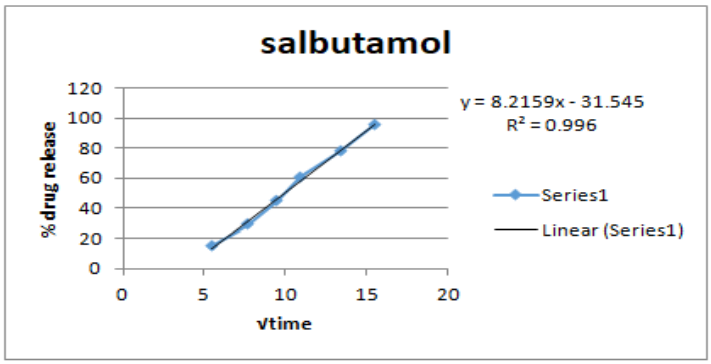

Fig. 9. Curve fitting data of the release rate profile of Higuchi model

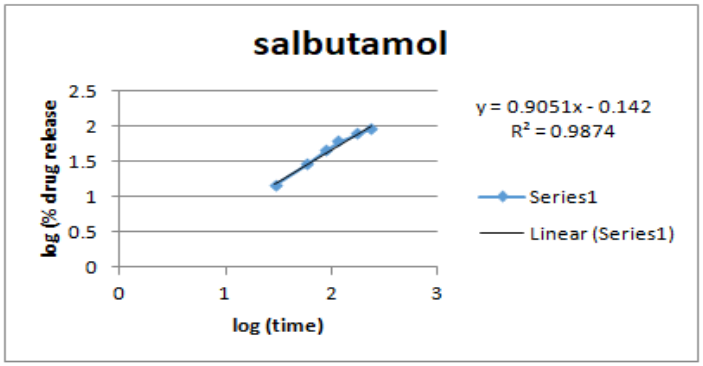

Fig. 10. Curve fitting data of the release rate profile of Korsmeyer-peppas

2.9.2 Sugar Based Excipients

This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouthfeel.

2.10 Pharmacology [4-6]

Solbutamol is a beta(2)-adrenergic agonist and thus it stimulates beta(2)-adrenergic receptors. Binding of albuterol to beta(2)- receptors in the lungs results in relaxation of bronchial smooth muscles. It is believed that salbutamol increases cAMP production by activating adenylate cyclase, and the actions of salbutamol are mediated by cAMP. Increased intracellular cyclic AMP increases the activity of cAMP-dependent protein kinase A, which inhibits the phosphorylation of myosin and lowers intracellular calcium concentrations. A lowered intracellular calcium concentration leads to a smooth muscle relaxation. Increased intracellular cyclic AMP concentrations also cause an inhibition of the release of mediators from mast cells in the airways.

2.10.1 Dosage and administration

For oral use as a means of extending the broncho adults and children over 12 years - 2.4 mg 3-4 times / day; if necessary, the dose may be increased to 8 mg 4 times / day. Children aged 6-12 years - 2 mg 3-4 times / day; children 2-6 years - 1-2 mg 3 times / day.

2.10.2 Allergic reactions

In a few cases - angioedema, allergic reactions in the form of skin rashes, urticaria, hypotension, collapse.

2.10.3 Contraindications

The threat of miscarriage in I and II trimesters of pregnancy, premature placental abruption, bleeding or toxemia in the III

trimester of pregnancy, infancy to 2 years; hypersensitivity to salbutamol.

2.10.4 Using during pregnancy and breastfeeding

Salbutamol is contraindicated in threatened miscarriage in I and II trimesters of pregnancy, premature detachment of the placenta, bleeding, or toxicosis in the III trimester of pregnancy. If necessary, the use of salbutamol during pregnancy should be related to the expected benefits of treatment for the mother and the potential risk to the fetus. Currently is insufficient data on the safety of salbutamol in early pregnancy. salbutamol is excreted in breast milk, so if you need to use during lactation should also assess the potential benefits of treatment for the mother and the potential risk to the child.

2.10.5 Special instructions

With caution used when tachyarrhythmia and other cardiac arrhythmias, arterial hypertension, myocarditis, heart defects, aortic stenosis, diabetes, thyrotoxicosis, glaucoma, acute heart failure (with careful medical supervision).

