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RESEARCH ARTICLE

FORMULATION DEVELOPMENT AND CHARACTERIZATION OF FAST DISSOLVING TABLET OF ATENOLOL BY DIRECT COMPRESSION METHOD

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Abstract

Finally in the project work Atenolol is an anti-hypertensive drug. It has been formulated into fast dissolving tablets by direct compression method by using the Excipients like lactose, sucrose magnesium stearate, sodium lauryl and sulphate and many type super disintegrates such as crosscarmellose and sodium starch glycolate and the prepared by the tablets were evaluated for the pre-compression parameter such as angle of repose, bulk density, tapped density, % index, Hausner's ratio, partition coefficients, melting points, UV spectroscopy, % assay, TLC, loss on drying and post compression parameter such as thickness, hardness, friability, drugs contents, weight variation, water absorbance ratio, Invitro disintegrating time , Invitro dissolution studies. All the parameter shows good results. FDTs are prepared by direct compression method are results found to be that the among of nine formulation as the F9 to be best as its shows 87.10% (direct compression method) maximum drug release respectively. The stability testing of manufactured tablets have being at 40^0 c having 75% relativity humidity for 1month and found to be stable. Prepared fast dissolving tablets of Atenolol 10 mg was found to be under fasting federal condition.

Introduction:-

Oral routes of drug administration have been most acceptances UP to 50-60% of total dosage forms. Solid dosages forms are drug have most popular and easy because of simple administration, accurate dosage, self- medication, pain avoidance and most importantly the patient compliance [1]. The solid dosage forms are most popular are being tablets and capsules; this dosage forms one important drawback for some patients, is the difficulty to swallow [2]. The Drinking water has been important role in plays by swallowing of oral dosage forms. Practice in usefulness often times people in swallowing usefulness dosage forms such as tablet when water is not available, in the case of the motion sickness and sudden episodes of coughing is during the common cold, Condition of allergic and bronchitis [3] Those tablets are also or disintegrate or dissolve speedily in the oral cavity have connected a great contract of attention for this reason. The Orodispersible tablets are haves not only indicated for people who have been swallowing difficulties, but also are ideal for active people [4]. Mouth-dissolving tablet are also called Fast dissolving tablets are melt- in mouth tablets, quick dissolving etc. Which the drug dissolve or disperses in the saliva as he fast dissolving tablets are those when put on the tongue disintegrate instantaneously releasing [5]. The Faster absorption of drug and onset of action for clinical effect, the faster the drug into solution, some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach [6]. In such cases,

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bioavailabilities of drug have been significantly greater than those observed from conventional tablets dosage form. The fast dissolving dosage is advantage of increasingly being recognized in both, academics and industry [7].

Mechnism of Action Atenolol

A relativey selective beta1 blocker having low lipid solubility. The absorbed orally not clearly, but first pass metabolism is not significant. Because of longer duration of action. Once daily dose is often sufficient, side effect related to CNS action are less likely. No deleterious effect on lipid profile have been noted. Effective dose for most individuals false in a narrow range. It is one of the most commonly used beta1 blocker for hypertension and angina.

Use

1. Hypotension
2. Acute myocardial interaction
3. Symptomatic heart failure
4. Super ventricular tachycardia
5. Angina
6. Chest pain
7. B.P
8. Heart attacks
9. kidney problem

Side Effects

1. Constipation indigestion
2. Dizziness of faintness
3. Low blood pressure
4. Dry cough
5. Angioedema [8-11]

Method and Materials:-

The Atenolol is obtained as gift sample from Aristo Pharma,pvt Ltd Mumbai,Sodium Starch Glycolate obtained from S.Dfine chem,limited Mumbai ,Manitol S.D fine limited,Mumbai All the ingredients used were of analytical grade.

Micromeritics

Pre-Compression Method

Angle of Repose

The angle of repose is measured by accepting mass of powdered to flow freely through an orifice from a certain height and form a conical heap on the horizontal surface. The angle of repose is noted by the formula.

