

COMPARATIVE EVALUATION OF NATURAL AND SYNTHETIC SUPERDISINTEGRANTS FOR FAST DISSOLVING TABLET

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ABSTRACT

In the present study, fast dissolving tablets of Salbutamol sulphate were prepared by direct compression method for better patient compliance and immediate action in asthma. The tablets were prepared by using synthetic superdisintegrants (Croscarmellose sodium and Sodium starch glycolate) and natural superdisintegrant (mucilage of *Plantago ovata* and *Plantago ovata* husk powder) at different concentrations as 2, 4, 6, 8 and 10 %. The *Plantago ovata* mucilage was extracted from the seeds of *Plantago ovata* (Plantaginaceae). The tablets were characterized for weight variation, hardness, friability, disintegration time, wetting time, water absorption ratio, drug content and *in vitro* dissolution tests. The Drug excipients compatibility study was performed by DSC and IR spectroscopy and no incompatibility was found. The tablets were subjected for accelerated stability study at 40°C /75% RH and were found to be stable. The results clearly shows Natural superdisintegrants requires less disintegration time as compared to synthetic superdisintegrants. Hence present study reveals that the fast dissolving tablets prepared by using mucilage of *Plantago ovata* and husk powder of *Plantago ovata* as superdisintegrants having better appearance and rapid disintegration time.

Key-words: Fast dissolving tablets, Superdisintegrants, *Plantago ovata*, Croscarmellose sodium and Sodium starch glycolate.

INTRODUCTION

Fast dissolving tablets (FDT) are solid single-unit dosage forms that are placed in the mouth, allowed to disperse/dissolve in the saliva and then swallowed without the need for water. FDT's are not only indicated for people who have swallowing difficulties, but also are ideal for active people. FDT's are those when put on tongue disintegrates instantaneously releasing the drug, which dissolves or disperse in saliva¹.

Salbutamol sulphate is a short-acting β_2 -adrenergic receptor agonist used for the relief of bronchospasm in conditions such as asthma and COPD. (Chronic Obstructive Pulmonary Disease). Salbutamol is well absorbed from the gastrointestinal tract having 50% oral bioavailability due to first pass metabolism. Hence an attempt was made for preparing fast dissolving tablet of salbutamol sulphate and compares along with natural and synthetic superdisintegrants. With an aim of reducing the lag time and providing faster onset of action to relieve immediately acute asthmatic attack. This would be advantageous as conventional solid oral dosage forms are often associated with first pass effect, longer lag time and slower onset of action but require careful handling. Aerosol systems are specific but fail to deliver actual dose of drug with only 10 % of administered dose deposited on the bronchi while rest of the drug is deposited in oropharynx and is swallowed. Also, metered dose system are less portable while dry powder inhalers cause clogging of device and require skilful operation. FDT's would be advantageous, as salbutamol sulphate is water soluble and its preparation into FDT's would render it to dissolve rapidly and thereby result in rapid absorption improved oral bioavailability without any lag time².

Various natural substances have been used in the formulations of FDT's. Mucilage of natural origin is

preferred over semi-synthetic and synthetic substances because they are comparatively cheaper, abundantly available, non-irritating and nontoxic nature. In the present investigation, the preparation and evaluation of fast dissolving tablets by using different concentrations of natural superdisintegrant that is *Plantago ovata* mucilage is studied. The reasons for selection of *Plantago ovata* mucilage because it's high swelling index. Mucilage of *Plantago ovata* has various characteristics like binding, disintegrating and sustaining properties. Hence, in present study, mucilage of *Plantago ovata* was used to develop FDT's of salbutamol sulphate. The concept of formulating FDT's of salbutamol sulphate increases the water uptake with shortest wetting time and there by decrease the disintegration time of the tablets by simple and cost effective direct compression techniques^{3,4}.

MATERIALS AND METHODS

Materials:

Salbutamol Sulphate was gifted by Glenmark Pharmaceuticals Ltd. Nashik. *Plantago ovata* seeds were purchased from local market Mumbai. *Plantago ovata* husk powder was obtained as a gift sample from Gayatri Psyllium husk powder, Unjha Gujarat. Crosscarmellose sodium, Sodium starch glycolate, Microcrystalline cellulose, Mannitol, Colloidal silicon dioxide, Talc, Aspartame and Vanillin used were of analytical grades.

Methods:

Formulation of FDT's by direct compression method:

Salbutamol sulphate, directly compressible (microcrystalline cellulose), superdisintegrants (POM/POH/croscarmellose sodium/sodium starch glycolate), colloidal silicon dioxide, mannitol, were sifted

through the sieve #44 and admixed for about 15 minutes to make a uniform blend. Talc, aspartame, vanillin were passed through sieve #100 and mixed with the above blend for approximately 5-7 minutes. The blend was evaluated for precompression parameters. The resulting uniform blends were directly compressed using 6mm, round convex faced tooling to make the tablets using 10 station compression machine (Rimek, Mini Press-1, Karnavati Engineering Limited). The tablet press setting was kept constant across all formulations.

