

DEVELOPMENT AND EVALUATION OF FAST DISINTEGRANT TABLETS (FDTs) OF TERBUTALINE SULPHATE

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ABSTRACT

The purpose of this study was to evaluate the effect of superdisintegrants on the mouth dissolving property of fast disintegrants tablets (FDTs) of terbutaline sulphate. Fast dissolving tablets of terbutaline sulphate were prepared by direct compression method; using superdisintegrants sodium starch glycolate (F1-F3) and sodium carboxy methyl cellulose (F4-F6), designated as six different types of formulation at different concentration of 6%, 12%, 18% respectively and keeping constant concentration of drug and excipients were used to formulate fast disintegrants tablets. Formulations were evaluated for Precompression parameters such as bulk density, tapped

density, angle of repose, Carr's index and Hausner's ratio. Post compressed parameters like thickness, hardness, friability, wetting time, weight variation, drug content uniformity, in-vitro disintegration time and in-vitro dissolution studies of compressed tablets. Drug-superdisintegrants interaction studies were characterized by FTIR spectroscopy. The values of Pre-compression parameters evaluated were within prescribed limits and indicated good free flowing property. All the post compression parameters evaluated were found within IP acceptable limits. No chemical interaction between drug and superdisintegrants confirmed by FTIR. Thickness of tablets was found in the acceptable range of 2.20 mm. Hardness and friability of tablets was found to be 2.5-4.2 Kg/cm² and 0.13-0.26% respectively. The *in vitro* disintegration time were found to be 14-38 sec. result fulfil the official requirements. The drug content uniformity and wetting time was found in between 91-97% and 35-78 sec respectively, results were within IP acceptable limits. The *in vitro* dissolution release of drug was found to be in acceptable range of 73-98%.

KEYWORDS: Fast disintegrants tablets, Superdisintegrants, Terbutaline sulphate, Direct compression method, FTIR.

INTRODUCTION

A fast disintegrants tablets (FDTs) can be defined as an oral solid dosage form which when placed on tongue disintegrates rapidly, releasing the drug, which dissolves or disperses in the saliva and then swallowed. Some drugs are absorbed from the mouth, pharynx, and oesophagus as the saliva passes down in to the stomach. The main problem with the common oral dosage forms is that they have to be swallowed along with water. Many patients find it difficult to swallow tablets, especially in elderly and paediatrics, because of the physiological changes associated with these groups. Due to this dysphagic condition, they do not comply with prescription which results in patient non-compliance. The other causes of patient non-compliance include sudden episodes of allergic attacks, motion sickness, coughing and unavailability of water etc. These problems can be resolved by fast dissolving tablets, which do not require water to aid in swallowing.^[1,2]

‘Fast Dissolve’, ‘Quick Dissolve’, ‘Rapid Melt’, ‘Quick Disintegrating’, ‘Mouth Dissolving’, ‘Orally Disintegrating’, ‘Oro Dispersible’, ‘Melt-in-Mouth’ etc. are terms that represent the same drug delivery systems. Recently Orally Disintegrating (OD) Tablet technology has been approved by United States Pharmacopoeia (USP), Centre for Drug Evaluation and Research (CDER). USFDA defined OD tablet as “A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue”. Recently European Pharmacopoeia also adopted the term “Oro-Dispersible tablet” as a tablet that is to be placed in the mouth where it disperses rapidly before swallowing. These dosage forms dissolve or disintegrate in the patient’s mouth within 15 seconds to 3 minutes without the need of water or chewing. Despite various terminologies used, Oro-Dispersible tablets are here to offer unique form of drug delivery with many advantages over the conventional oral solid dosage forms.^[3]

Terbutaline is a β_2 selective bronchodilator. It is effective when taken orally, subcutaneously or by inhalation. Effects are observed rapidly after inhalation or parental administration. After inhalation its action may persist for 3 to 6 hours. With oral administration, the onset of effect may be delayed for 1 to 2 hours.^[4,5] The type of actions of representative agents at peripheral adrenergic neuro-effector junctions of Terbutaline sulphate or β_2 adrenergic receptor is by mimicry of transmitter at post synaptic receptor. The effect is produced by the selective

inhibition of smooth muscle contraction. Terbutaline is used in the treatment of asthma, chronic bronchitis, emphysema and other bronchopulmonary disorders involving bronchospasm. Terbutaline sulphate FDTs were prepared to achieve quick onset of action and for maximum bioavailability, for quick response for better patient's compliance and effective treatment.