Tan θ=h/r

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

Where, h = height r = radius [12]

Bulk Density: Bulk density is ratio of given mass of powder and its bulk volume. Bulk density was determined by measuring the volume mass of powder sample that has been passed through the screen in to graduated cylinder or through volume measuring apparatus in to cap.

Bulk density =M /V0

Where M= mass of powder

V0=bulk volume of powder

Tapped Density

For purpose of the bulk density, a weigh quantity of the granular powder is insert into a graduated measuring cylinder and is tapped mechanically either manually or using a tapping instrument trough a never endind volume is obtain.

Tapped density = M/Vr
Where M=Mass of the powder.
Vr = final tapped volume of powder.

Compressibility Index
The main routine is to measure the uncomfirmed unmistakable volume, (VO), and the final tapped volume, (Vf), of the powder after tapping the material until no further volume changes occur. The Calculated are the Hausner's ratio and compressibility index as follows.

Compressibility index = 100 × Vo- Vf/Vo
Hausner's ratio = Vo/Vf
Where, VO = unmistakable volume,
Vf= final tapped volume.

Alternatively, the Hausner's ratio and compressibility index may be calculated by using measured values of bulk density and tapped density as follows:

Compressibility index = 100 × Tapped density-bulk density / bulk density
Hausner's ratio = tapped density/ bulk density

UV Spectroscopy: ʎmax for pure Atenolol in water Apparatus
VU spectroscopy (semadzu) Prepared by 1 µg/ml sample and scanned between 200-400nm. The drug showed maximum absorption at 208nm. So the ʎmax of Atenolol was found to be 226nm.[16]

Preparation of standard curve for Atenolol
10mg of Atenolol pure drug was accurately weighed & transferred into a 10ml volumetric flask, dissolved in little quantities of distilled water, then made up to 10ml with water (1000µg/ml). From this solution, withdrawn 1ml of solution into a 10ml volumetric flask & made up to 10ml with distilled water to get a concentration of 100µg/ml. From this, again pipette out 1ml of solution & diluted to 10ml with distilled water to get a concentration of 10µg/ml.It was measured and absorbance at 226 nm using UV/VIS spectrophotometer against blank (distilled water).[12-15]

Various techniques for fast dissolving tablets.
1. Freeze drying / lyophilization
2. Tablet Moulding
3. Spray drying
4. Sublimation
5. Direct compression
6. Mass extrusion

Formulation Development
By Direct Compression Method
The critical parameters to systematize a fast dissolving tablet are selection of superdisintegrant and optimization of concentration of superdisintegrant. The main criteria for fast dissolving tablets is to disintegrate or dissolve rapidly in buccal cavity in 15-60 seconds, without need of water and should have pleasant mouth feel. The super disintegrate (crosscarmellose, and Sodium Starch Glycolate) were used to formulate the tablets. All the ingredients as shown in Table 4 were co-ground in a pestle and motor and then lactose and magnesium stearate re added and mixed for 10 minutes.The passed through were the all ingredients # 60-mesh separately. The mixed blend of drug-excipient was compressed using a single punch tablet machine. [16-17]

Evaluation of the Fast Dissolving tablets (FDT)
The Quality control tests is formulation for FDTs were performed, and they were calculated the average values. The evaluated for different parameters for the all tablets were as weight variation, hardness, friability, wetting time, water absorption ratio, drug content,disintegration time and *in vitro* dissolution study.

Tablet Thickness
The take the three tablets of the each batch and thickness determined using a Vernier caliper. The thickness was measured in centimeters.

Weight Variation
They were selected 20 tablets randomly from each batch and weighed individually on electronic balance (Shimadzu). Then the compared with average weight for the weight variations by the individual weighed.

