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FORMULATION AND IN VITRO EVALUATION OF ORAL DISINTEGRATING TABLETS OF TERBUTALINE SULPHATE

SHAIK RAHANAPARVEEN[1], MARINAGANTI RAJEEV KUMAR[1], B. SATYANARAYANA[1], M. SAILAJA[1]

Department of Pharmaceutics, Max Institute of Pharmaceutical Sciences, Velugumatla, Khammam, A.P.

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Abstract: Recent development in fast disintegrating tablets has brought convenience in dosing to elderly and children who have trouble in swallowing tablets. The objective of present study was to prepare the fast disintegration tablets of Terbutaline sulphate to increase the bioavailability and enhance the onset of action. Terbutataline sulphate is a selective β2-adrenergic agonist widely used as a bronchodilator. It forms part of initial therapy of acute as well as chronic asthma. In the present work an attempt has been made to formulate and evaluate fast mouth dissolving tablets of Terbutaline sulphate by using three different technologies direct compression , sublimation method, wet granulation method . A total of 9 bathes were prepared and evaluated. The sublimation method contain camphor as a subliming agent showed more 90% of drug release with in 30 min.

Keywords: Direct compression, sublimation, wet granulation, Fast dissolving tablet, Terbutaline Sulphate

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Corresponding Author: MR. SHAIK RAHANAPARVEEN

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INTRODUCTION

Advancements in oral delivery of active ingredients include a number of technologies, many of which may be classified as oral disintegrating tablets (ODTs). The new generation of orally disintegrating tablet (ODT) technologies is no longer limited by dosage strength, bitter active pharmaceutical ingredients (APIs), and narrow therapeutic applications.

Today's emerging technologies can produce robust, versatile tablets with exceptional taste masking and controlled release, broadening the applications of this dosage form. Over the last decade, ODTs have grown steadily in demand and importance as a convenient, potentially safer alternative to conventional tablets and capsules.

US FDA defined ODT tablets as "A solid dosage form containing medicinal substances that disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". 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 despite various terminologies used. The basic approach used in development of MDT is the use of superdisintegrants like Crospovidone, Sodium starch glycolate (Primogel, Explotab). etc. which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pre gastric absorption of saliva containing dispersed drugs that pass down into the stomach. Different types of technologies have been employed for the formulation of mouth dissolving tablets viz freeze-drying, Tablet Molding, Direct Compression Method, spray drying and sublimation Technology etc. have been tried by researchers to maximize the pore structure of tablet matrix.

In present study, Terbutaline sulphate, a selective β2-adrenergic agonist, an anti asthmatic drug, this is administered for symptomatic relief of bronchial spasm and in obstructive airway disease. This drug was selected as it is not available in fast dissolving tablets

In this work we have tried to formulate a mouth Dissolving dosage form of Terbutaline Sulphate by using three techniques like direct compression, sublimation and wet granulation methods.by utilizing superdisintegrants [Crospovidone (CP) and sodium starach glcolate, so as to know which method or technique shows best resuts.

MATERIAL AND METHOD

Materials:

Terbutaline Sulphate is obtained from Astrazeneca pharmaceuticals Ltd.., Banglore, sodium starach glycolate Crospovidone , camphor, lactose, Micro crystalline cellulose are obtained from S.D. fine chemicals, Mumbai.

Compatibility study

Fourier Transform Infrared Spectroscopy (FT-IR) is used to study the compatibility of drug Terbutaline sulphate (TBS) and exicipients**.** The samples of TBS, SSG (sodium starch glycolate), CP (crospovidone), camphor were prepared in the form of KBr pellets and subjected for scanning from 4000 to 400 cm-1.

Preparation of TBS FDTs by Sublimation Method[7]

All ingredients were sifted through the sieve no 60 individually and weighed as per the formula displayed in Table2.Weighed ingredients were mixed using a glass mortar and pestle. Finally, magnesium stearate and aerosil were added as lubricating agent. Powder blend were then directly compressed using 8 mm, round-shaped tooling in a 8 station tablet compression machine. After compression tablets were heated in a hot air oven at 60°C until constant weight was obtained to ensure the complete removal of volatilizable component.