Superdisintegrants are a crucial aspect of an orally disintegrating tablet formulation. In order to accomplish disintegration in under 1-3 minute, tablets are composed of special ingredients including superdisintegrants such as crospovidone, croscarmellose sodium or sodium starch glycolate⁹. These materials allow for rapid uptake of water and are manufactured with low compression force to achieve the fast disintegrants effect.^[6,7]

Fast disintegrants tablet formulated by direct compression method,^[8] spray drying,^[9,10] tablet moulding^[11-12], wet/dry granulation techniques by using superdisintegrants,^[13-14] sublimation,^[15-16] freeze drying techniques,^[17] effervescent techniques.^[18,19]

Characteristics of ideal fast dissolving tablets^[20-23]

1. They should not require water for administration, yet dissolve or disintegrate in the mouth within a few seconds.
2. They should be compatible with taste masking.
3. They should be portable without fragility concerns.
4. They should have a pleasing mouth feel.
5. They should leave minimal or no residue in the mouth after oral administration.
6. They should allow high drug loading.
7. They should exhibit low sensitivity to environmental conditions such as humidity and temperature.
8. They should be manufactured using conventional tablet processing and packaging equipments at low cost.

The aim of present study was to formulation development and characterization of fast disintegrants tablets of Terbutaline sulphate in the presence of two different superdisintegrants. Moreover, the objective was to evaluate the effect of Superdisintegrant in formulation development.

MATERIALS AND METHODS

The standard API of Terbutaline sulphate was purchased from Yarrow Chem Products, Wadala Mumbai, India. Superdisintegrants sodium starch glycolate and sodium carboxy methyl cellulose was obtained from Yarrow Chem Product, Mumbai, India provided by R. V. Northland Dadri, Greater Noida, G. B. Nagar. Mannitol, magnesium stearate and microcrystalline cellulose were procured from Central Drug House (P) Ltd, New Delhi and Talc was obtained from Qualikems Fine Chemical (P) Ltd, New Delhi.

METHODS

Preformulation study

Identification of drug

The identification of drug was observed for their organoleptic properties, physical appearances and melting point, solubility and determination of purity of API by UV-Spectroscopy.

Determination of λ_{\max} and preparation of calibration curve of drug

1. Preparation of standard stock solution

100 mg of terbutaline sulphate was accurately weighed and transferred in to a 100 ml volumetric flask and dissolved in distilled water. Then volume was made up to 100 ml. This was the standard stock solution of 1000 $\mu\text{g/ml}$ of Terbutaline Sulphate (Stock A).

2. Spectrophotometric scanning of terbutaline sulphate

From the standard stock solution prepared in distilled water (Stock A), 0.5 ml solution was pipette out and volume was made up to 10 ml in a 10 ml volumetric flask, and the UV scan was taken between wavelengths of 200-400 nm. The blank used here was distilled water and the wavelength for maximum absorbance was noted from the scan at 276.0 nm.

3. Preparation of calibration curve of terbutaline sulphate

From the standard stock solution of terbutaline sulphate (Stock A), 1 ml was pipette out and volume was made up to 10 ml in a 10 ml volumetric flask (Stock B). From this stock B, again aliquots of samples pipette out ranging from volumes 1,2,3,4,5 and 6 ml into 10 ml volumetric flasks and volume was made up using distilled water to produce concentrations 10, 20, 30, 40, 50 and 60 $\mu\text{g/ml}$ respectively. The absorbance was measured at 276.0 nm against distilled water as blank. Plotted a calibration curve of Terbutaline Sulphate using concentration and absorbance on X and Y-axis respectively.

Drug – excipient interaction study by Fourier transform infrared spectroscopy: FTIR

The Fourier Transform Infrared (FTIR) spectra of Terbutaline sulphate, sodium starch glycolate, sodium carboxy methyl cellulose, Terbutaline sulphate + sodium starch glycolate and Terbutaline sulphate + sodium carboxy methyl cellulose were obtained by using a FTIR spectrophotometer (Perkin Elmer). About 1-2 mg sample was mixed with dried KBr (1:200) and compressed to form a transparent KBr pellets. The samples were scanned from 400-4000 cm^{-1} .