Hardness
The strength of tablet s is expressed as tensile strength (kg/cm2). Which is the force required for the tablet crushing load, to break a tablet into pieces by compression. Hardness tester (Monsanto hardness tester). The tablets were measure using a tablet. The formulation of three tablets from each batch was tested randomly and the average readings were noted.

Friability
The tablets fsriability was determined using Roche Friabilator. Consist of this device is made by plastic chamber that is set to revolve around 25 rpm for 4 min dropping the tablets at a distance of 6 inches with each revolution. Take the 20 tablets and again time weight and it was placed in to the friabilator tester and were subjected to 100 revolutions. The dust tablets were using a reweighed and soft muslin cloth. The friability (% F) is express by this formula.

% Friability = (Initial weight - Loss in weight) / Initial weight×100
Below of the friability 1% was considered as acceptable.

Drug Content
Twenty tablets were weighed and powdered. An amount of the powder equivalent to 10mg of Atenolol was dissolved in 100 ml of phosphate buffer solution, pH 6.8., diluted suitably, filtered and analyzed for drug using UV-Visible spectrophotometer content at 216 nm (Shimadzu 1700, Tokyo, Japan).

Wetting Time & Water Absorption Ratio
A parts of tissue paper folded twice was placed in a small petri dish (internal diameter = 6.5 cm) containing 6 ml of phosphate buffer solution, pH 6.8. Placed to the tablets on the paper and time required for complete wetting was measured using a stop watch. The wetted tablet was then weighed. Water absorption Ratio (R) was determined using following equation,

R = Wa -Wb ×100
Wa = Weight of tablet after water absorption,
Wb = Weight of tablet before water absorption.

Wetting Time
In Vitro Disintegration Time
The phosphate buffer solution is the 10 ml, pH 6.8 was placed in a petridish of 10 cm diameter. Then the carefully positioned in the tablets center of the petridish and the time required for the tablet to completely disintegrate into fine particles was noted.In-vitro disintegration times for Fast dissolving tablets of Atenolol were determined using USP disintegration test apparatus with 900 ml of phosphate buffer solution, pH 6.8 as medium maintained at a temperature of 37 } 2°C. The complete disintegration to the seconds time of the tablets was taken with the no palpable mass remaining in the apparatus was measured.

In-vitro Dissolution Study
The release rates of Atenolol from fast dissolving tablets were determined using The XXIV dissolution testing apparatus II (paddle method) by United State Pharmacopoeia (USP). The dissolution test was performed using 900 ml of phosphate buffer 6.8, at 37±0.5°C and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at regular intervals of 1 mins for 30 mins. The fresh dissolution medium of same quantity of the samples had been replaced. The filtered through of a samples were a Whitman filter. Absorbance of these solutions was measured at 226 nm using UV Spectrophotometer. Then the calculated cumulative percentage of drug release.

Stability studies

The stability studies is in order to determine the change in In-vitro release profile on stability studies, storage of optimized batch i.e, F9 had been carried out at 40°C in a humidity chamber having 75% RH . The regular intervals of samples were withdrawn at 15 days during the study of 30 days. Formulation is evaluated for change in In-vitro drug release pattern, hardness, wetting time, percent drug content. [18-19]

Results and Discussion:-

Pre-formulation study: In Preformulation studies various characteristic of drug such as identification analytical method, Micromeritic, solubilities study, loss on drying and partition coefficients were evaluated. The results for these studies are shown in table no.7.

Formulation and evaluation Atenolol fast dissolving tablet were prepared by direct compression method was carried out by using superdisintegrant (crosscarmellose and sodium starch glycolate) and other excipient as mention in formulation chart (table no.4). By the direct compression method of nine formulations were prepared.

The Preformulation studies such as bulk density, tapped density, angle of repose, compressibility index, Hausner's ratio. All the Preformulation studies were found the prescribed limits and indicated fair flow properties Calibration curve of was prepared in distilled water at ʎmax 226 nm. Regression value (R2) was found to be 0.994, y=1.069x in the range of 0.1-0.6 µg/ml. and Calibration curve of was prepared in Phosphate buffer pH 6.8 at ʎmax 226 nm.