Increase doses or frequency of receiving albuterol (salbutamol) should be under the supervision of a doctor. Reducing the interval may be only in exceptional cases and should be strictly justified.In the application of salbutamol there was a risk of hypokalemia, so the period of treatment in patients with severe asthma should monitor the flow levels of potassium in the blood. The risk of hypokalemia increases with hypoxia.

2.10.6 Precautionary measures

To increase the effectiveness of therapy the patient should be trained in the proper use of inhalers and the beginning of treatment to use an inhaler under the supervision of medical personnel. Receiving high doses of salbutamol in patients with acute asthma leads to the fact that each subsequent attack of breathlessness becomes more intense the previous syndrome (rebound). In severe asthma interval between inhalations should be at least 20 minutes. In the absence of the minimal effect of inhalation or the appearance of pronounced tremor, tachycardia, cardiac arrhythmias continued uncontrolled use of the inhaler is contraindicated, and should appeal to the doctor. The risk of complications increases as in the long duration of treatment, and at a sharp lifting of the drug.

2.10.7 Salbutamol in case of emergency / overdose

Symptoms: tachycardia (heart rate to 200 bpm), ventricular flutter, reducing blood pressure, increased cardiac output, hypoxemia, acidosis, hypokalemia, hyperglycemia, muscle tremors, headache, agitation, hallucinations,convulsions. Treatment: removal of preparation and holding of symptomatic therapy of beta-blockers (selective) in patients with bronchial asthma requires extreme caution because of the risk of severe bronchospasm reaction.

2.11 Preformulation Study

Preformulation testing is an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. It is the first step in the rational development of dosage forms.

2.11.1 Pre-compression evaluations [2]

2.11.1.1 Bulk density (ρ_b)

Apparent bulk density (ρb) was determined by pouring the blend into a graduated cylinder. The bulk volume (Vb) and weight of the powder (M) was determined. The bulk density (ρb) was calculated using following formula:

$$\rho b = Vb / M$$

Where- M is mass of powder, V_b is the Bulk volume of the powder.

2.11.1.2 Compressibility Index (I)

The simplest method of measurement of free flow of powder is compressibility, an indication of the ease with which material can be induced to flow and is given by compressibility index (I) which is calculated as follows:

$$I=\rho t - \rho b / \rho t *100$$

Where:

ρb = bulk density
ρt = tapped bulk density

The value below 15% indicates a powder which usually gives rise to excellent flow characteristics, whereas above 25% indicate poor flowability.

2.11.2 Hausner's Ratio (H)

This is an indirect index of ease of powder flow. It is calculated by the following formula,

$$H = \rho t / \rho b$$

Where:

ρb = bulk density
ρt = tapped bulk density

2.11.3 Angle of repose

Angle of repose is an indicative of the frictional forces existing between the particles. It is defined as the maximum angle possible between the surface of the pile of powder and the horizontal plane.

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

Where: θ = angle of repose, h = height of the heap of powder in cm, r = radius

2.11.4 Preparation of orodispersible tablets by wet granulation method

Orodispersible tablet were prepared by superdisintegrant addition method. The tablets were formulated employing direct compression method using 8 mm biconcave punches. It is the process by which tablets are compressed directly from mixtures of the drug and excipients without preliminary treatment such as granulation.Salbutamol (8 mg), super disintegrants in different ratios and excipients were blended using mortar and pestle. The drug and the disintegrants were sieved through mesh # 120 before blending. The mixture was evaluated for angle of repose, bulk density and compressibility. The mixture was mixed with 1% magnesium stearate as lubricant and mint as flavoring agent. The powder blends were then compressed by using Fluidpack multistation rotary tablet machine using 8 mm punch. The hardness was adjusted to 2-5 kg/cm^2.

2.12 Procedure for Evaluation of Tablets [2]

2.12.1 Hardness/crushing strength

The limit of crushing strength for an ODT is usually kept in a lower range to facilitate early disintegration in the mouth. The crushing strength of the tablet may be measured using conventional hardness testers.

2.12.2 Friability

To achieve % friability within limits for an ODT is a challenge to the formulator since all methods of manufacturing of ODT are responsible for increasing the % friability values. Thus, it is necessary that this parameter should be evaluated and the results are within bound limits (0.1-0.9%).