Formulation of Fast Mouth Dissolving Tablets

Fast dissolving tablets of terbutaline sulphate were prepared using direct compression method incorporating superdisintegrants sodium starch glycolate (SSC) and Sodium Carboxy Methyl Cellulose (SCMS). The drug, diluents, superdisintegrants and sweetner were screened through 40 mesh and properly mixed together. Talc and magnesium stearate were passed through 80 mesh size sieve and blended with motor pistol. Powder thus obtained was compressed into tablets on an 8 station single punch rotary tablet compression machine. A biconvex punch 8 mm in diameter was used for tablet. Compression force of the machine was adjusted to obtain the hardness of 3-5 kg/cm^2 . The prepared tablets were packed in an aluminium foil pouch.

EVALUATION PARAMETER OF FAST MOUTH DISSOLVING TABLETS^[24-30]**PRE-COMPRESSION PARAMETERS****• Bulk density**

Apparent bulk density (g/ml) was determined by placing pre-sieved bulk powder blend into a graduated cylinder via a large cylinder and measuring the volume and weight by following.

$$\text{Bulk Density} = \frac{\text{Mass of the powder}}{\text{Bulk volume of the powder}}$$

• Tapped density

Tapped density was determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 10 cm at 2 second intervals. The tapping was continued until no further change in volume was noted.

$$\text{Tapped density} = \frac{\text{Mass of the powder}}{\text{volume of the tapped packing}}$$

- **Compressibility index**

The simplex way of measurement of the free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility index of the powder was determined by Carr's compressibility index (C) which is calculated by using the following formula.

$$\text{Carr's compressibility index} = \frac{\text{Tapped density} - \text{bulk density}}{\text{Tapped density}}$$

- **Hausner's ratio**

Flow property of powder was determined by Hausner's ratio calculated by following formula.

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{bulk density}}$$

- **Angle of repose**

The frictional force of blend powder can be measurement by the angle of repose. The powder was allowed to flow through the funnel fixed to a stand at definite height. The angle of repose was then calculated by measuring the height and radius of the heap of powder formed.

$$\text{Tan } \theta = \frac{h}{r}$$

Where, θ is the angle of repose, h is height and r is radius.

POST COMPRESSED PARAMETERS

- **Thickness of tablets**

The thickness of tablets was measured using vernier calliper. The extent to which the thickness of each tablet deviated from $\pm 5\%$ of the standard value was determined.

- **Hardness and friability of tablets**

Hardness of the Tablet was determined by Monsanto Hardness Tester. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet, and a zero reading is taken. The upper plunger is then forced against a spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded and zero reading is deducted from it. Six tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded.

Friability of Tablets was performed in a Roche Friabilator. It consists of a plastic chamber that revolves at 25 rpm. About ten tablets were weighed together and then placed in the chamber. The Friabilator was operated for 100 revolutions and the tablets were subjected to the combined effects of abrasion and shock because the plastic chamber carrying the tablets drops them at a distance of six inches with every revolution. The tablets are then dusted and re-weighed.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W_1} \times 100$$

- **Wetting time of tablets**

A piece of tissue paper folded twice was placed in a small petridish (internal diameter = 6.5 cm) containing 6 ml of simulated saliva pH (phosphate buffer pH 6.8). A tablet was put on the paper and the time required for complete wetting was measured expressed as average wetting time and standard deviation.

- **Weight Variation and content uniformity**

Uniformity of weight test as described in the IP was followed. Twenty tablets were selected at random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with the average weight. The percentage deviation was calculated and checked for weight variation. Using this procedure weight variation range of all batches of formulations were determined and recorded.

Uniformity of drug content was determined as described in the IP, one tablet was powdered and transferred to a 50 ml volumetric flask containing 10 ml of distilled water and mixture was shaken for 10 minutes. The volume was made up to mark with distilled water and filtered. The first 5 ml of filtrate was rejected, and after suitable dilution (here 10 times) the sample was analyzed spectrophotometrically at 276 nm and drug content was determined.

- ***In-vitro* disintegration test**

A tablet was put into 10 ml of Phosphate buffer solution; pH 6.8 (simulated saliva pH) at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Time required for complete disintegration of a tablet was recorded. This test was performed for six tablets from each batch and average time taken for dispersion with standard deviation was recorded.