Regression value (R2) was found to be 0.999, y=0.491x in the range of 0.1-0.6 µg/ml.

Assay of Atenolol is determined by UV Spectroscopy method. The % assay or purity of standard value is 98.5% to 101.5%. The observed value was 98.35% within the range of official standard. Not any impurity was detected. Purity of Atenolol was carried out by TLC. The standard Rf value of Atenolol is 0.55. The observed value was 0.53 within the range as per official standard. None of the inactive ingredient was detected.

The moisture uptake was determined by Loss on drying (LOD) method at 105ºC.The Standard value of loss of drying is not more than 1%. The observed value was 1% within range per official standard. It was observed that Drug form in lower mean particle Out of all formulation in direct compression method, F9 direct compression was found satisfactory.

The angle of repose was ranged between 25.519±0.865 the compressibility index value were found to be in the range of 80.34% the Hausner's ratio were found to be in the range of 1.40±0135. The bulk density and tapped were found to be in range of 0.56±0.006 & 0.52±0.0058.

All evaluation parameter of F9 was here, the hardness was found 3.09±0.10. Thickness of varied from 4.44±0.044mm. The loss of total weight of tablets due friability was 0.19±0.18. the drug content was 99.69±0.63 %. The wetting time was 35.11±0.22 sec.

Disintegration time was found 69.60±0.63 sec. the water absorption ratio was 209.65±0.89. Dissolution test was carried out 50rpm using phosphate buffer (PH 6.8) 87.10%. In direct compression method F9 was show satisfactory results.

Table no.1:- Flow properties and corresponding Angle of repose, Compressibility index and Hausner's ratio.

S.NO.	Flow properties	Angle of repose(θ)	Compressibility Index (%) or Carr's index	Hausner's ratio
1.	Excellent	<25	<10	1.00-1.11
2.	Good	25-30	11-15	1.12-1.18
3.	Fair	31-35	16-20	1.19-1.25
4.	Passable	41-45	21-25	1.26-1.34
5.	Poor	46-55	26-31	1.35-1.45
6.	Very poor	56-65	32-37	1.46-1.59
7.	Very very poor	>66	>38	>1.6

Pre-Compression Study of Powder Blend

Table no.2:- Pre-compression parameter of powder blend (direct compression method).

Formulation code	Bulk density (gm/ml)±SD	Tapped density(gm/ml)±SD	Angle of ±SD	Carr index(%)±SD	Hausner's ratio ±SD
F1	0.38±0.0059	0.65±0.0022	25.519±0.86	12.9±1.12	1.40±0.02
F2	0.40±0.0060	0.47±0.0018	30.00±1.66	14.93±1.34	1.18±0.03
F3	0.37±0.0038	0.40±0.0032	27.75±1.03	6.41±1.21	1.07±0.04
F4	0.39±0.0037	0.44±0.0023	33.57±0.38	12.23±1.41	1.14±0.04
F5	0.41±0.0028	0.49±0.0039	35.34±0.45	16.31±1.61	1.19±0.02
F6	0.50±0.0083	0.60±0.0041	28.60±3.88	16.7±1.53	1.20±0.03
F7	0.43±0.0055	0.51±0.0044	25.74±1.80	16.94±1.58	1.20±0.04
F8	0.43±0.0024	0.51±0.0036	27.95±2.26	15.00±2.23	1.18±0.04
F9	0.43±0.0058	0.52±0.0058	32.85±1.45	18.34±2.02	1.22±0.02

Table no.3:- Standard calibration curve in water.

S.no.	Concentration	Absorbance
1.	0	0
2.	0.1	0.256
3.	0.2	0.345
4.	0.3	0.423
5.	0.4	0.497
6.	0.5	0.531
7.	0.6	0.562

Table no. 4:- Formulation of Atenolol fast dissolving tablet (Direct compression method).