STANDARD CALIBRATION CURVE

The solutions of salbutamol sulphate in the range of 60-100 µg/ml and 20-100 µg/ml in phosphate buffer pH 6.8 and distilled water were prepared respectively. Absorbance was measured for each solution at λ_{max} of 276.4 nm and 275nm respectively, using UV-Vis Spectrophotometer (Jasco- V630, Japan).

AUTHENTICATION OF *Plantago ovata* SEEDS

The seeds of *Plantago ovata* were authenticated from Botany Department NDMVP's junior college, Nashik. The authentication results proves that the seeds are of *Plantago ovata* belonging to family Plantaginaceae.

METHODOLOGY FOR ISOLATION OF MUCILAGE

Seeds of *Plantago ovata* were soaked in distilled water for 48 hrs. Soaked seeds were boiled for 120 minutes till mucilage get released into the water completely. As soon as mucilage gets released the mucilage was squeezed out and separated from seeds with the help of nylon muslin cloth. The mucilage collected and precipitated using 95% ethanol (1: 2) and washed twice with the same. Collected mucilage was dried in the tray dryer at 50-55°C. Dried mucilage was scraped and powdered using mortar and pestle. This crushed and fine powder was then passed through # 80. The mucilage was then kept in dessicator until its use⁵.

Physicochemical and Phytochemical evaluation of dried powdered mucilage^{6, 7, 8}

Organoleptic properties

Organoleptic properties such as physical appearance, colour, odour and taste of dried powdered mucilage were determined.

Solubility profile

The solubility of dried powdered mucilage was checked by adding a pinch in the solvent such as water.

Charring

A few milligrams of dried mucilage powder and husk powder were placed in a melting-point apparatus. The temperature was taken and recorded when the material started to char.

pH determination

The pH values of solutions prepared in specified strength were determined using calibrated (pH 4 and pH 7) digital pH meter.

Preliminary phytochemical screening

A preliminary phytochemical screening of dried powdered mucilage was carried out for the detection of various phytoconstituents.

Ash values (WHO GUIDELINES)

Total ash, acid-insoluble ash, water-soluble ash, sulphated ash values were evaluated.

Loss on Drying

Loss on Drying was determined for an appropriate quantity of dried powdered mucilage at 105°C for 5 hours.

$$LOD (\%) = (Wt \text{ of water in sample} / Wt \text{ of dry sample}) \times 100$$

Swelling power

The swelling power of the dried mucilage powder was performed as outlined in Indian Pharmacopoeia.

Viscosity determination

Rheological studies of dried mucilage were carried out using varying concentrations (0.1–0.5%) prepared in distilled water. The viscosities were measured using a Brookfield viscometer spindle no.62 at 100 rpm at 25°C.

Microbial count

The microbial count of the dried mucilage powder was performed as outlined in Indian Pharmacopoeia for the presence of bacteria as well as for fungi. Total count of bacteria and fungi was calculated using plate count method.

Particle size determination

The particle size of the dried-powder mucilage and husk powder were determined by the microscopic method.

Hydration capacity (water retention capacity)

1gm of dried-powder mucilage was placed in a centrifuge tube and covered with 10 mL of distilled water. The tube was shaken intermittently over 2 hours and left to stand for 10 minutes at 3000 rpm. With the supernatant decanted and the weight of the powder after water uptake and centrifugation, x was determined.

$$\text{Hydration capacity} = x / y$$

Where x is the weight of moist powder after centrifugation and y is the weight of dry powder respectively.

Flow properties of dried mucilage powder

The flow properties of dried mucilage powder were characterized.

Drug excipients Compatibility studies

Fourier Transform Infra-Red Spectroscopy (FTIR)

The drug and physical mixture of drug and excipients were subjected to IR spectroscopic study using FT-IR spectrophotometer (Bruker Alpha ATR).

Differential Scanning Calorimetry

Thermogram of drug and physical mixture (drug: POM); (ratio1:5) were employed (DSC60 SHIMADZU) for the determination of glass transition temperature (T_g).

Assignment of formulation code

Various formulations of Salbutamol sulphate (API) fast dissolving tablets (FDTs) were designed utilizing natural superdisintegrants as mucilage of *Plantago ovata* (POM), husk of *Plantago ovata* (POH) and synthetic superdisintegrants as Crosscarmellose sodium (CCS), Sodium starch glycolate (SSG) each varied at different concentrations (2, 4, 6, 8 and 10 %). All of the other ingredients were kept constant. A total of such fifteen formulations prepared were designated with their codes and will be referred with the same in further sections. The assigned formulation codes were as follows: SM1, SM2, SM3, SM4 and SM5 for formulations containing mucilage of *Plantago ovata* and SH1, SH2, SH3, SH4 and SH5 for formulations containing husk of *Plantago ovata* as a superdisintegrant with concentrations 2, 4, 6, 8 and 10 % respectively. Similarly, SC1, SC2, SC3, SC4 and SC5 also SS1, SS2, SS3, SS4 and SS5 were the assigned codes for the formulations prepared with crosscarmellose sodium, Sodium starch glycolate as superdisintegrants at the percentage levels provided for PO above.