Preparation of TBS FDTs by wet granulation method:

All ingredients were sifted through the # 100 mesh screen individually and weighed as per the formula displayed in Table3. Weighed ingredients were transferred into Polythene bag and mixed vigorously for 15 minutes. The blend was taken in a stainless steel container, to which a sufficient volume of granulating agent, alcoholic solution of PVP (5% w/v) as granulating agent was added to form a damp mass. The damp mass was passed through the # 16 mesh screen to get wet granules. Wet granules were dried in a hot air oven for 1 hour at 60ºc. and then compressed in to tablets.

Preparation of TBS FDTs by Direct compression method

Fast dissolving tablets were prepared by direct compression method. Each ingredient was weighed individually and passed through sieve no 60. and weighed as per the formula displayed in Table1.After passing each ingredient, all ingredients were mixed using a glass mortar and pestle. Powder blend were then directly compressed using 8 mm, round-shaped tooling in a 6 station tablet compression machine.

EVALUATION OF POWDER BLENDS:

Pre compression parameters: [2,3,4]

Bulk density (D_b)

It is ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weighed powder into a measuring cylinder and the volume was noted. It is expressed in gm/cc and is given by

$D_b = M/V_o$

Where,

M is the mass of the powder

V_o is the bulk volume of the powder.

Tapped density (D_t)

It is the ratio of total mass of powder to the tapped volume of powder. The tapped volume was measured by tapping the powder to constant volume. It is expressed in gm/cc

$D_t = M/V_t$

Where,

M is the mass of powder

V_t is the tapped volume of the powder.

Angle of repose (θ):

The frictional forces in a loose powder can be measured by the angle of repose, θ. This is the maximum angle possible between the surface of a pile of powder and the horizontal plane and it is given as,

$\tan \theta = h / r$,

$\theta = \tan^{-1}[h / r]$

Where

$\theta$is the angle of repose

h is the height in cm

r is the radius.

The powder mixture 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.

Carr's index (I):

It indicates the ease with a material can be induced to flow .it is expressed in percentage and is given by

$I = D_t - D_b / D_t \times 100$

Where,

D_t is the tapped density of the powder.

D_b is the bulk density of the powder.

Hausner'sratio:

Hausner's ratio indicates the flow properties of the powder and measured by the ratio of tapped density to bulk density. The relationship between Hauser's ratio and flow property**.**

Hausner's ratio was calculated by using the formula.

Hausner's Ratio = Tapped density / Bulk density

Hausner's Ratio = V_f/Vo

Where V_0 = Initial volume, Vf = Final volume

Post compression parameters:

General appearance and physical parameters:

Shape, Colour and Odour of Tablets:

Organoleptic properties such as taste, colour and odour were evaluated. Ten tablets from each batch were randomly selected and the taste tested, colour visually compared and odour checked.

Thickness of Tablets:

The thickness of six tablets was measured using Vernier calipers. The extent to which the thickness of each tablet deviated from ± 5% of the standard value was determined. The results obtained were shown in Table 7.

Hardness and Friability of Tablets:

Hardness of tablet was determined by using Monsanto hardness tester. Six tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded.

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed ($W_{initial}$) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (W_{final}). The % friability was then calculated by the following formula:

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100 \text{ --------- } (1)$$

% Friability of tablets less than 1% is considered acceptable.

Weight Variation Test:

Twenty tablets were selected randomly from each batch and weighed individually to check for weight variation

Wetting Time of Tablets[5]

A piece of tissue of paper folded twice was placed in a small petri dish (internal diameter = 6.5cm) 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. Three trials for each batch were performed; average time for wetting with standard deviation was recorded.

Water absorption ratio

A piece of tissue paper folded twice was placed in a small Petridis containing 6ml of water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using following equation.