Ingredients (in mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Atenolol	10	10	10	10	10	10	10	10	10
Crosscarmellose	5	20	25	30	25	20	35	37	45
SSG	30	50	50	38	35	26	25	38	20
Mg. stearate	90	90	90	100	90	90	100	100	90
Lactose	25	50	65	60	20	40	50	65	60
Sucrose	110	100	110	100	110	110	100	110	110
SLS	50	60	50	40	50	60	50	30	50
Starch(20%conc)	q.s	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Evaluation Parameter by Direct Compression Method

Table no.5:- Evaluation of fast dissolving tablet of Atenolol (Direct compression method).

Evaluationp parameter	F1	F2	F3	F4	F5	F6	F7	F8	F9
Thickness(mm)±SD	4.71±0.041	4.5±0.040	4.56±0.10	4.87±0.050	5.01±0.051	4.83±0.043	4.87±0.041	4.53±0.049	4.44±0.045
Hardness (kg/cm^2)±SD	3.83±0.11	3.71±0.30	3.56±0.24	3.56±012	3.49±0.24	3.42±0.38	3.41±0.35	3.20±0.05	3.09±0.11
%Friability ± SD	0.52±0.19	0.60±0.15	0.62±0.20	0.58±0.12	0.59±0.17	0.59±0.13	0.64±0.09	0.68±0.11	0.19±0.19
Disintragration time (sec) ± SD	98.16± 0.60	96.11` 0.43	90.51± 0.24	88.20± 0.24	87.86± 0.83	86.52± 0.42	78.52± 0.85	71.69± 0.77	69.60± 0.64
Wetting (sec)±SD	40.22± 0.26	38.90± 0.10	37.45± 0.19	36.65± 0.25	36.75± 0.34	36.25± 0.54	35.90± 0.46	35.78± 0.59	35.11± 0.21

Water absorption a ratio	141.68 ±0.57	149.27 ±0.78	156.34 ±0.81	150.65 ±0.46	148.36 ±0.78	155.28 ±0.90	180.91 ±0.78	193.69 ±0.55	209.65 ±0.88
Content uniformity(%)±SD	99.27± 0.62	96.99± 0.54	99.81± 0.34	98.85± 0.21	97.81± 0.43	98.92± 0.88	69.97± 0.37	98.64± 0.30	99.69± 0.64

Table no.6:- Drugs release profile of direct compression method (F9).

TIME (mints)	ABS	CONC(µg/ml)	CONC(mg/ml)	AMT IN 900ml * D.F.	%DR	LOG%DR
0	0	0	0	0	0	0
1	0.256	0.521384929	0.001564155	1.407739308	28.15479	1.449552
2	0.345	0.702647658	0.002107943	1.897148676	37.94297	1.579131
3	0.423	0.861507128	0.002584521	2.326069246	46.52138	1.667653
4	0.497	1.012219959	0.00303666	2.73299389	54.65988	1.737669
5	0.531	1.081466395	0.003244399	2.919959267	58.39919	1.766407
6	0.562	1.144602851	0.003433809	3.090427699	61.80855	1.791049
7	0.591	1.203665988	0.003610998	3.249898167	64.99796	1.812981
8	0.692	1.409368635	0.004228106	3.805295316	76.10591	1.881418
9	0.762	1.551934827	0.004655804	4.190224033	83.80448	1.923267
10	0.792	1.613034623	0.004839104	4.355193483	87.10387	1.940037

Table no.7:- Results Preformulation study.