Evaluation of fast dissolving tablets^{9, 10}

Weight variation

Twenty tablets were selected randomly from each formulation and weighed individually. The individual weights were compared with the average weight for the weight variation.

Hardness and Friability

Hardness of the tablets was measured using the Monsanto hardness tester. The friability of a sample of twenty tablets was measured using a USP type Roche friabilator. Pre-weighed tablets were placed in a plastic chambered friabilator attached to a motor revolving at a speed of 25 rpm for 4 min. The friability was calculated.

Drug content uniformity

For the content uniformity test, twenty tablets were weighed and pulverized to a fine powder. A quantity of powder equivalent to 4mg of salbutamol sulphate was taken in 100ml volumetric flask containing distilled water. An aliquot of 2ml sample was withdrawn and diluted to 10ml and analysed by UV spectrophotometer at 275nm against blank. Then the amount of drug present was calculated using standard calibration curve. The mean percent drug content was calculated as an average of three determinations.

In vitro disintegration time

Six tablets were placed individually in each tube of disintegration test apparatus and discs were placed. Distilled water was maintained at a temperature of $37 \pm 2^\circ\text{C}$ and time taken for the entire tablet to disintegrate completely was noted.

Wetting time and water absorption ratio (R)

Twice folded tissue paper was placed in a Petri dish having an internal diameter of 6.5 cm to that added 6 ml of purified water. A tablet was carefully placed on the surface of the tissue paper in the Petri dish. The time required for water to reach the upper surface of the tablet and to completely wet it was noted as the wetting time. Water

absorption ratio (R) was then determined according to the following equation:

$$R = [(W_a - W_b) / W_b] \times 100$$

Where; W_b and W_a were tablet weights before and after water absorption, respectively.

In vitro drug release study

In vitro dissolution of the tablets was determined using USP- Type-II dissolution test apparatus rotating at 50 rpm in 900 ml pH6.8 phosphate buffer solution as medium maintained at $37 \pm 0.5^\circ\text{C}$. The amount of drug in solution was determined spectrophotometrically at 276.4 nm.

Stability study

The fast dissolving tablets were packed in aluminium foil and stored under the following environmental conditions for a period as prescribed by ICH guidelines for accelerated studies at 40°C and 75% RH. The tablets were withdrawn at end of 90 days and evaluated for parameters including disintegration time, drug content and dissolution study.

RESULT AND DISCUSSION

Phytochemical, microbial and physicochemical characterization of *Plantago ovata* mucilage

Organoleptic properties

It is creamish fine powder odourless with mucilaginous taste.

Solubility profile

Mucilage does not dissolve in water, it swells.

Table 1: Charring and pH determination of dried mucilage powder

Charring	
Dried mucilage powder	Husk powder
183-184°C	182-183°C
pH determination	
0.5% solution	6.2

Table 2: Preliminary phytochemical screening

Tests	Observations	Inferences
Ruthenium test Take a small quantity of dried mucilage powder, mount it on a slide with ruthenium red solution and observe it under microscope.	Pink colour develops	Mucilage is present
Dried mucilage powder	Aqueous potassium hydroxide	Swells

The presence of mucilage was confirmed using ruthenium positive. red and aqueous potassium hydroxide. Both tests were

Table 3: Physical properties of dried powder mucilage

Identification tests	Observed results	Reported standards (BP 1988, IP 1996)
Ash value		Not More Than 4.5%
Total ash (%)	3.46	-
Acid-insoluble ash (%)	0.33	Not More Than 0.45%
Water soluble ash (%)	2.0	-
Sulphated ash(gm)	0.149	-
Loss on Drying (%)	11.25	Not More Than 12.0% determined on 0.5 g
Swelling power(ml)	42	Not Less Than 40ml
Viscosity(cp)	8.42 for 0.3% solution	-
Microbial count (cfu/g)		-
For bacteria	6	
For fungi	3	
Particle-size determination (μm)		-
Dried mucilage powder	150-200	
Husk powder	150-200	
Hydration capacity	9.5	-
Bulk density (g/ml)	0.49	-
Tapped density (g/ml)	0.56	-
Carr's index (%)	12.745	-
Hausner's ratio	1.142	-
Angle of repose ($^{\circ}$)	29.05	-