R = 100 (Wa – Wb)/ Wb ------- (g)

Where,

Wb – weight of tablet before absorption

Wa – weight of tablet after absorption

Three tablets from each formulation were tested. Average and standard deviation were determined.

Uniformity of drug content:

Twenty tablets from each batch were weighed accurately and powdered. An amount of powder equivalent to 50 mg of the drug was transferred in to a 100 ml volumetric flask. The volume was made with 6.8 pH phosphate buffer and sonicated for 10 min. The resulting solution was filtered and assayed at 276.5 nm using UV spectrophotometer and drug content per tablet was determined.

Disintegration test[9]

The disintegration test was carried out using USP disintegration test apparatus type II. Six tablets were placed individually in each tube of disintegration test apparatus and discs were placed over each tablet. Distilled water was used as the medium maintained at 37°C + 0.5°C and the time taken for each tablet to disintegrate completely was recorded.

***In vitro* Dissolution Studies**

Dissolution study was carried out using USP dissolution test apparatus type II. The dissolution medium used was 900 ml of 6.8 pH buffer at 37±0.5º. The paddle speed was kept at 50 rpm throughout the study. Aliquot of 10 ml was withdrawn at predetermined time interval and equivalent amount of fresh medium was replaced to maintain a constant volume. Each sampling was analyzed spectro photometrically at 276.50 nm against suitable blank using UV-visible spectrophotometer and drug content per tablet was determined.

In *vitro* dispersion time:

In *vitro* dispersion time was measured by dropping a tablet in a glass cylinder containing 6ml of phosphate buffer (pH 6.8). Six tablets from each formulation were randomly selected and in *vitro* dispersion time was performed.

RESULT AND DISCUSSION

CALIBRATION CURVE OF TERBUTALINE SULPHATE

The calibration curve of TBS was obtained in the range of 2 to 14µg at the wave length of 276.50 nm. It has shown good linearity with a regression coefficient of 0.997(r2 value), slope 0.027 and intercept 0.003.

FORMULATION OF FAST DISSOLVING TABLETS OF TBS

Nine formulations of Terbutaline sulphate FDTs were prepared according to the procedure described in methodology. Tables 1, 2, and 3 show different formulations used in the study. Micro crystalline cellulose and lactose were used as diluents, sodium starch glycolate, and cross povidone as disintegrants, poly vinyl pyrollidone as binder, camphor as subliming agent, orange as a flavour, magnesium stearate as a lubricant, and aerosil as a glidant.

EVALUATION PARAMETERS FOR FAST DISSOLVING TABLETS OF TBS

1) FT-IR Spectroscopy

The FT-IR spectra of TBS, SSG, CP, physical mixture (TBS: SSG: CP), CMP, physical mixture (TBS:CMP). All the formulations showed similar absorption bands as their respective physical mixtures. This result suggested that there was no chemical interaction between drug, super disintegrants and subliming agent in their combinations.

2) Pre-compression Parameters

The pre-compression data's were shown in Table5. The values for angle of repose were found in the range of 23.43' - 28.30'. This indicates good flow property of the mixed powder. Bulk densities and tapped densities of various formulations were found to be in the range of 0.45±0.01 to 0.50±0.05 (g/cc) and 0.49±0.006 to 0.67±0.00 (g/cc) respectively. Compressibility index of the prepared blends/granules are fall in the range of 7.67%-12.33% indicating that the blends/granules have the excellent compressibility. Hausner's ratio of the prepared blends/granules fall in the range of 0.73-1.18 indicated that the blends/granules have the required flow property and strength for compression.

3) Post compression Parameters

Visual examination of tablets from each formulation batch showed circular shape.

Thickness

The dimensions determined for formulated tablets were tabulated in Table6.Tablets mean thicknesses were almost uniform in all the formulations and were found to be in the range of 2.40 mm-2.80 mm.

