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Design and Evaluation of Fast Dissolving Tablet of Terbutaline Sulphate

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ABSTRACT

Terbutaline sulphate is a selective β_2 receptor blocker used in the treatment of several cardiovascular disorders such as hypertension, angina pectoris, disturbances of cardiac rhythm, myocardial infarction and functional heart disorders. The fast dissolving tablets of Terbutaline sulphate were prepared employing by using Sodium starch glycol ate, microcrystalline cellulose. Present work was carried out to design and evaluate the tablets of fast dissolving. The conclusion of these, Terbutaline sulphate is a selective β_2 receptor blocker used in the treatment of several cardiovascular disorders such as hypertension, angina pectoris, disturbances of cardiac rhythm, myocardial infarction and functional heart disorders. It has a shorter half-life of 2-3 hrs, oral availability is 38 ± 14% and it is eliminated rapidly from the plasma compartment within few hours. So, frequent administration is necessary to maintain its therapeutic concentration. In order to maintain the therapeutic concentration of terbutaline sulphate modified release formulations are necessary. In the present work the fast dissolving tablets of Terbutaline sulphate was prepared to prolong the residence time at the site of application (or) absorption and to facilitate the intimate contact with the underlying absorption surface to improve and enhance the bioavailability. Preformulation study and drug excipients compatibility study was done initially and results directed the further course of formulation. IR spectra studies revealed that the drug and the polymers used were compatible. The tablets were formulated using various concentrations of polymers such as micro crystalline cellulose and sodium starch glycolate.The parameters like diameter, thickness, hardness, friability, weight variation and content uniformity were evaluated for all the formulated batches of tablet. The results were complies with the official specifications within the limits. The in-vitro dissolution data it was found that formulation f1 and f5 containing microcrystalline cellulose and sodium starch glycolate was released 95.2% and 96.8% of drug within 10 min. of the study indicating that the polymer amount is not sufficient to control the drug release. F3 containing sodium starch glycolate (190 mg) alone released 98.1% of drug with in 10 min. It concludes f3 had better for fast dissolving tablets than the other formulation (f1, f2, f4& f5).

Keywords: cardiovascular disorders, angina pectoris, myocardial infarction, absorption, preformulation, polymer, fast dissolving tablets

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INTRODUCTION

The oral route of drug administration is the most important method for administering drugs for systemic effects. Except in certain cases the parenteral route is not routinely used for self administration, e.g. insulin. The topical route of administration has only recently been employed to deliver drugs to the body for systemic effects. The parenteral route of administration is important in treating medical emergencies in which the subject is comatose or cannot swallow. Nevertheless it is probable that at least 90% of all drugs used to provide systemic effects are administered by the oral route. When a new drug is discovered one of the first questions, a pharmaceutical company asks is whether or not the drug can be effectively administered for its intended effect by the oral route. Of drugs that are administered orally, solid oral dosage forms represent the preferred class of products. Tablets and capsules represent unit dosage forms in which usual dose of a drug has been accurately placed.

TYPES OF TABLETS [1]

1. Tablets ingested orally. e.g. standard compressed tablets, enteric coated tablets, delayed release tablets and mouth dissolving tablets
2. Tablets used in the oral cavity. e.g. buccal and sublingual tablets,
3. Tablets used to prepare solution. e.g. effervescent tablets
4. Tablets administered through other routes. e.g. vaginal tablets and implants

HISTORICAL DEVELOPMENT OF FAST DISSOLVING TABLETS

A) Difficulty in swallowing (Dysphagia) is a common problem in all age groups, especially the elderly and pediatrics, because of physiological changes associated with these age groups. It is common to see those afflicted carrying a small device with them, which is used for crushing tablets, enabling easy ingestion. Other categories that experience problems using conventional oral dosage forms include are the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack and coughing. Sometimes, it may be difficult to swallow conventional products due to unavailability of water. These problems led to the development of a novel type of solid oral dosage form called mouth-dissolving tablets, which disintegrate and dissolve rapidly in saliva without the need of the water. They are also known as fast dissolving tablets, melt-in-mouth tablets, rapimelts, porous tablets, oro-dispersible, quick dissolving or rapidly disintegrating tablets.

B) Since 1986 when the Zydis® lyophilized, fast-dissolving dosage forms were first introduced, a number of other fast-dissolving formulations were developed, and the technology is still improving. Using the concept of Gregory et al [2], Scherer has patented the Zydis technology. Using the freeze-drying process, this technology converts the mixture of active ingredient and water dispersible carrier materials into open matrix network that disintegrates rapidly.

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C) The network is highly porous solid form, which allows rapid penetration of liquid and facilitates quick disintegration of the dosage unit. The freeze-drying approach produces the fastest dissolving tablets, but the process is expensive, and the resulting tablets are mechanically weak. The other most widely used method to manufacture these tablets is via regular compression that can produce tablets with higher mechanical strengths. The disintegration or melting time of the compressed tablets is not as fast as the freeze-dried dosage forms, but the compressed tablets provide many advantages, such as high mechanical strength facilitating their handling and processing. The technology of the compressed tablets is also making major improvements, producing tablets that can melt within several seconds in the mouth.

D) The fast-melting tablets present the combined benefits of a liquid formulation and a solid dosage form. They are easy to handle and ingestible as a liquid dosage form. An ideal fast-melting tablet should possess the following characteristics. The tablet should melt or disintegrate in the mouth within 60 seconds. The tablets should also be mechanically strong for easier handling, and the production cost should be similar to that of conventional tablets. The use of existing tablet machinery and procedures dictates the low production cost and has another advantage of producing mechanically strong tablets. The ideal fast-melting tablets should also be less sensitive to humidity, thus allowing multi-tablet packaging.