Drug excipients Compatibility studies

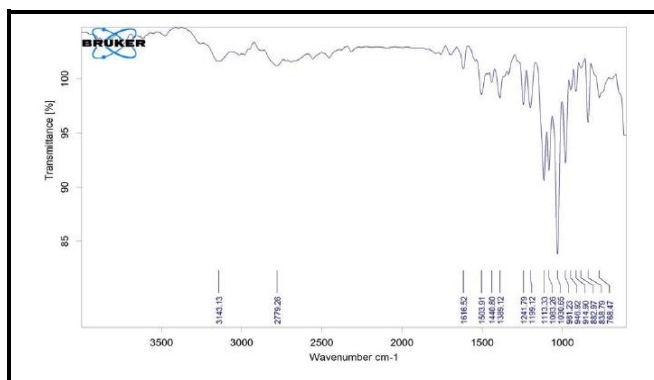


Figure 1: IR Spectrum of Salbutamol sulphate

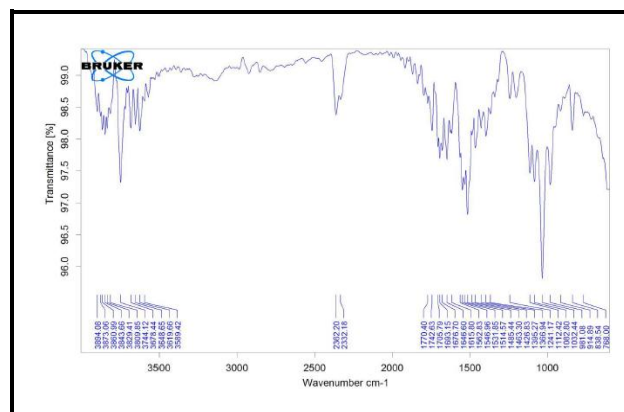


Figure 2: FTIR spectra of Drug + POM

Sr.No.	Functional groups	Pure drug	POM	Pure drug + POM
1	C-O(alkyl, aryl)	Yes	Yes	Yes
2	N=O(aromatic nitroso group)	Yes	Yes	Yes
3	C-H(bending)	Yes	Yes	Yes
4	P=O (phosphine oxide)	Yes	Yes	Yes
5	O-H (bending)	Yes	Yes	Yes

Figure 1 and 2 represents the FTIR spectra of pure drug and drug + POM which were found to contain the same peaks as that found in pure drug, and no any additional peak was observed in physical mixture revealing that no incompatibility exist between them.

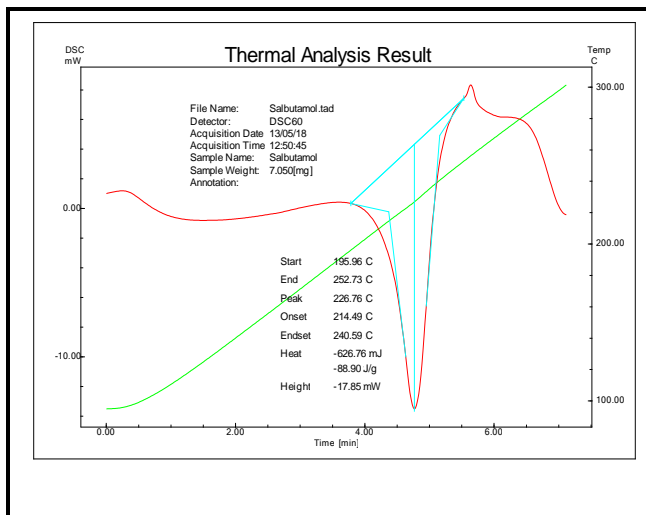


Figure 3: DSC thermogram of Salbutamol sulphate

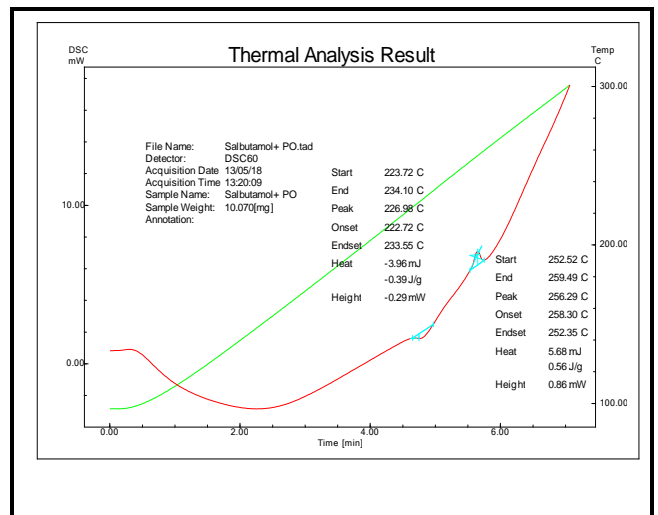


Figure 4: DSC of drug with POM

DSC thermograms of drug and its physical mixture exhibited a sharp endothermic peak at 226.76°C and at 226.98°C then the intensity was reduced and the peak slightly shifted to 256.29°C respectively revealing that no incompatibility exist between them.