Hardness test

Hardness of the three tablets of each batch was checked by Monsanto hardness tester and the data's were shown in Table6. The results showed that the hardness of the tablets was in the range of 3.60±0.17 to 4.07±0.15 kg/cm2.

Friability test

Friability of the ten tablets of each batch was checked by Roche friabilator tester and the data's were shown in Table6. The results showed that the friability of the tablets was in the range of 0.334% to 0.922%. The friability of FDT formulation by sublimation method is higher; because of the technique used (sublimation) makes the tablet more porous which makes them less hard and more friable. So the maximum friability was 0.922% and the minimum friability 0.334% observed for SB3 and DC1respectively.As per official requirement of IP indicating good mechanical resistance of tablets.

Weight variation test

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table7. The average weight of the tablet is approximately 150 mg; so the permissible limit is ±7.5%. The results of the test showed that, the tablet weight was within pharmacoepial limit.

Wetting time

Wetting is closely related to inner structure of tablets and the hydrophilicity of excipients. The record of the wetting time was shown in Table7. The wetting time in all the formulation was very fast. This may be due to ability of swelling and also capacity of absorption of water. MCC, SSG and cross povidone absorbs water rapidly in the formulations and shows fast wetting time. This parameter also duplicates disintegration time in oral cavity as tablet is kept motionless on tongue; hence correlation between wetting time and disintegration time in oral cavity can also be made. Overall the wetting time for FDT by sublimation method was found to be the lowest. This is due to highly porous nature of the tablets formulated. The results showed that wetting time of the tablets was in the range of 28.63±0.31 to 61.03±1.56 sec.

Water absorption ratio

The result of water absorption ratio was shown in Table7. The water absorption ratio is up taking of water it was very fast in all formulations. Overall the water absorption ratio for FDT by sublimation method is very high. This is due to highly porous nature of the tablets formulated. The result showed that water absorption ratio of the tablets was in the range of 73.37±0.68 to 95.70±0.60 %.

Drug content

Drug content uniformity study was carried out on the tablets of every batch and the data was shown in the Table7. The content uniformity of all the formulations was found to be in the range of 94.73±0.40 % to 99.43±0.35 % which showed that there was uniform distribution of the drug throughout the batch. The IP standard says that terbutaline sulphate tablets must contain not less than 90.0% and not more than 110.0% of the stated amount of terbutaline sulphate. Thus all the FDT formulations of Terbutaline sulphate complies with IP limit for assay.

***In vitro* disintegration time**

Tablets of each batch were evaluated for *in vitro* disintegration time and the data was shown in the Table7. The results showed that the disintegration time of prepared tablets were in the range of 19.60±0.66 to 51.60±0.26 sec. The internal structure of tablets that is pore size distribution, water penetration into tablets and swelling of disintegration substance are suggested to be the mechanism of disintegration. Compare the three techniques of the disintegration time. The rapid disintegration was seen in the sublimation method containing camphor as a subliming agent. This is due to the porous nature of tablets. So rapid buffer medium penetration and rapid disintegration of the tablet. As the concentration of superdisintegrants and subliming agent as camphor increases the disintegration time decrease.

***In vitro* dispersion time:**

In vitro dispersion is a special parameter in which the time taken by the tablet for complete dispersion is measured. The time for all the 09 formulations varied between 29.7 ± 0.72and 56.3± 0.25 second the values are given in the table7

***In vitro* dissolution studies**

Finally, the tablets were evaluated for *in vitro* dissolution studies in simulated saliva and the results were calculated. The highest dissolution rate and drug release was shown by FDT by sublimation method. The results shows that the order of drug release in dissolution studies is FDT by sublimation method > direct compression method > wet granulation method. The

sublimation method contain camphor as a subliming agent showed 90% of drug release within 30 min, whereas direct compression method containing superdisintegrants showed 88% of drug release within 30 min, and the remaining method showed more than 86% of drug release within 45 minutes. Overall the FDT formulations of terbutaline sulphate showed the rapid dispersion and drug dissolution in sublimation method. It is mainly due to the highly porous nature of tablets. So rapid penetration of dissolution fluid in to the tablets, which results in rapid bursting and dissolution of tablets.