CHARACTERISTICS OF FAST DISSOLVING DELIVERY SYSTEM [2]

1. Taste of the medicament
2. Hygroscopicity
3. Friability

CONVENTIONAL TECHNIQUES USED IN THE PREPARATION OF FAST DISSOLVING TABLETS [2-4]

1. Lyophilization
2. Spraydrying
3. Sublimation

AIM AND OBJECTIVE [5-16]

Terbutaline sulphate is a selective β_2 receptor blocker used in the treatment of several cardiovascular disorders such as hypertension, angina pectoris, disturbances of cardiac rhythm, myocardial infarction and functional heart disorders. It has a shorter half-life of 2-3 hrs, oral availability is 38 $\pm$ 14% and it is eliminated rapidly from the plasma compartment within few hours. So, frequent administration is necessary to maintain its therapeutic concentration. In order to maintain the therapeutic concentration of terbutaline sulphate modified release formulations are necessary.

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In the present work the fast dissolving tablets of Terbutaline sulphate was prepared to prolong the residence time at the site of application (or) absorption and to facilitate the intimate contact with the underlying absorption surface to improve and enhance the bioavailability.

The fast dissolving tablets of Terbutaline sulphate were prepared employing by using Sodium starch glycol ate, Microcrystalline cellulose.

PLAN OF WORK

Present work was carried out to design and evaluate the tablets of fast dissolving.

The study was proposed to carry out in the following stages.

A. Construction of standard curve for terbutaline sulphate in pH 6.2 soren sons buffer.
B. Selection of superdisitegrants Sodium starch glycolate, Microcrystalline cellulose.
C. Preformulation study- Fourier Transform Infrared Spectroscopy (FTIR)
D. Formulation of fast dissolving tablets of terbutaline sulphate by using direct compression.
E. Evaluation of Physical characteristics of blend of terbutaline sulphate
    1. Angle of repose.
    2. Bulk density.
    3. True density
F. Evaluation of prepared fast dissolving tablets of terbutaline sulphate.
    1. Hardness.
    2. Tablet size.
    3. Weight variation.
    4. Friability.
    5. Drug content uniformity
    6. Water absorption studies.
    7. In-vitro dissolution studies.

METHODOLOGY

MATERIALS USED

Table no.1

S.NO	MATERIALS
1.	Terbutaline sulphate
2.	Microcrystalline cellulose
3.	Sodium starch glycol ate
4.	Mannitol
5.	Talc
6.	Magnesium state

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INSTRUMENT USED

Table no.2

S.NO	INISTRUMENTS
1.	Electronic Balance
2.	Double beam U-V Spectrophotometer
3.	FT-IR
4.	Sieve sets
5.	Hot air oven
6.	Single punch Tablet compression machine
8.	Tablet hardness tester
9.	Friability tester
10.	Tablet dissolution tester USP XXIII
11	pH meter

EVALUATION OF BLEND CHARACTERISTICS OF TERBUTALINE SULPHATE

Flow Property:

The flow property was determined by measuring the angle of repose. In order to determine the flow property, the angle of repose(s) was determined. It is the maximum angle that can be obtained between the free standing surface of a powder heap and the horizontal plane. Values of θ are rarely less than 20^o, and values of up to 40^o indicate reasonable flow potential. Above 50^o, however, the powder flows only with difficulty if at all.

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

Where h = height the pile
r = radius of the pile
θ = angle of repose

The sample was taken in a funnel, which fixed in a holder (5cm) above the surface at an appropriate height and a graph of sheet was placed below the funnel. The sample was passed through the funnel slowly. The height of the powder heap formed was measured. The circumference formed was drawn with a pencil on the graph paper. The radius was measured and the angle of repose was determined. This was repeated three times for a sample.

Determination of bulk density and tapped density:

The powder (W) was carefully poured into the graduated measuring cylinder and the volume (V_O) was measured. Then the graduated cylinder was closed with lid and tapped 100times and after that, the volume (V_f) was measured and continued operation till the two consecutive readings were equal. The bulk density, and tapped density were calculated using the following formulas

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Bulk density = W / V_O

Tapped density = W / V_f

Where,

W = weight of the powder

V_O = initial volume

V_f = final volume

Compressibility index (Carr's index):

Compressibility index is an important measure that can be obtained from the bulk and tapped densities. In theory, the less compressible a material the more flow able it is. A material having values of less than 20 to 30% is defined as the free flowing material.

$$C_I = 100 \frac{(V_O - V_f)}{V_0}$$

Table no.3

% Comp. Index	Properties
5-12	Free flowing
12-16	Good
18-21	Fair
23-35	Poor
33-38	Very poor
>40	Extremely poor

EVALUATION OF FAST DISSOLVING TABLETS

1. **Tablet size:** Thickness of the tablet was measured by using Vernier Caliper (Mitutoyo) in mm.
2. **Hardness test:** Hardness test was carried out by using Monsanto hardness tester.
3. **Friability test:** Friability of the tablets was tested using a Roche friabilator. The weight of 10 tablets was noted initially (W_1) and placed in the friabilator for 4min/100rpm. The tablets were reweighed and noted as (W_2). The difference in the weight is noted and expressed as percentage

$$\text{Percentage friability} = \frac{(W_1 - W_2)\ 100}{W_1}$$

4. **Weight variation test:** Twenty tablets were selected at random and the average weight was determined. Not more than two of the individual weights deviate from the average weight by more than the percentage deviation shown in table and none deviates by more than twice the percentage. IP official limits of percentage deviation of tablet are presented in the Table.no.4.

IP official limit of percentage deviation.

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Table no.4

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

5. **Drug content uniformity:** Determine the content of active ingredient(s) in each of 10 tablets taken at random using the method given in the monograph or by any other suitable analytical method. The tablets comply with the test if not more than one of the individual values thus obtain is outside the limits 85 to 115% of the average value and none is outside the limits 75 to 125% of the average value.