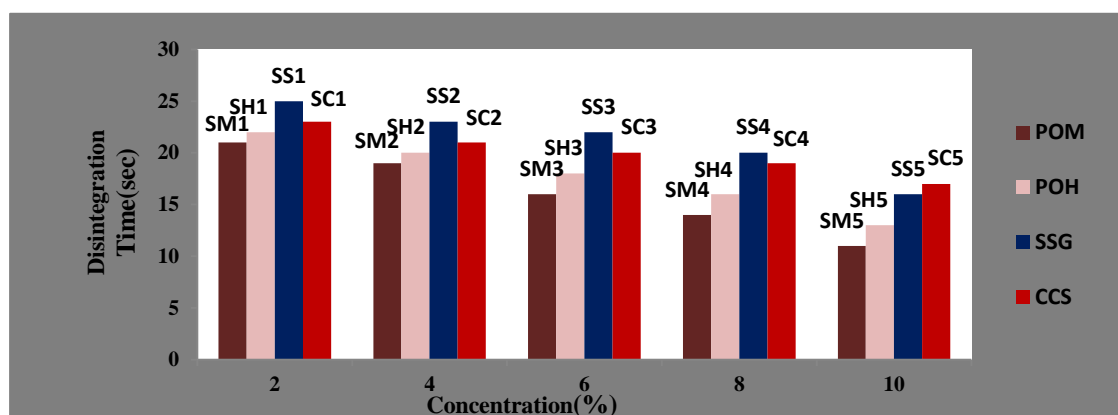
Table 4: Composition of formulation batches for fast dissolving tablet of Salbutamol sulphate having weight 100mg

Ingredients(mg)	Salbutamol Sulphate	PO M	PO H	CC S	SS G	Tal c	MC C	Colloidal SiO ₂	Mannitol	Aspartame	Vanillin
Formulation Code SM1	4	2	-	-	-	2	35	0.5	50	4	2
Formulation Code SM2	4	4	-	-	-	2	33	0.5	50	4	2
Formulation Code SM3	4	6	-	-	-	2	31	0.5	50	4	2
Formulation Code SM4	4	8	-	-	-	2	29	0.5	50	4	2
Formulation Code SM5	4	10	-	-	-	2	27	0.5	50	4	2
Formulation Code SH1	4	-	2	-	-	2	35	0.5	50	4	2
Formulation Code SH2	4	-	4	-	-	2	33	0.5	50	4	2
Formulation Code SH3	4	-	6	-	-	2	31	0.5	50	4	2
Formulation Code SH4	4	-	8	-	-	2	29	0.5	50	4	2
Formulation Code SH5	4	-	10	-	-	2	27	0.5	50	4	2
Formulation Code SC1	4	-	-	2	-	2	35	0.5	50	4	2
Formulation Code SC2	4	-	-	4	-	2	33	0.5	50	4	2
Formulation Code SC3	4	-	-	6	-	2	31	0.5	50	4	2
Formulation Code SC4	4	-	-	8	-	2	29	0.5	50	4	2
Formulation Code SC5	4	-	-	10	-	2	27	0.5	50	4	2
Formulation Code SS1	4	-	-	-	2	2	35	0.5	50	4	2
Formulation Code SS2	4	-	-	-	4	2	33	0.5	50	4	2
Formulation Code SS3	4	-	-	-	6	2	31	0.5	50	4	2
Formulation Code SS4	4	-	-	-	8	2	29	0.5	50	4	2
Formulation Code SS5	4	-	-	-	10	2	27	0.5	50	4	2

Table 5: Evaluation of blend for formulation batches

Formulation Code	Bulk Density (g/ml) ± S.D	Tapped Density (g/ml) ± S.D	Carr's Index (%) ± S.D	Hausner's Ratio ± S.D	Angle of repose (°) ± S.D	Flow ability
SM1	0.680± 0.007	0.782± 0.007	12.995±1.235	1.149±0.014	24.593± 1.120	Excellent
SM2	0.590± 0.010	0.672± 0.006	12.107±2.119	1.138 ±0.027	23.311±1.675	Excellent
SM3	0.613± 0.016	0.702± 0.011	12.738±1.958	1.146 ±0.025	23.408±1.331	Excellent
SM4	0.669 ±0.024	0.680± 0.018	11.599±1.213	1.137± 0.024	24.789±0.911	Excellent
SM5	0.598± 0.014	0.754± 0.010	11.088±1.837	1.129± 0.038	21.738±0.894	Excellent
SH1	0.668± 0.031	0.640± 0.023	10.809±1.259	1.130± 0.031	24.200±1.379	Excellent
SH2	0.567± 0.034	0.629± 0.010	12.895±1.215	1.125± 0.023	23.436±0.895	Excellent
SH3	0.618± 0.029	0.682± 0.050	12.117±2.117	1.136 ±0.030	24.962±1.611	Excellent
SH4	0.553± 0.019	0.783± 0.005	12.748±1.858	1.121± 0.015	24.485±1.380	Excellent
SH5	0.608± 0.041	0.674± 0.008	11.597±1.273	1.142±0.015	24.475±1.281	Excellent
SS1	0.681± 0.008	0.712± 0.011	11.098±1.877	1.134± 0.022	24.216±1.247	Excellent
SS2	0.588± 0.011	0.634± 0.028	10.819±1.279	1.123± 0.034	23.418±1.231	Excellent
SS3	0.611± 0.015	0.753± 0.011	12.985±1.245	1.128± 0.034	24.769±0.812	Excellent
SS4	0.665 ±0.028	0.643± 0.022	12.117±2.119	1.127± 0.022	21.758±0.874	Excellent
SS5	0.596± 0.012	0.627± 0.011	12.728±1.948	1.144 ±0.035	24.201±1.349	Excellent
SC1	0.638± 0.034	0.689± 0.053	11.589±1.113	1.177± 0.027	23.437±0.875	Excellent
SC2	0.609± 0.011	0.752± 0.011	11.088±1.437	1.124± 0.035	24.912±1.651	Excellent
SC3	0.661 ±0.023	0.641± 0.024	10.809±1.259	1.120± 0.021	24.475±1.280	Excellent
SC4	0.586± 0.011	0.621± 0.011	11.188±1.837	1.145± 0.024	24.455±1.381	Excellent
SC5	0.633± 0.032	0.642± 0.051	10.819±1.259	1.136± 0.021	24.226±1.217	Excellent