- ***In-vitro* dissolution studies**

In-vitro dissolution study was performed by using USP Type II Apparatus (Paddle type) at 100 rpm. Distilled water 900 ml was used as dissolution medium, and the temperature of which maintained at $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Aliquots of dissolution medium (10 ml) were withdrawn at specific time intervals (3 minutes) and were filtered and the first 5 ml of the filtrate was rejected. The amount of drug dissolved was determined by UV spectrophotometer by measuring the absorbance of the sample at 276.0 nm. Three trials for each batch were performed and average percentage drug release with standard deviation was calculated and recorded.

RESULTS AND DISCUSSION

Preformulation study

Colour	White to greyish white crystalline powder
Nature	It exhibits polymorphism.
Odour	Odourless or with a faint odour of acetic acid.
Melting point	Melting point was found to be 248°C which was determined by capillary method
Solubility	Freely soluble in water, slightly soluble in alcohol and in methyl alcohol; practically insoluble in chloroform and ether.

Determination of λ_{max} and preparation of calibration curve of drug

The standard stock solution was prepared as per the method described in method and scanned by UV Spectrophotometric. The λ_{max} was found to be 276 nm against distilled water as blank. (Fig. 1)

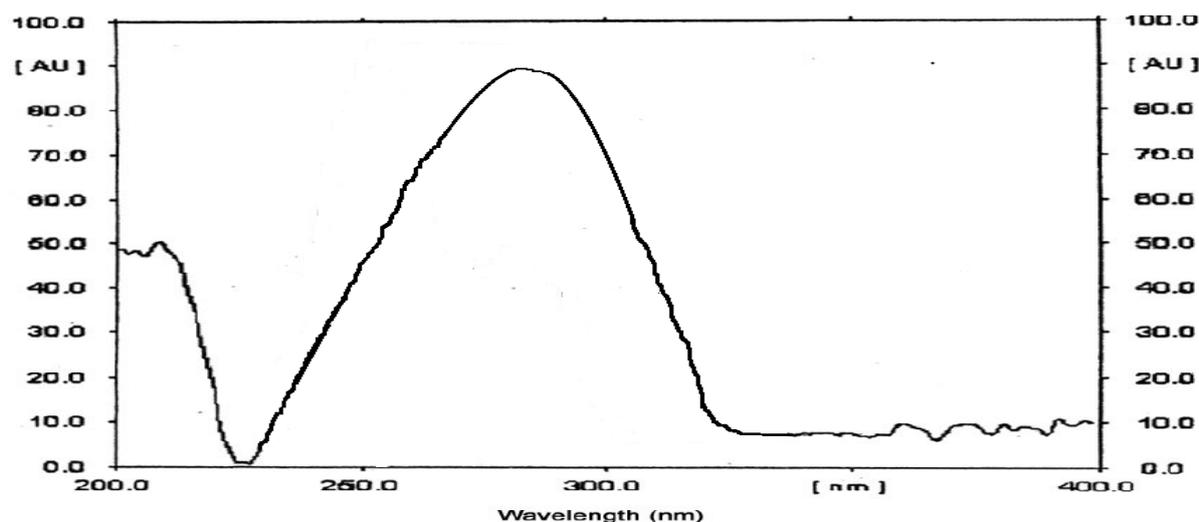


Figure 1: UV scanning graph of terbutaline sulphate in distilled water.

Linearity was observed in the concentration range of 10-60 $\mu\text{g/ml}$ (Table 1). Linear absorbance versus concentration gives regression equation; $Y = 0.019X + 0.204$, with a

correlation coefficient (r^2) 0.999 in distilled water. (Fig. 2)

Table1. Concentration range of calibration curve

Sr.No	Concentration ($\mu\text{g/ml}$)	Absorbance
1	10	0.400
2	20	0.590
3	30	0.800
4	40	1.010
5	50	1.190
6	60	1.380