FORMULATION OF FAST DISSOLVING TABLETS

Table no.5

INGRIDIENS	F1	F2	F3	F4	F5
Terbutaline sulphate	50mg	50mg	50mg	50mg	50mg
Sodium starch glycol ate	30mg	40mg	50mg	_	_
Microcrystalline cellulose	_	_	_	30mg	40mg
Mannitol	50mg	50mg	50mg	50mg	50mg
Magnesium state	30mg	20mg	20mg	30mg	30mg
Talc	30mg	30mg	20mg	30mg	20mg
Total tablet weight	190mg	190mg	190mg	190mg	190mg

PREPARATION OF FAST DISSOLVING TABLETS

1. Required amount of drug i.e. Terbutaline sulphate was weighed.
2. Then required quantities of polymer (Microcrystalline cellulose, sodium starch glycolate) and other additives are weighed.
3. Then the drug, polymer and other additives are grinded.
4. Then the drug and polymer are mixed thoroughly.
5. To that Mannitol, Magnesium stearate and Talc were added as other additives.
6. Mix all the ingredients, by using compression machine the tablets were punched.

RESULTS AND DISSCUSSIONS

STANDARD CURVE OF TERBUTALINE SULPHATE AT 260nm

PROCEDURE:

- 100mg of drug was weighed accurately& dissolve in Sorennsen buffer. Volume was made up to 100ml with Sorennsen buffer.

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- From that different solutions are prepared such as10µg/ml, 20µg/ml, 30µg/ml, 40 µg/ml, 50µg/ml, and 60µg/ml.
- The absorbance was determined at 260nm by using u.v.spectrophotometry.
- A graph was plotted using concentration on x-axis & absorbance on y-axis.(Table no.6) AND Fig.no.1

Table no.6

S.no	CONCENTRATION	ABSORBANCE
1	10	0.454
2	20	0.829
3	30	1.239
4	40	1.659
5	50	2.051
6	60	2.456

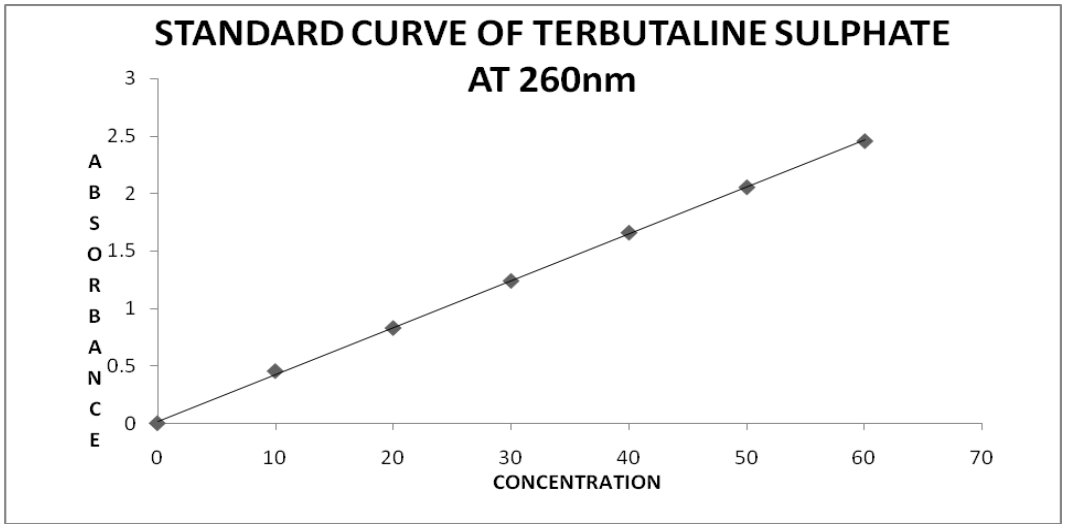

Fig no.1

EVALUATION OF INTRAGASTRIC BUOYANT TABLET FORMULATIONS:

1. Pre-compression Parameters:

A) Angle of Repose (θ):- The angle of repose for the formulated blend was carried out and the results were shown in table no 3. It concludes all the formulations blend was found to be in the range $25^0.28'$ to $29^0.52'$.

B) Compressibility Index:- Compressibility index was carried out, it found between 12.84% to 17.39% indicating the powder blend have the required flow property for compression.

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Table no 7: Angle of Repose, Compressibility Index

BATCH	*Angle of Repose (□)	BULK DENSITY g/cc	TAPPED DENSITY g/cc	*Compressibility Index (%)
F1	25□.30'±0.11	0.4952	0.5742	13.94
F2	26□.41'±0.51	0.4785	0.5654	15.87
F3	25□.28'±0.42	0.4865	0.5857	17.39
F4	28□.56'±0.47	0.4586	0.5236	12.84
F5	29^0.52'±0.32	0.4726	0.5621	16.22

*Average of three, ± - standard deviation

2. Post-compression Parameters:

A) Shape of the Tablet:- Microscopic examinations of tablets from f1 to f5 were found to be circular shape with no cracks.

B) Tablet Dimensions:- The dimensions determined for formulated tablets were tabulated in table no4. Tablets mean thickness (n=3) were uniform in f1 to f5 formulations and were found to be in the range of 5.12mm to 5.18mm. The diameter of the tablets ranges between 13.08mm to 13.09mm.

C) Hardness Test:- The measured hardness of tablets of each batch ranged between 5.5 to 7.0kg/cm^2 (table no4). This ensures good handling characteristics of all batches.