(± S.D represents mean standard deviation)

Figure 5: Comparison of natural and synthetic superdisintegrants at different concentrations Vs *In vitro* disintegration time of tablet

Pre-compression parameters were within prescribed limits and indicated good free flowing property. Batches which show best results are used for further study.

Here, Friability is less than 1 %, Drug content was found to be in the range of 98 to 101 % which is within acceptable limits. Hardness of the tablets was found to be in the range of 2.5-3.0 kg/cm². From the result it was found that formulations SM5, SH5, SS5, SC5 shown best results.

Disintegration time of salbutamol sulphate FDT's using mucilage of *Plantago ovata*, *Plantago ovata* husk powder, crosscarmellose sodium and sodium starch glycolate as superdisintegrants are shown in Figure 5.

Table 6: Evaluation of compressed tablets for formulation batches

Formulation Code	Weight Variation (% deviation) ± S.D	Hardness (kg/cm ²) ± S.D	Thickness (mm) ± S.D	Friability (%) ± S.D	In-vitro DT (sec) ± S.D	Drug Content (%) ± S.D	Water Absorption Ratio (%) ± S.D	Wetting Time (sec) ± S.D
SM1	98.7± 7.40	2.53± 0.057	3.6± 0.063	0.36± 0.007	21± 1.213	98.942± 0.12	55.46± 0.623	49± 0.164
SM2	101± 7.6	2.56± 0.052	3.4± 0.061	0.38± 0.006	19± 1.105	99.891± 0.17	53.30± 0.635	47± 0.197
SM3	98.9± 7.41	2.52± 0.053	3.2± 0.065	0.34± 0.009	16± 1.132	99.242± 0.45	55.58± 0.659	45± 0.164
SM4	98± 7.2	2.53± 0.057	3.76± 0.067	0.256± 0.002	14.67± 1.154	99.64± 0.82	55.25± 0.138	43± 2.645
SM5	102± 7.69	2.55± 0.061	3.7± 0.066	0.39± 0.015	12± 1.152	98.212± 0.23	55.56± 0.432	42± 0.136
SH1	99.05± 7.42	2.56± 0.059	3.5± 0.059	0.35± 0.016	22± 1.165	99.215± 0.26	54.63± 0.645	52± 0.187
SH2	98± 7.3	2.55± 0.051	3.9± 0.058	0.33± 0.005	20± 1.134	98.220± 0.29	53.54± 0.635	50± 0.465
SH3	101± 7.5	2.59± 0.056	3.3± 0.056	0.38± 0.042	18± 1.132	98.221± 0.26	53.62± 0.125	48± 0.152
SH4	100± 7.42	2.56± 0.057	3.86± 0.057	0.461± 0.002	16.33± 1.154	99.27± 0.91	54.23± 0.703	46± 0.215
SH5	98.2± 7.36	2.63± 0.054	3.4± 0.063	0.27± 0.003	14± 1.145	98.721± 0.26	53.45± 0.345	44± 0.175
SS1	98± 7.41	2.69± 0.058	3.9± 0.065	0.29± 0.019	25± 1.123	97.210± 0.53	54.54± 0.345	73± 0.365
SS2	100± 7.43	2.54± 0.062	2.9± 0.064	0.31± 0.015	23± 1.102	98.212± 0.65	55.00± 0.345	71± 0.145
SS3	99± 7.42	2.47± 0.064	3.1± 0.066	0.28± 0.005	20± 1.131	98.450± 0.26	54.64± 0.659	69± 0.136
SS4	99± 7.43	2.56± 0.057	3.76± 0.057	0.153± 0.001	18.67± 1.52	99.15± 0.81	55.213± 0.114	64± 0.154
SS5	98.7± 7.40	2.53± 0.063	3.9± 0.059	0.26± 0.004	16± 1.326	98.254± 0.28	55.64± 0.263	59± 0.132
SC1	98± 7.41	2.58± 0.052	3.4± 0.061	0.37± 0.006	23± 1.147	98.654± 0.27	54.52± 0.645	54± 0.135
SC2	99± 7.42	2.65± 0.061	3.6± 0.063	0.45± 0.009	21± 1.132	98.214± 0.42	55.62± 0.152	53± 0.132
SC3	101± 7.57	2.56± 0.049	3.5± 0.065	0.48± 0.016	19± 1.156	99.254± 0.46	55.66± 0.356	51± 0.215
SC4	99± 7.42	2.66± 0.057	3.83± 0.057	0.35± 0.0152	16.33± 1.154	99.12± 1.045	56.71± 0.762	49± 0.154
SC5	101± 7.57	2.54± 0.053	2.9± 0.059	0.44± 0.006	14± 1.152	98.247± 0.49	54.66± 0.236	47± 0.214