CONCLUSION:

In the present study, we have successfully prepared and developed fast dissolving tablets containing Terbutaline sulphate. The FDT formulations of Terbutaline sulphate were prepared by using three techniques i.e., direct compression method, sublimation method and Wet granulation method. A total of 9 batches (3 batches using each technique) were prepared. Overall FDT prepared by sublimation method appears to be the best formulation. The order for the best methods is as follows. FDT by sublimation method > direct compression method > wet granulation method. Sublimation method is the best suited method for formulation of FDT of Terbutaline sulphate. The order for the best three formulations in each method SB3 > DC3 > WG3. Higher the concentration of subliming agent, higher will be the porosity, friability rapid will be the dispersion and drug release, and lower will be the hardness of the FDT. Higher the super disintegrate concentration increases, the disintegration time decrease and the dissolution rate increases. It may be concluded that the FDTs of Terbutaline sulphate can be successfully prepared. It is more cost effective than aerosol inhalation pumps available.

Table 1: Composition of TBS FDTs prepared by Direct compression Method.

S. No	Ingredients (mg)	Formulation Code		
		DC1	DC2	DC3
1	Terbutaline Sulphate	5	5	5
2	Micro crystalline cellulose	100	100	100
3	Lactose	33	32	31
4	Sodium starch glycolate + cross povidone	6	7	8
5	Saccharine sodium	1	1	1
7	Orange flavor dried	1	1	1
8	Aerosil	2	2	2
9	Magnesium stearate	2	2	2

Table- 2: Composition of TBS FDTs prepared by sublimation Method

S. No	Ingredients(mg)	Formulation Code		
		SB1	SB2	SB3
1	Terbutaline Sulphate	5	5	5
2	Micro crystalline cellulose	100	100	100
3	Lactose	15	12	9
4	Sodium starch glycolate + crospovidone	6	7	8
5	Camphor	18	20	22
6	Saccharine sodium	1	1	1
7	Orange flavor dried	1	1	1
8	Aerosil	2	2	2
9	Magnesium stearate	2	2	2

Table-3: Composition of TBS FDTs prepared by Wet Granulation Method[1]

S. No	Ingredients(mg)	Formulation Code		
		WG1	WG2	WG3
1	Terbutaline Sulphate	5	5	5
2	Micro crystalline cellulose	100	100	100
3	Lactose	28	27	26
4	Sodium starch glycolate + crospovidone	6	7	8
5	PVP (5%)	Q.S	Q.S	Q.S
6	Saccharine sodium	1	1	1
7	Orange flavor dried	1	1	1
8	Aerosil	2	2	2
9	Magnesium stearate	2	2	2

Table -4: calibration curve of Terbutaline sulphate

Concentration (µg/ml)	Absorbance
0	0
2	0.061
4	0.114
6	0.172
8	0.221
10	0.273
12	0.321
14	0.396

Table-5:Pre-compression Parameters of developed formulations

Formulation code	Angle of repose(Ø)	Bulk density (g/cc)	Tapped density (g/cc)	Carr's index (%)	Hausner's ratio
DC1	25.03±0.81	0.49±0.06	0.59±0.05	10.00	**0.83**
DC2	23.43±0.58	0.47±0.05	0.49±0.06	9.00	**0.73**
DC3	24.57±0.64	0.45±0.22	0.59±0.05	11.33	**1.18**
SB1	24.27±0.64	0.45±0.01	0.63±0.06	12.33	**0.90**
SB2	24.40±0.68	0.49±0.06	0.60±0.07	11.00	**0.93**
SB3	27.40±0.87	0.47±0.01	0.59±0.05	9.67	**0.90**
WG1	24.33±0.68	0.50±0.05	0.59±0.05	10.00	**0.93**
WG2	23.97±0.64	0.47±0.01	0.55±0.01	11.33	**0.97**
WG3	**23.97±0.92**	**0.46±0.01**	**0.67±0.00**	**8.67**	**0.90**