D) Friability Test:- The values of friability test were tabulated in table no 4. The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

E) Weight Variation Test:- The percentage weight variations for all formulations were tabulated in table no 4. All the formulated (f1 to f5) tablets passed weight variation test as the % weight variation was within the pharmacopoeial limits of ±5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values.

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F) Drug Content Uniformity:- The percentage of drug content for f1 to f5 was found to be, 95.2% to 98.9%of metformin hcl, it complies with official specifications. the results were shown in(table no. 8).

Table no 8: Physical Properties of Tablets of Batch F1 toF5

Batches	*DIAMETER (MM)	*THICKNESS (MM)	*HARDNESS (KG/CM^2)	*FRIABILITY (%)	*WEIGHT VARIATION (MG)	Disintegration Time (sec)	DRUG CONTENT UNIFORMITY	WETTING TIME (SEC)
F1	13.09 ±0.040	5.16 ±0.010	5.5 ±0.47	0.96± 0.14	800.65 ±1.29	24±2.00	98.9± 0.56	15±1.00
F2	13.08 ±0.006	5.14 ±0.012	4.0 ±0.32	0.72± 0.26	801.50 ±1.74	29±2.00	96.1± 0.41	23±0.00
F3	13.09 ±0.067	5.12 ±0.06	5.0 ±0.54	0.91±0.11	799.55 ±1.18	35±0.00	95.8± 0.72	32±1.00
F4	13.08 ±0.070	5.16 ±0.011	4.5 ±0.42	0.86±0.19	800.05 ±1.37	10±1.00	95.2± 0.19	08±0.00
F5	13.08 ±0.056	5.16 ±0.012	5.0 ±0.35	0.79±0.21	801.65 ±1.49	12±1.00	96.7± 0.35	17±1.00

***-** average of three values ± - standard deviation

INVTRO DISSOLUTION STUDIES:

Table no 9: INVITRO DISSOLUTION STUDIES OF FORMULATION –F1

Time(mins)	Absorbance	Concentration(µg/ml)	Concentration(mg/900ml)	$^0/_0$ Of drug release
1	0.571	14	126	66.3
2	0.61	15	135	71.0
4	0.69	17	153	80.5
6	0.79	19	171	90.0
8	0.82	20	180	94.7
10	0.83	20.2	181	95.6

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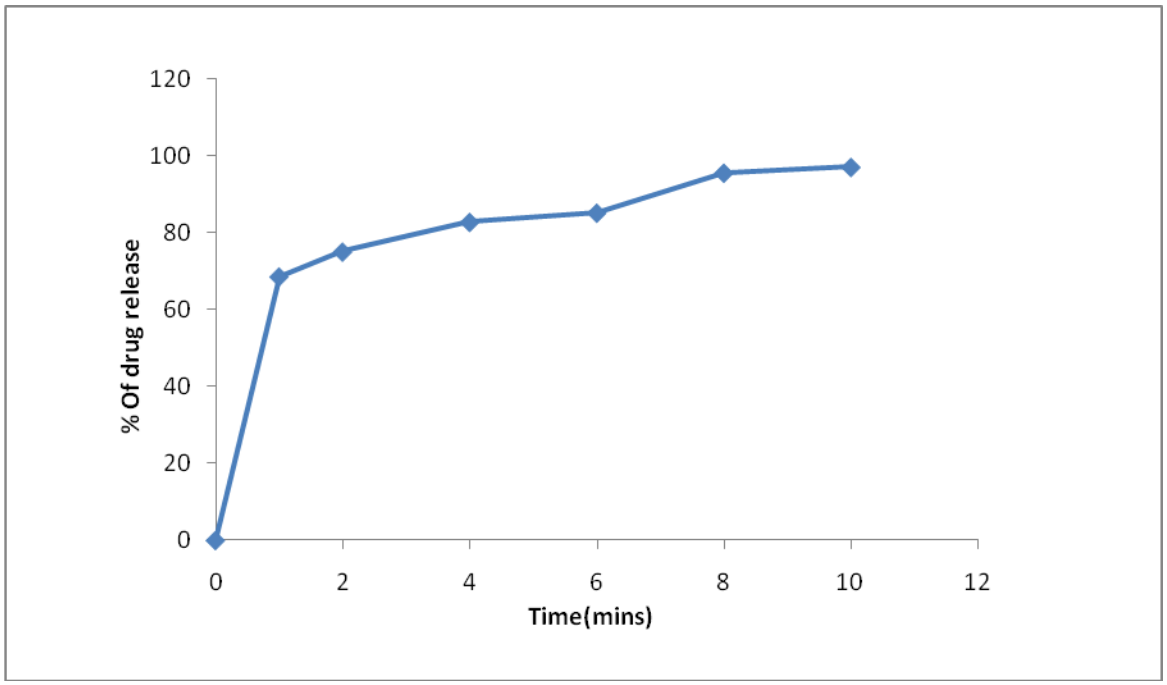

Fig no.2

Table no 10: INVITRO DISSOLUTION STUDIES OF FORMULATION - F2

Time(mins)	Absorbance	Concentration(µg/ml)	Concentration(mg/900ml)	$^{0}/_{0}$ Of drug release
1	0.58	14.5	130.5	68.6
2	0.69	15.5	148.5	75.07
4	0.7	17.5	157.5	82.8
6	0.75	18	162	85.2
8	0.83	20.2	181	95.6
10	0.85	20.5	184.5	97.1