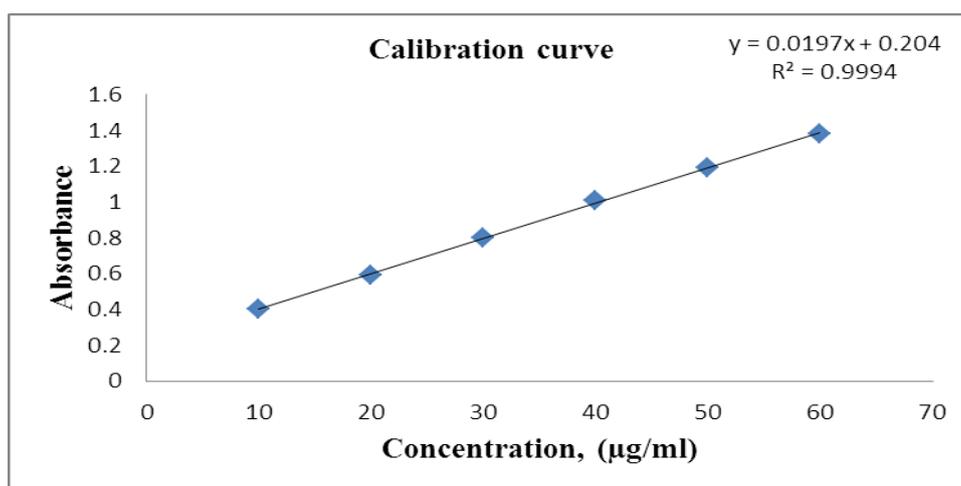


Figure 2: Calibration curve of terbutaline sulphate

Drug – excipients interaction study by Fourier transform infrared spectroscopy: FTIR

Fourier transform infrared analysis was conducted to verify the possibility of interaction of chemical bonds between drug and superdisintegrants. In the present investigation FTIR spectra of pure drug and mixture of superdisintegrants was analyzed using FTIR spectrophotometer for characteristics absorption bands, indicative of their interaction. There was no interaction found between drugs, Superdisintegrant as well as in physical mixture of drug and superdisintegrants as shown in (Fig. 3a-e) and interpretation was shown in (Table2).

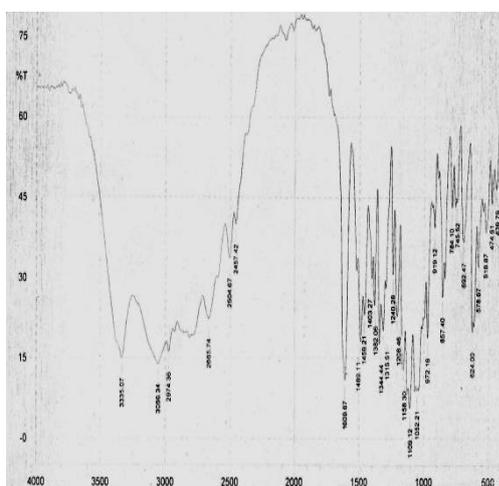
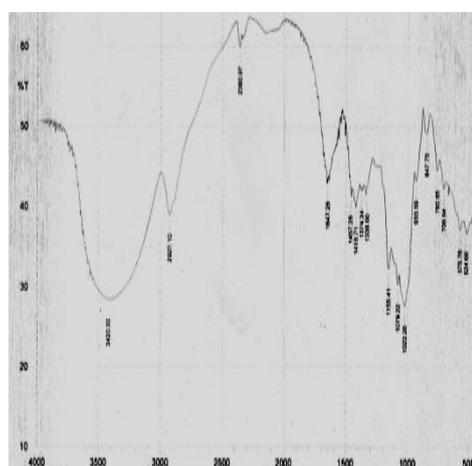
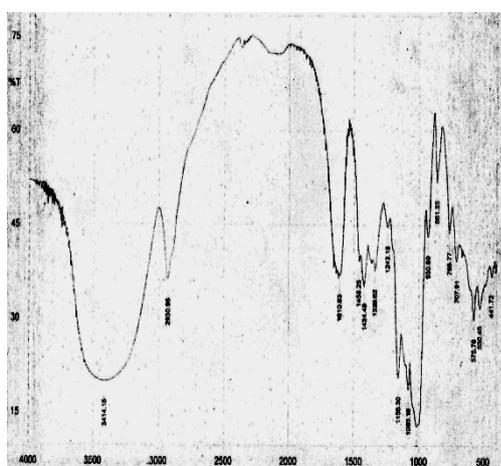
Table2: Interpretation of IR spectra

Sample	Interpretation of IR Spectra		
A	3335 cm^{-1} (hydroxyl group), confirm by C-O-H at 1315 cm^{-1} .	847-706 cm^{-1} (ortho and meta disubstituted compound)	1315 cm^{-1} (indicate presence of C-O-H group)
B	3414 cm^{-1} (hydroxyl group)	2974 cm^{-1} (C-H, SP^3 stretch- ing)	1339-1080 cm^{-1} (ester group)
C	3420 cm^{-1} (hydroxyl group)	847-706 cm^{-1} (substituted aromatic compound)	1338-1079 cm^{-1} (ester group)