Table-6: Post compression Parameters of developed formulations

Formulation code	Thickness (mm)	Hardness (kg/cm)	Friability (%)
DC1	2.60±0.22	3.60±0.17	0.334
DC2	2.60±0.24	4.03±0.12	0.350
DC3	2.60±0.22	3.90±0.10	0.346
SB1	2.40±0.05	3.93±0.15	0.916
SB2	2.40±0.05	3.87±0.25	0.875
SB3	2.40±0.05	3.87±0.06	0.922
WG1	2.80±0.07	3.93±0.15	0.403
WG2	2.60±0.06	3.87±0.25	0.465
WG3	2.80±0.06	4.00±0.26	0.554

Table 7: Post compression Parameters of developed formulations

Formulation code	Weight variation (mg)	Wetting time (sec)	Water Absorption ratio (%)	Disintegration time (sec)	Drug content (%)	In vitro Dispersion time
DC1	150.3±1.53	41.5±1.78	90.2±0.25	28.5±0.52	94.7±0.40	**35±1.78**
DC2	148.0±1.00	40.8±1.75	88.6±0.93	28.3±0.57	96.5±0.35	**34.55±0.52**
DC3	151.6±1.53	35.8±0.10	86.5±0.44	26.8±0.55	97.6±0.51	**31.3±1.75**
SB1	150.3±2.31	34.5±1.27	95.7±0.60	24.9±0.72	97.4±0.35	**29.7±0.72**
SB2	150.0±2.00	30.6±0.20	94.4±0.42	22.5±0.38	98.2±0.35	**26.55±0.42**
SB3	151.6±1.53	28.6±0.31	92.3±0.17	19.6±0.66	99.4±0.35	**24.1±0.38**
WG1	149.3±2.52	61.0±1.56	75.5±0.32	51.6±0.26	94.8±0.50	**56.3±0.25**
WG2	151.3±2.08	57.7±0.26	73.5±0.49	49.4±0.44	96.5±0.32	**53.55±0.26**
WG3	**150.3±0.58**	**55.4±0.42**	**73.3±0.68**	**48.1±0.72**	**96.6±0.32**	**51.75±0.42**

Table 8: *In vitro* drug release profile of TBS FDTs by Direct compression

Time (min)	Cumulative %drug release		
	DC1	DC2	DC3
0	0	0	0
5	44±0. 52	43.2±0.07	45±0.55
10	58.6±0.72	55.1±0.34	54.8±0.37
15	63.1±0.02	64.6±0.71	65.2±0.13
20	71.8±0.42	72.2±0.18	74±0.27
25	79.6±0.31	80±0.49	82.6±0.29
30	84.8±0.70	87.2±0.16	88±1.78

Table -9: *In vitro* drug release profile of TBS FDTs by SB[7]

Time (min)	Cumulative % drug released		
	SB1	SB2	SB3
0	0	0	0
5	46±0.17	47±0.48	47.5±0.24
10	57.2±0.76	58.8±0.41	60.4±0.22
15	67.5±0.44	68.8±0.09	70.4±0.25
20	76.7±0.22	77.8±0.64	79.2±0.46
25	81.1±0.85	83.8±0.14	86±0.26
30	87.6±0.12	88.8±0.05	90±0.35

Table 10: *In vitro* drug release profile of TBS FDTs by WG

Time (min)	cumulative% drug released		
	WG1	WG2	WG3
0	0	0	0
5	17.8±0.01	18±0.01	22.±0.02
10	26.1±0.02	27.3±0.03	29.5±0.01
15	30.1±0.03	32.8±0.01	35.4±0.03
20	36.2±0.03	38.6±0.03	40.6±0.03
25	46.6±0.02	49.6±0.01	53±0.02
30	57.9±0.01	60.6±0.01	63±0.03
35	66±0.01	69±0.01	71.2±0.02
40	74.4±0.03	76.4±0.03	79.6±0.01
45	82.8±0.02	81.8±0.01	86±0.02