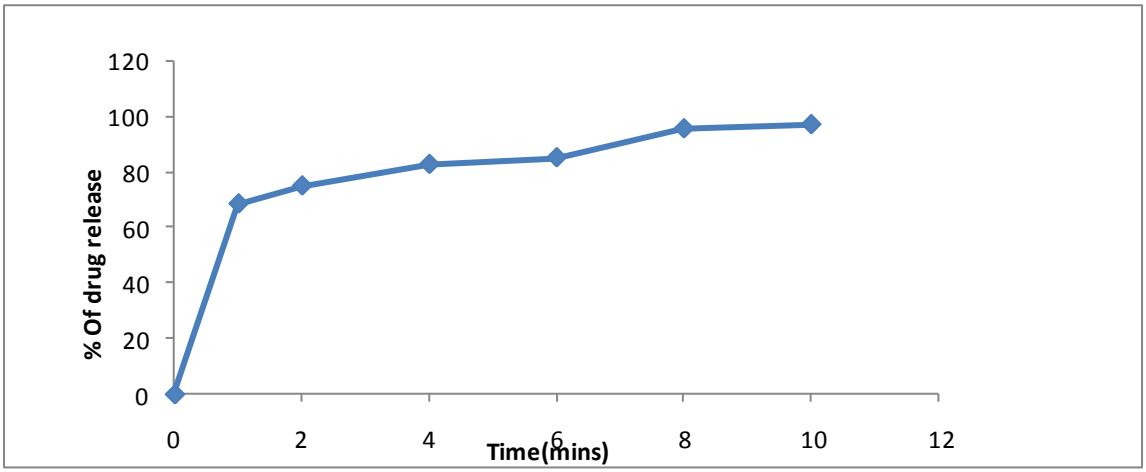

Fig no.3

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Table No 11:INVITRO DISSOLUTION STUDIES OF FORMULATION –F3

Time(mins)	Absorbance	Concentration(µg/ml)	Concentration(mg/900ml)	$^0/_0$ Of drug release
1	0.58	14.5	130.5	68.6
2	0.69	15.5	148.5	75.07
4	0.7	17.5	157.5	82.8
6	0.75	18	162	85.2
8	0.83	20.2	181	94.6
10	0.85	20.5	184.5	98.1

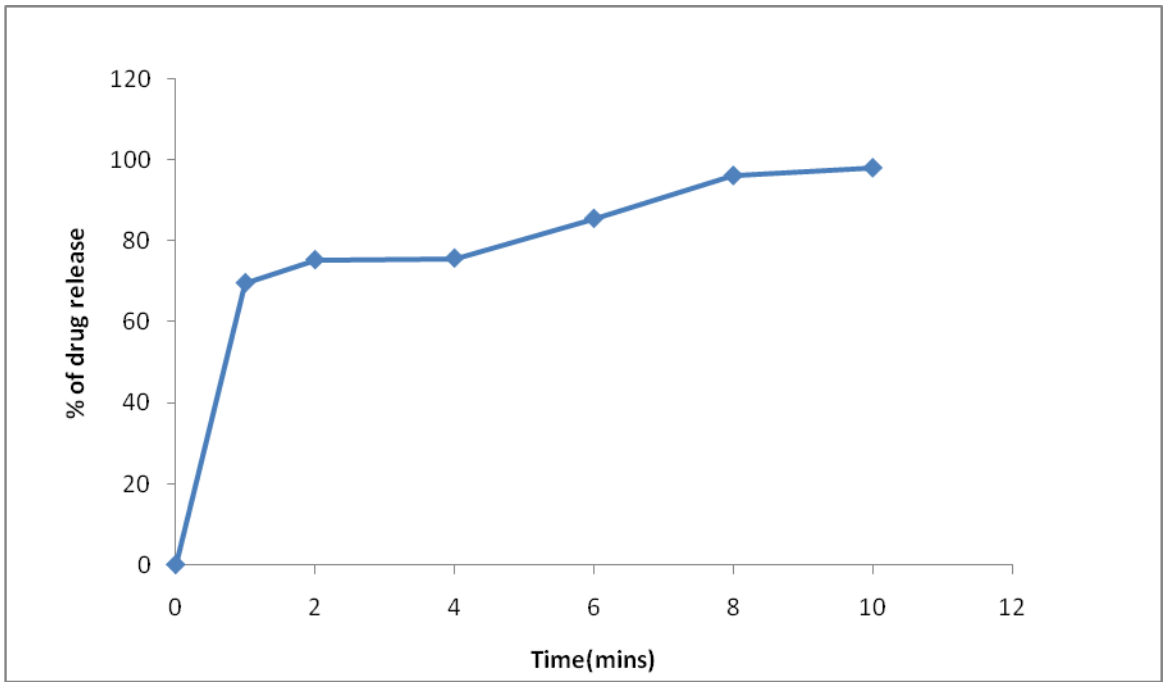

Fig no.4

Table no.12: INVITRO DISSOLUTION STUDIES OF FORMULATION –F4

Time(mins)	Absorbance	Concentration(µg/ml)	Concentration(mg/900ml)	$^0/_0$ Of drug release
1	0.58	14.5	130.5	68.6
2	0.69	15.5	148.5	75.07
4	0.7	17.5	157.5	82.8
6	0.75	18	162	85.2
8	0.83	20.2	181	95.6
10	0.85	20.5	184.5	97.1