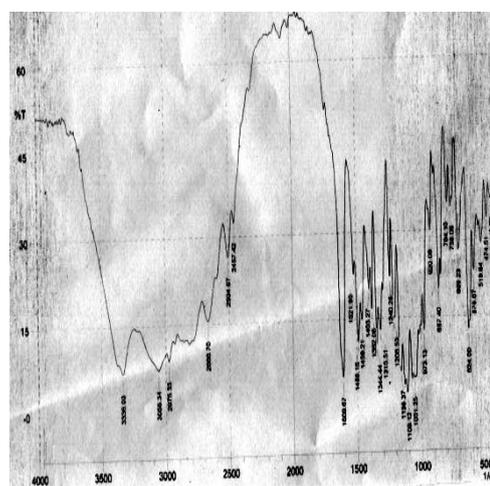
A+B	3335 cm ⁻¹ (hydroxyl group)	2930 cm ⁻¹ (C-H, SP ³) and 1242- 1039 cm ⁻¹ (ester group)	760 cm ⁻¹ (ortho disubstituted aromatic compound)
A+C	3336 cm ⁻¹ (hydroxyl group)	784-699 cm ⁻¹ (disubstituted aromatic compound)	1315-1051 cm ⁻¹ (presence of ester group)

A - Terbutaline sulphate, B - Sodium starch glycolate (SSC), C - Sodium carboxy methyl cellulose

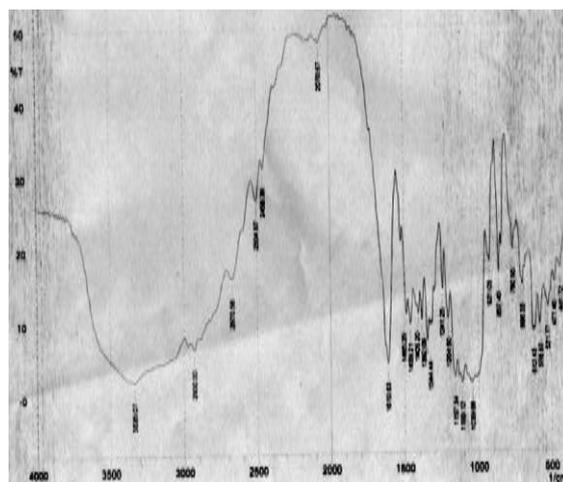
A+B - Terbutaline sulphate+Sodium starch glycolate, A+C - Terbutaline sulphate+ Sodium carboxy methyl cellulose



(c)



(d)



(e)

Figure 3. FTIR of (a) FTIR of sodium starch glycolate (b) sodium carboxy methyl cellulose (c) terbutaline sulphate and SSC (d) terbutaline sulphate and (e) terbutaline sulphate and sodium carboxy methyl cellulose.

Formulation of Fast Mouth Dissolving Tablets

Fast dissolving tablets of Terbutaline sulphate were prepared using direct compression method. Typically, different concentration of incorporating superdisintegrants sodium starch glycolate (SSC) and Sodium Carboxy Methyl Cellulose (SCMS) and keeping constant concentration of terbutaline sulphate, mannitol, magnesium stearate, talc and microcrystalline cellulose were used to formulate fast disintegrants of tablets. The six composition of formulation (F1-F6) were formulated as shown in the (Table-3).

Table 3: Composition of fast disintegrants tablets of terbutaline sulphate

S. No	Tablet Ingredients (mg/tab)	Formulation code					
		F ₁	F ₂	F ₃	F ₄	F ₅	F ₆
1	Terbutaline sulphate	015	015	015	015	015	015
2	Sodium starch glycolate	012	018	024	-	-	-
3	Sodium Carboxy Methyl Cellulose	-	-	-	012	018	024
4	Mannitol	030	030	030	030	030	030
5	Magnesium Stearate	006	006	006	006	006	006
6	Talc	006	006	006	006	006	006
7	Microcrystalline cellulose	231	225	219	231	225	219
	Total weight	300	300	300	300	300	300

Evaluation Parameter of Fast Mouth Dissolving Tablets^[24-30]**Pre-compression Parameters**

Precompression parameters like bulk density, tapped density, compressibility index, Hausner's ratio and angle of repose of prepared compositions were determined as per specification limit found in the acceptable range results were shown in (Table 4).