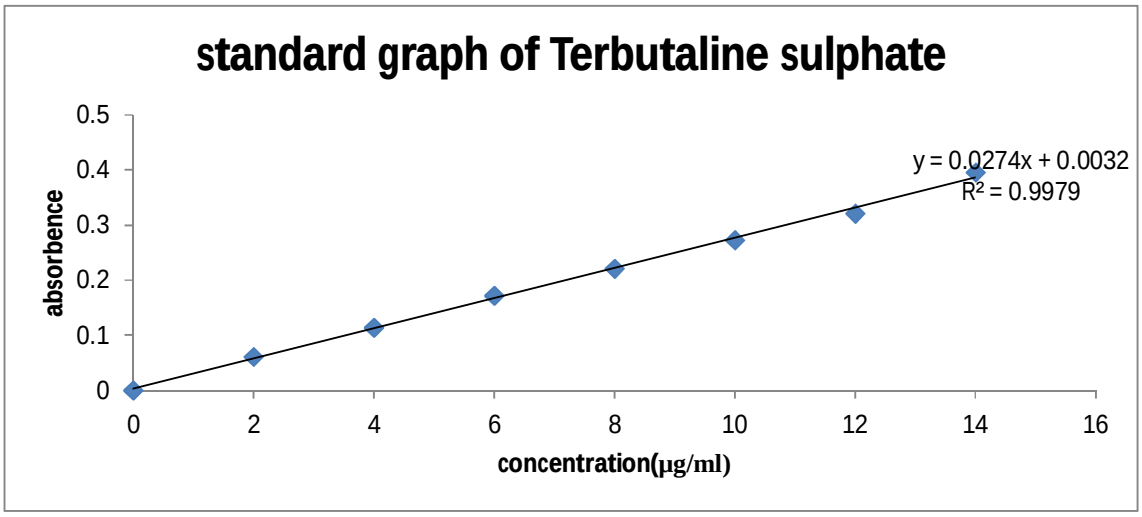

Figure -1: Calibration curve for Terbutaline sulphate

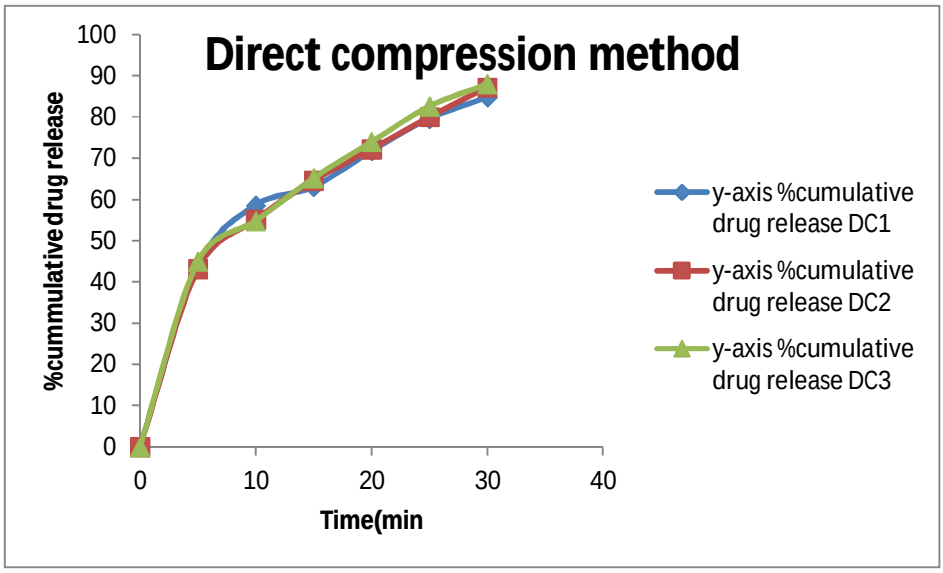

Figure -2: Dissolution profile of TBS FDTs by DC

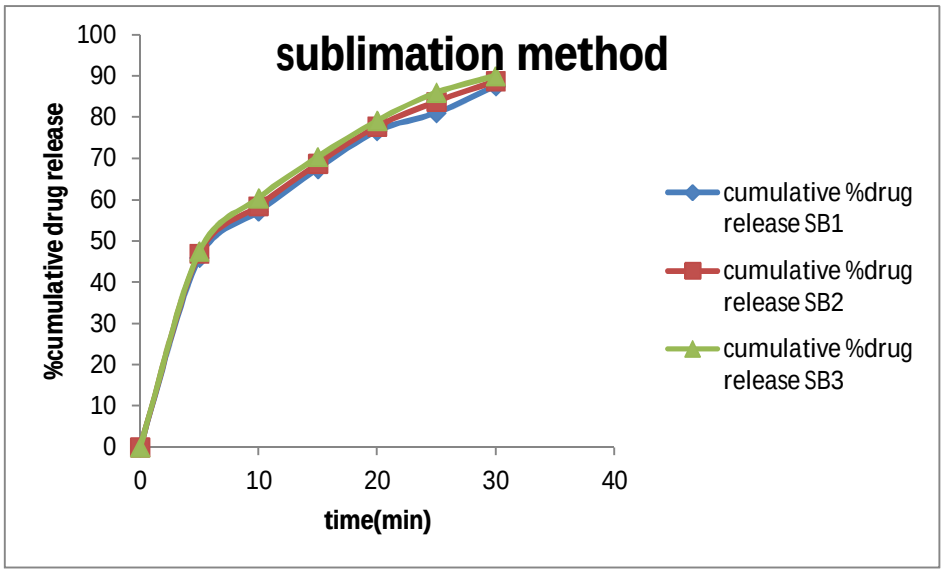