(± S.D represents mean standard deviation)

Comparative Dissolution Profiles of all the formulations

The *in-vitro* dissolution profiles of prepared tablets are shown in Table 7.

Table 7: Comparative Dissolution Profiles of all the formulations

Time (min) / Formulations	1 ± S.D	2 ± S.D	4 ± S.D	6 ± S.D	8 ± S.D	10 ± S.D
SM1	74.23± 0.11	78.86± 0.16	82.24± 0.21	86.34± 0.24	91.32± 0.26	94.97± 0.31
SM2	75.36± 0.13	80.72± 0.11	83.31± 0.16	87.46± 0.15	92.23± 0.31	95.48± 0.33
SM3	76.98± 0.14	80.23± 0.14	84.63± 0.13	88.43± 0.17	93.62± 0.12	96.32± 0.21
SM4	77.87± 0.22	79.93± 0.16	85.14± 0.31	89.42± 0.24	94.31± 0.31	97.62± 0.31
SM5	78.27± 0.12	81.36± 0.21	86.21± 0.16	91.47± 0.11	95.21± 0.31	99.43± 0.32
SH1	73.23± 0.16	77.76± 0.12	81.21± 0.15	87.83± 0.16	90.32± 0.38	92.47± 0.16
SH2	75.67± 0.17	78.97± 0.16	82.13± 0.25	88.42± 0.21	92.46± 0.32	94.84± 0.18
SH3	76.43± 0.11	79.72± 0.17	82.42± 0.21	88.81± 0.21	93.12± 0.34	95.44± 0.31
SH4	76.61± 0.21	80.76± 0.23	82.83± 0.24	88.94± 0.31	93.42± 0.24	96.48± 0.34
SH5	77.21± 0.11	83.88± 0.16	86.11± 0.35	89.42± 0.31	94.47± 0.32	98.83± 0.24
SS1	74.46± 0.13	76.23± 0.13	81.42± 0.25	85.66± 0.35	91.23± 0.32	94.69± 0.24
SS2	75.42± 0.11	77.21± 0.21	82.42± 0.21	87.98± 0.31	93.42± 0.21	96.69± 0.21
SS3	76.62± 0.16	79.21± 0.16	82.89± 0.14	88.21± 0.16	94.49± 0.19	97.21± 0.22
SS4	77.29± 0.26	80.84± 0.24	83.21± 0.24	89.62± 0.24	95.12± 0.22	98.89± 0.23
SS5	78.92± 0.11	82.05± 0.15	86.87± 0.16	91.21± 0.21	97.98± 0.23	98.92± 0.31
SC1	73.73± 0.16	76.21± 0.22	81.58± 0.31	84.76± 0.31	89.82± 0.38	94.97± 0.35
SC2	75.17± 0.13	79.22± 0.35	84.56± 0.32	87.89± 0.42	91.92± 0.41	96.01± 0.42
SC3	76.38± 0.24	80.92± 0.16	85.43± 0.35	88.56± 0.32	92.66± 0.36	97.72± 0.25
SC4	77.69± 0.11	81.74± 0.39	86.92± 0.31	89.15± 0.36	93.33± 0.34	98.45± 0.37
SC5	77.93± 0.12	81.96± 0.11	87.23± 0.21	91.76± 0.21	94.21± 0.15	98.97± 0.25

(± S.D represents mean standard deviation)

The graphical representation of *in-vitro* dissolution profiles of prepare tablets are shown in Figure 6 and 7.

1) Comparative dissolution profiles of comparable formulations SM5, SH5, SC5 and SS5.