Table 4: Pre-compression parameters

Sr. No	Formulation Batches	Angle of Repose*	Bulk Density*	Tapped Density*	Carr's Index*	Hausner's Ratio*
1	F ₁	37.560	0.430	0.511	15.830	1.190
2	F ₂	38.659	0.463	0.569	18.690	1.230
3	F ₃	34.915	0.442	0.553	20.000	1.250
4	F ₄	33.023	0.483	0.576	17.240	1.190
5	F ₅	37.234	0.441	0.546	19.230	1.240
6	F ₆	29.030	0.468	0.568	17.500	1.210

*Average of two determination

Post compressed parameters

- **Thickness of tablets**

Acceptable range of 1 mm to 1.2 mm ($\pm 5\%$ of the average thickness of 10 tablets). Thickness of tablets was measured by vernier callipers and thickness of all the formulation was found in the acceptable range of 2.20 mm ($\pm 5\%$ of the average thickness of 10 tablets) (Table 5).

Table 5: Thickness of tablets

Formulation Code	F1	F2	F3	F4	F5	F6
Thickness* (mm) \pm SD	2.20 \pm 0.02	2.20 \pm 0.01	2.20 \pm 0.01	2.20 \pm 0.08	2.20 \pm 0.02	2.20 \pm 0.03

*Average of three determination, SD- standard deviation

- **Hardness and friability test of tablets**

The average hardness of tablets was found in the range of 2.5-4.2 Kg/cm². The friability of all formulations were checked by Roche Friabilator and the average friability of all formulations were found in the range of 0.13% to 0.26% indicate in acceptable range (Table 6).

Table 6: Hardness and friability of tablet

Formulation Code	Hardness* (Kg/cm ²) ± S.D.	Friability %
F1	3.63 ± 0.04	0.21
F2	3.31 ± 0.08	0.22
F3	2.50 ± 0.03	0.13
F4	3.32 ± 0.09	0.26
F5	4.23 ± 0.02	0.23
F6	3.63 ± 0.05	0.22

*Average of three determination, SD- standard deviation

- **Wetting time of tablets**

All the formulations were evaluated for the wetting time and the average wetting time of all the formulations were found in the range of 35 to 78 seconds which represent fast disintegrants nature of formulated tablets (Table 7).

Weight Variation and Uniformity of Content

Uniformity of weight test for all the formulations were carried out using the procedure described in methodology section. The result of weight variation is shown in (Table 8). And content uniformity of formulated tablets was obtained, found in the range compliance to IP limits (Table 9).

TABLE 7: Wetting time of tablets

Formulation Code	Wetting time (Seconds) ± SD*
F ₁	66 ± 0.04
F ₂	50 ± 0.06
F ₃	35 ± 0.05
F ₄	59 ± 0.03
F ₅	78 ± 0.09
F ₆	60 ± 0.05

*SD- Standard deviation

Table 8: Weight variation of tablets

Formulation Code	Average Weight of Tablet* (mg)	% Weight Variation Range
F1	302.2	-1.40 to 1.34%
F2	301.3	-2.21 to 1.76%
F3	305.2	-2.24 to 1.48%
F4	298.9	-1.71 to 1.72%
F5	302.4	-1.58 to 1.47%
F6	301.7	-1.68 to 1.56%

* Average of three determination

Table 9: Drug content of tablets

Formulation Code	% Drug Content* w/w	Compliance with the IP limit
F ₁	92.2908% - 96.4785%	Complies
F ₂	93.7965% - 101.6318%	Complies
F ₃	94.2412% - 103.9728%	Complies
F ₄	91.3023% - 98.8195%	Complies
F ₅	94.3023% - 101.8195%	Complies
F ₆	97.3023% - 102.8195%	Complies

*Average of two determination

***In-vitro* Disintegration Test**

The disintegrating time of formulated tablets was found in the range of 14.18-38.68 second. Which indicate acceptable composition of tablets with reference to disintegration time of fast disintegration tablets (1-3 min.) as per IP specification (Table 10).