Figure 3: Dissolution profile of TBS FDTs by SB

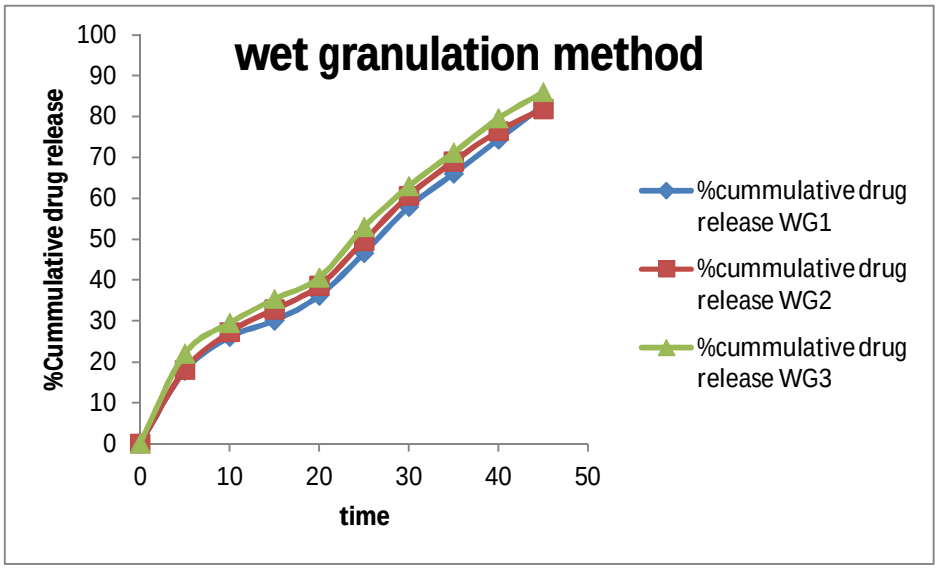

Figure – 4: Dissolution profile of TBS FDTs by WG

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