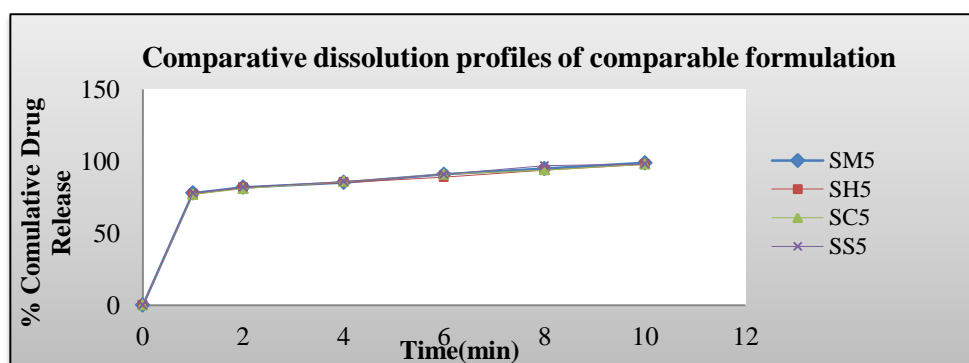


Figure 6: Comparative dissolution profiles of comparable formulations SM5, SH5, SC5 and SS5

2) Comparative dissolution profiles of all SM1-SM5, SH1-SH5, SS1-SS5, SC1-SC5 formulations

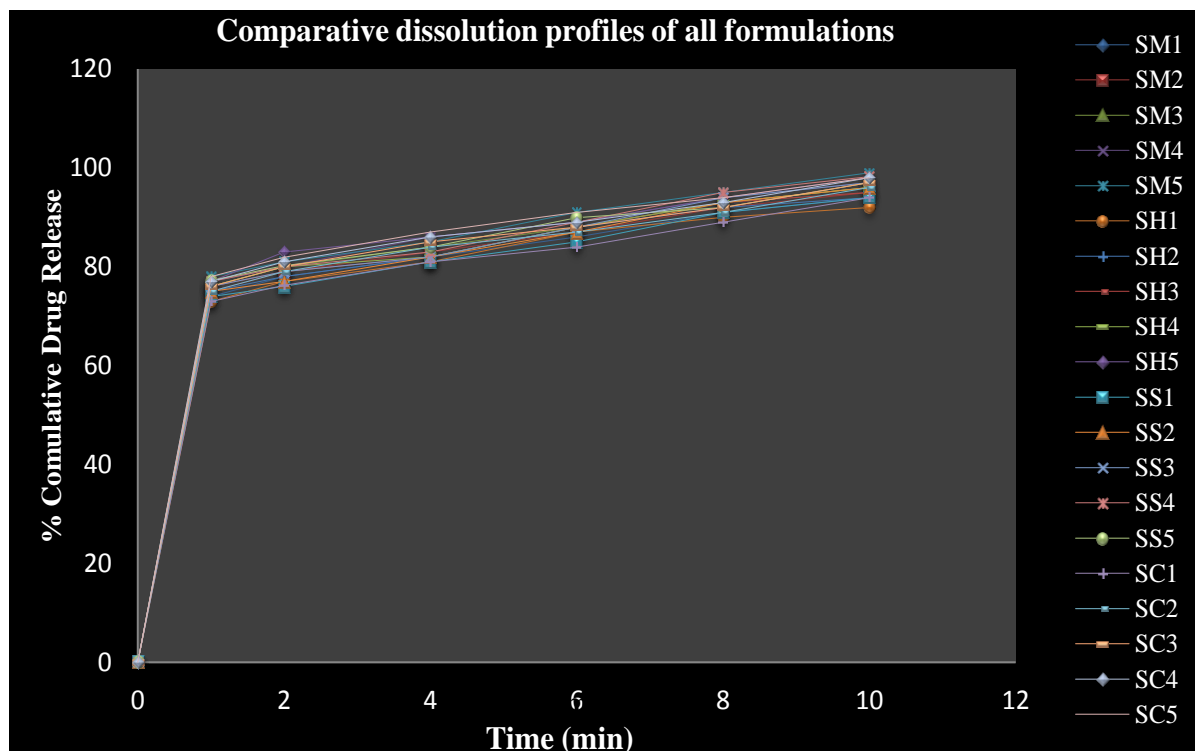


Figure 7: Comparative dissolution profiles of all SM1-SM5, SH1-SH5, SS1-SS5, SC1-SC5 formulations

Among all the designed formulations SM5, SH5, SC5, SS5 was found to be promising and displayed better results. The formulations SM5, SH5 10% w/w of mucilage of *Plantago ovata* and husk powder has shown comparable results in all respects than SC5 and SS5 formulations. *In-vitro* dissolution studies on these formulations revealed that more than 90% drug released within 10 min.

Stability studies

No appreciable change in physical characteristics, the results concluded that fast dissolving tablets of salbutamol sulphate were stable during accelerated stability conditions up to three months. (Data not shown).

CONCLUSION

Finally it is concluded that disintegrating properties of the mucilage and husk powder of *Plantago ovata* has been studied in comparison with croscarmellose sodium and

sodium starch glycolate. The isolated natural disintegrant exhibited faster drug dissolution in comparison to the synthetic superdisintegrants. These formulations improve the bioavailability and effective therapy using *Plantago ovata* mucilage as natural superdisintegrant. Therefore, in the years to come, there will be continued interest in natural mucilages and their modifications aimed at the development of better materials for drug delivery systems.

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