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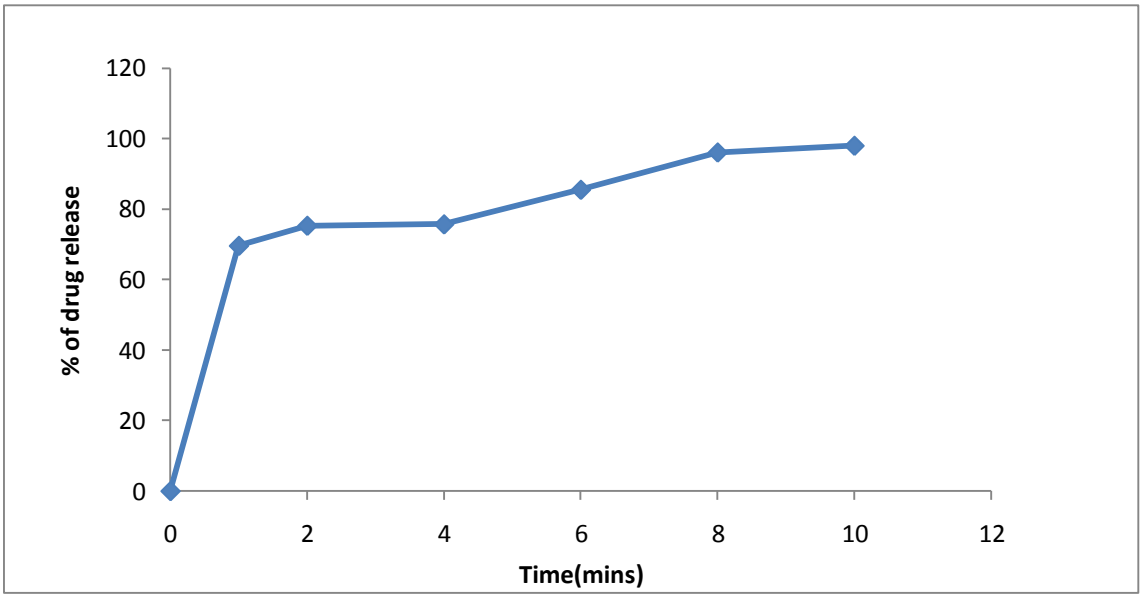

Fig no.5

Table no13: INVITRO DISSOLUTION STUDIES OF FORMULATION-F5

Time(mins)	Absorbance	Concentration(µg/ml)	Concentration(mg/900ml)	% Of drug release
1	0.60	14.8	133.2	70.1
2	0.61	15	135.0	71.0
4	0.68	16	144.0	75.7
6	0.79	19	171.0	90.0
8	0.83	20.2	181.0	94.6
10	0.84	20.3	182.7	96.8

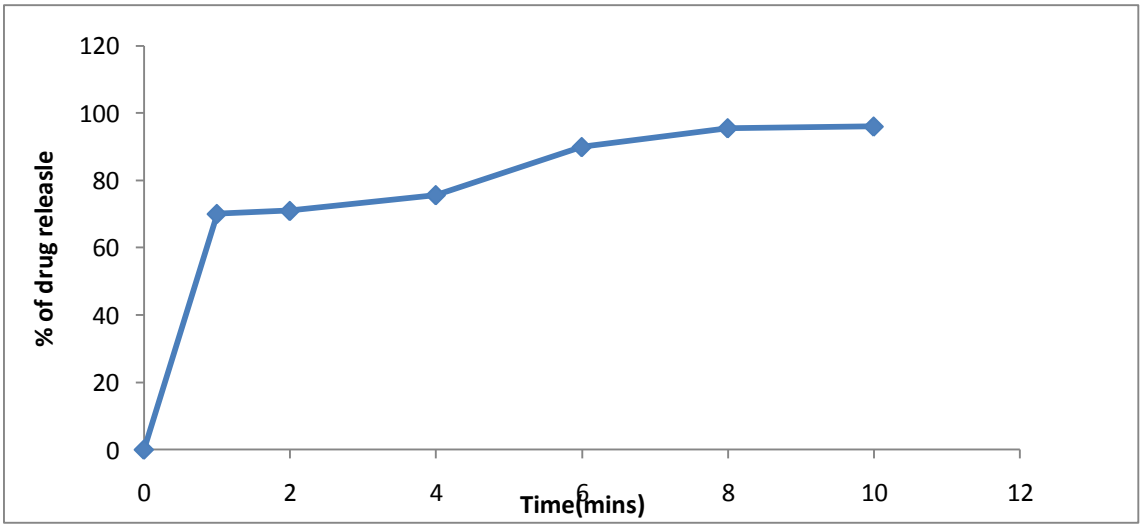

Fig no.6

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SUMMARY AND CONCLUSION

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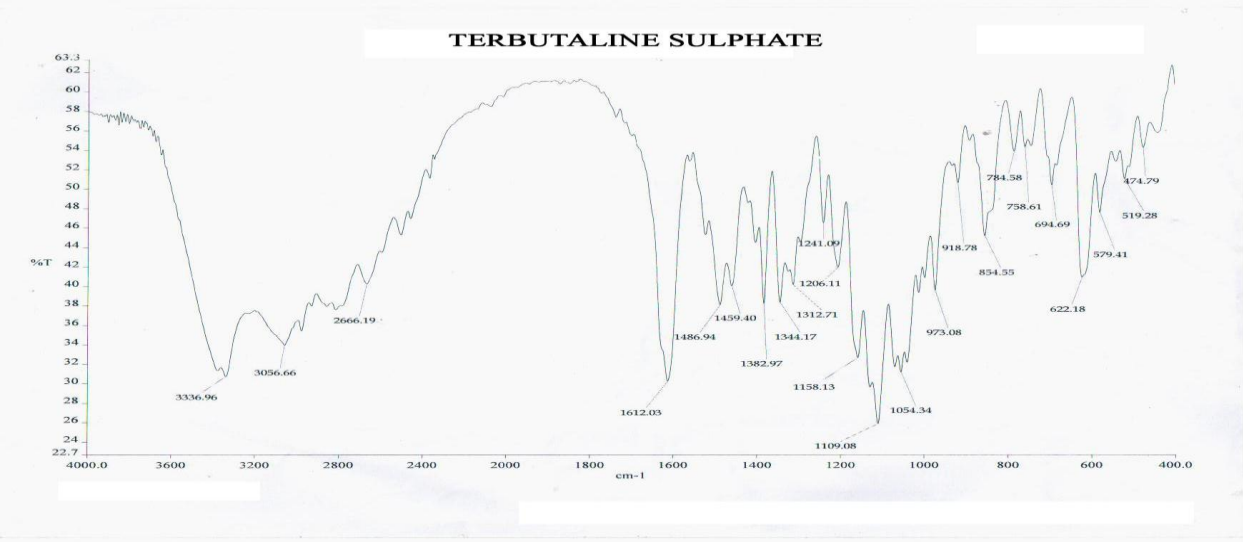
FT-IR STUDIES:



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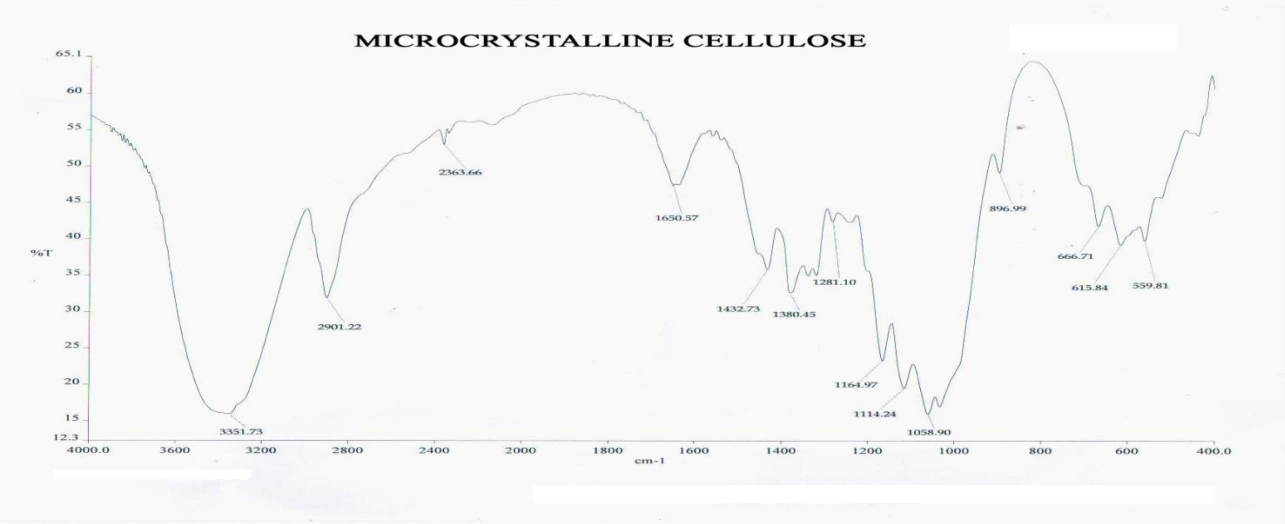