2.12.3 Wetting time and water absorption ratio

Wetting time of dosage form is related with the contact angle. Wetting time of the ODT is another important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablet. Lower wetting time implies The wetting time of the tablets can be measured using a simple procedure50five circular tissue papers of 10 cm diameter are placed in a petridish with a 10-cm diameter. Ten milliliters of water-soluble dye (eosin) solution is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time. For measuring water absorption ratio the weight of the tablet before keeping in the petridish is noted (W b). The wetted tablet from the petridish is taken and reweighed (W a). The water absorption ratio, *R* can be then determined accordingto the equation: $R = 100 (W a - W b)/W b$.

2.12.4 Moisture uptake studies

Moisture uptake studies for ODT should be conducted to assess the stability of the formulation. Ten tablets from each formulation were kept in a desiccator over calcium chloride at 37°C for 24 h. The tablets were then weighed and exposed to 75% relative humidity, at room temperature for 2 weeks. Required humidity was achieved by keeping saturated sodium chloride solution at the bottom of the desiccator for 3 days. One tablet as control (without superdisintegrant) was kept to assess the moisture uptake due to other excipients. Tablets were weighed and the percentage increase in weight was recorded.

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The time for disintegration of ODTs is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration test for ODT should mimic disintegration in mouth with in salivary contents.

2.12.6 Dissolution test

The development of dissolution methods for ODTs is comparable to the approach taken for conventional tablets and is practically identical. Dissolution conditions for drugs listed in a pharmacopoeia monograph, is a good place to start with scouting runs for a bioequivalent ODT. Other media such as 0.1 N HCl and buffers (pH - 4.5 and 6.8) should be evaluated for ODT much in the same way as conventional tablets. USP dissolution apparatus 1 and 2 can be used. USP 1 Basket apparatus may have certain applications, but sometimes tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle where little or no effective stirring occurs, yielding irreproducible dissolution profiles. USP 2 Paddle apparatus, which is the most suitable and common choice for ODTs, with a paddle speed of 50 rpm commonly used. Typically, the dissolution of ODT is very fast when using USP monograph conditions; hence, slower paddle speeds may be utilized to obtain a profile. The USP 2 Paddle apparatus at 50-100 rpm is suitable for dissolution testing of taste-masked drug as well. The media used for the taste-masked drug should match that of the finished product to maximize the value of the test. High performance liquid chromatography (HPLC) is often required to analyze dissolution aliquots due to presence of UV absorbing components, specifically flavors and sweetener. Excipient to drug ratio may be higher since the formulation is designed to have good taste and mouth feel, decreasing the detection of the drug to background (excipient) in the UV spectrophotometer.

2.13 Stability Study

The optimized Formulation was subjected to stability studied at 40ºC under humidity conditions (75%) for a period of four week. Samples were analysed for colour changes appearance, drug content and release characteristics.

2.14 Mechanism of Release from Matrix Tablets

From the data obtained after applying all suitable mathematical models we can conclude that the optimized formulations selected are proposed to explain the mechanism of release of drug from formulation are mentioned below.

3. RESULTS AND DISCUSSION

In the present study 9 formulations of Salbutamol tablets with variable concentration of polymer were prepared and evaluated for Physicochemical, in-vitro drug release studies.

3.1 Preformulation Studies

3.1.1 Melting point determination

Melting point of Salbutamolwas found to be in the range 151°C, which complied with IP standards, indicating purity of the drug sample.

3.1.2 Solubility

Salbutamol is soluble in water and ehanol.

3.1.3 Development of calibration curve of salbutamol

Calibration curve of Salbutamol sulphate was plotted in 0.1N HCl which was selected from solubility study. Salbutamol sulphate was estimated spectrophotometrically at λmax of 276nm.

4. CONCLUSION

In present study Salbutamol orodispersible tablet prepared using different types and concentrations of superdisintegrant by direct compression method which was confirmed by various characterization and evaluation studies.Indion 414 as superdisintegrant gives better result as compared to crosscarmellose sodium and crosspovidone.Tablets disintegrate within 30 sec in mouth having better mouth feel.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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