Table 10: *In vitro* Disintegration test of Terbutaline sulphate

No of Tablets	Formulation Batches (disintegrating time*, sec.)					
	F ₁	F ₂	F ₃	F ₄	F ₅	F ₆
1	15.8	22.3	12.8	19.2	38.6	22.9
2	14.6	19.1	14.1	20.0	40.3	23.9
3	15.4	21.5	15.6	20.6	36.6	23.1
4	20.8	22.7	14.5	22.9	39.8	20.6
5	17.2	23.2	13.9	18.2	38.1	21.0
n=5	Avg=16.76	Avg=21.76	Avg=14.18	Avg=20.18	Avg=38.68	Avg=22.30

*Average of five determination

***In vitro* Dissolution Studies**

In vitro dissolution studies were performed as per the procedure described in methodology section. The results of *in vitro* drug release studies of the formulations are shown in (Table 11). The percentage amount of drug released was plotted against time to obtain drug release profile as shown in (Fig. 4).

Table 11: *In vitro* dissolution profile data of tablets

Formulation Code	Percentage drug release* \pm SD			
	3 minutes	6 minutes	9 minutes	12 minutes
F1	73.23 \pm 0.029%	78.47 \pm 0.081%	86.39 \pm 0.142%	92.80 \pm 0.112%
F2	76.79 \pm 0.110%	83.06 \pm 0.293%	89.15 \pm 0.043%	94.27 \pm 0.025%
F3	87.73 \pm 0.242%	88.32 \pm 0.102%	94.11 \pm 0.018%	97.57 \pm 0.013%
F4	75.26 \pm 0.068%	79.14 \pm 0.089%	84.08 \pm 0.062%	89.04 \pm 0.018%
F5	77.26 \pm 0.004%	82.31 \pm 0.008%	86.06 \pm 0.008%	93.13 \pm 0.034%
F6	76.37 \pm 0.061%	78.23 \pm 0.065%	87.16 \pm 0.031%	96.45 \pm 0.051%

* Average of three determination

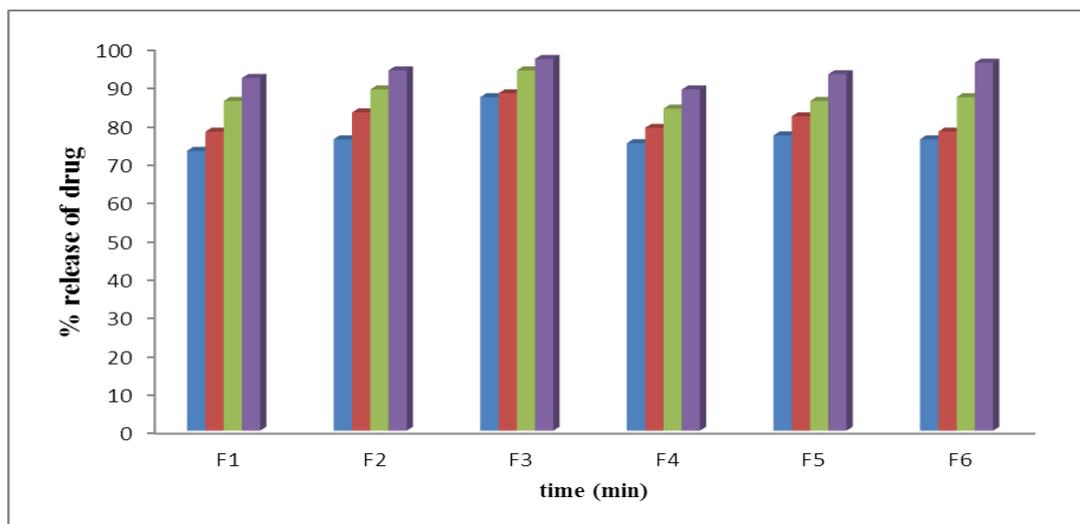


Figure4: In-vitro release graph of F1-F6 at 3, 6, 9 and 12 min. respectively.

CONCLUSION

From this study it is concluded that fast disintegrants tablets could be prepared by direct compression method using different superdisintegrants that enhanced dissolution will lead to improved bioavailability. A total of six formulations (F1-F6) were prepared with different concentration of superdisintegrants 6%, 12% and 18% respectively and keeping constant concentration of drug and other excipients used to formulate fast disintegrants tablets. Pre-compressed and post compressed parameters of formulations were evaluated and found to be within the acceptable limits and official specification and requirements. All the fast disintegrants tablets formulation gets dispersed within a time period of less than one minute. Tablets containing superdisintegrants sodium carboxy methyl cellulose exhibit quick disintegration time than tablets containing sodium starch glycolate.

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