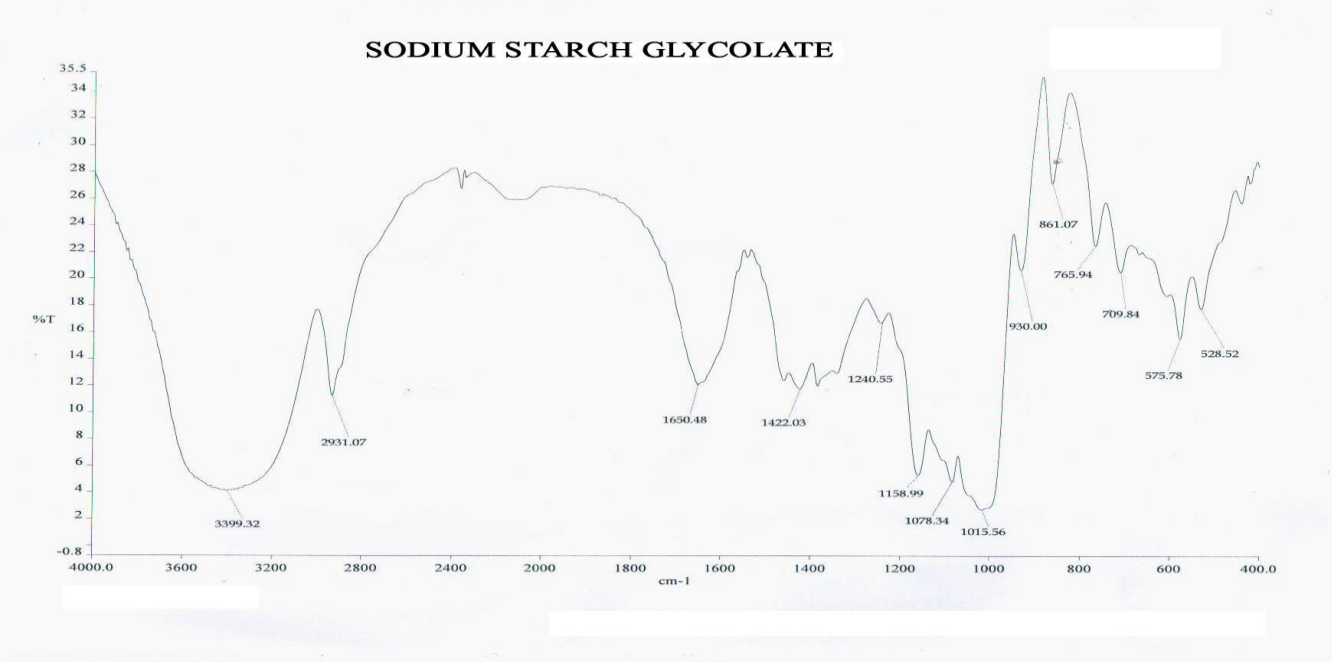

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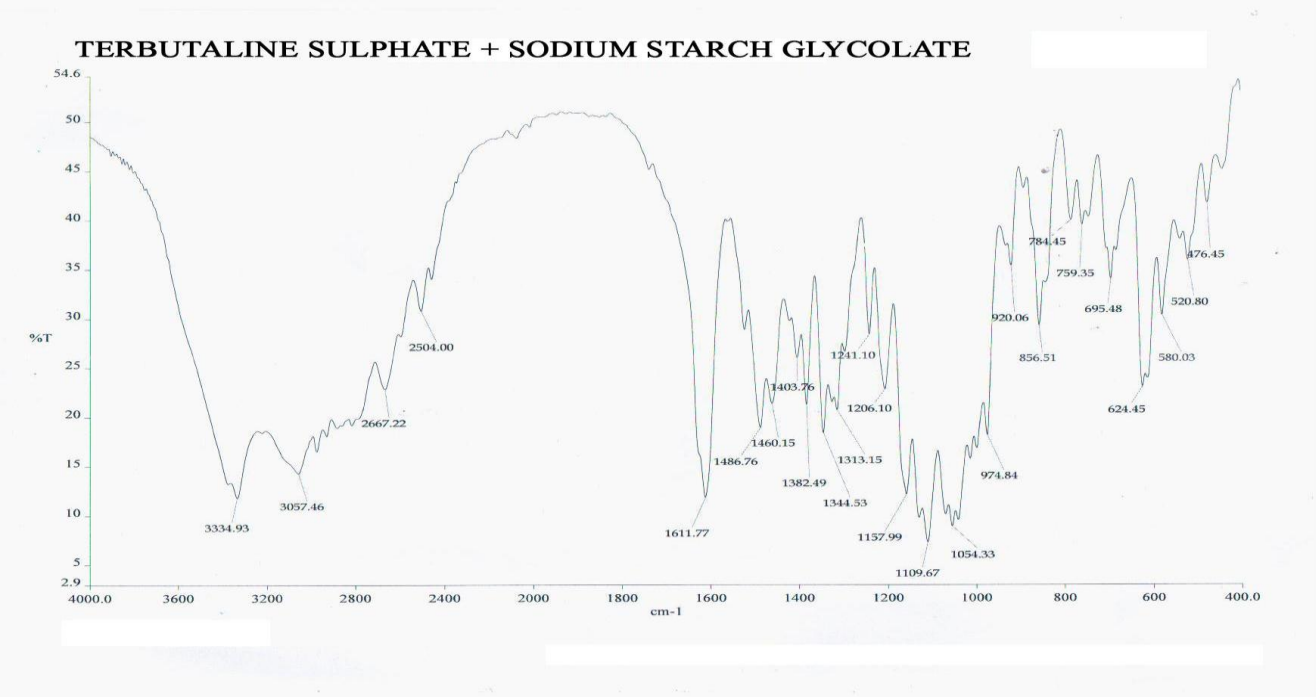

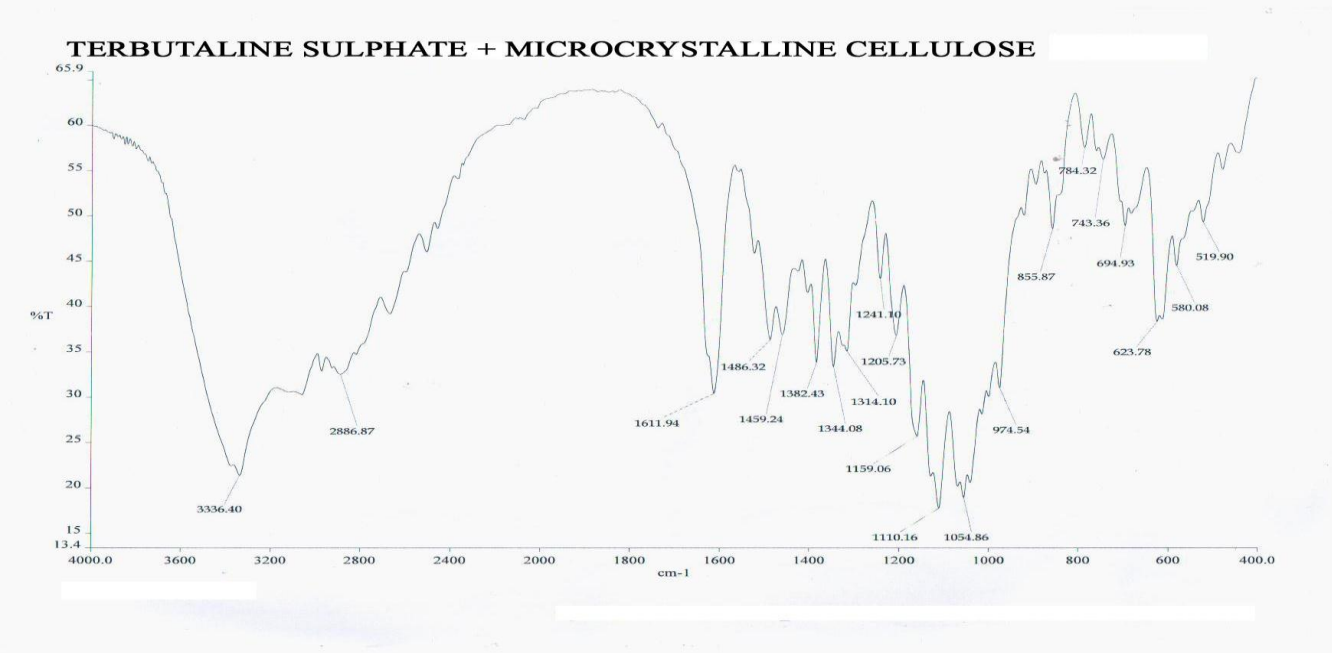

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