S.no.	PREFORMULATION STUDY	Results
1.	**Organoleptic properties** Description: Colour: Odour: Taste**:**	 White or almost white powder White Odourless Bitter
2.	IDENTIFICATION UV absorption maxima TLC Melting point	 208, 226 Rf =0.56 154-160^{oC}
4.	CALIBRATION CURVE In water In phosphate buffer P^H 6.8	 λmax y =1.069x λmax y =0.491x
5.	MICROMERITICAS Bulk density Tapped density Carr' s index Angle of repose	 0.38±0.03 gm/ml 0.56±0.06 gm/ml 12.9±1.22 (flow property –good) 25.519± 0.865(flow property- good)
6.	LOSS OF DRYING	1%
7.	pH	5.58±0.08
8.	SOLUBILITY	Atenolol, ethanol, distilled water, Chloroform.
9.	PARTITION COFFICIENTS	2.45±0.011(lipophilic in nature)
10.	DRUG- EXCIPIENTS INTRECTION	No interaction

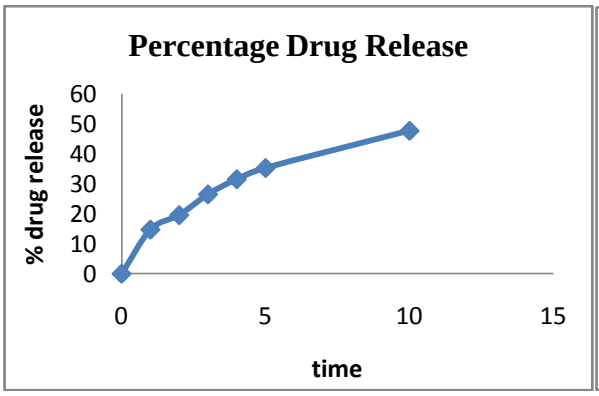
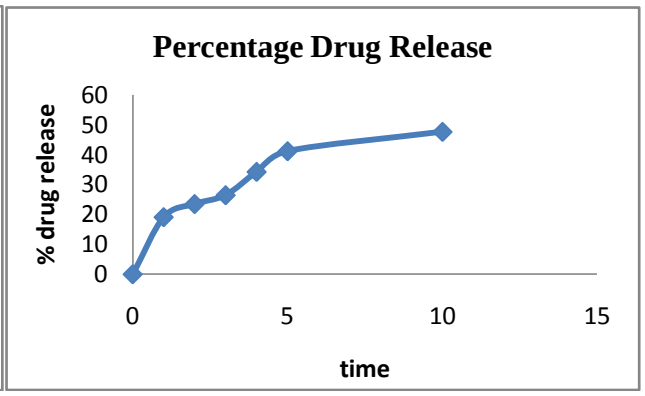


Fig no.1:- (F1)



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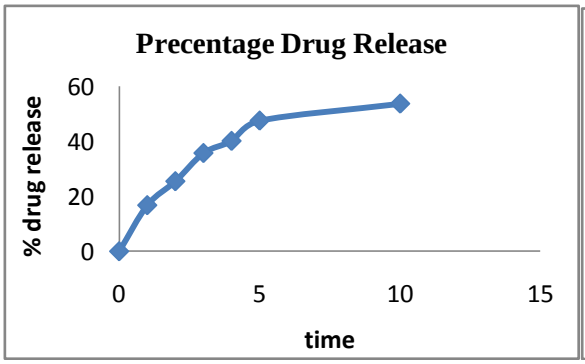

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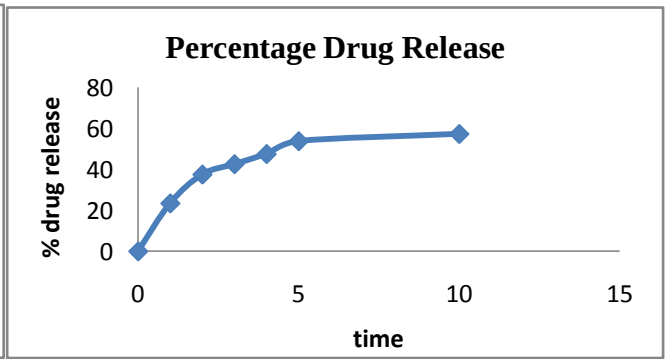

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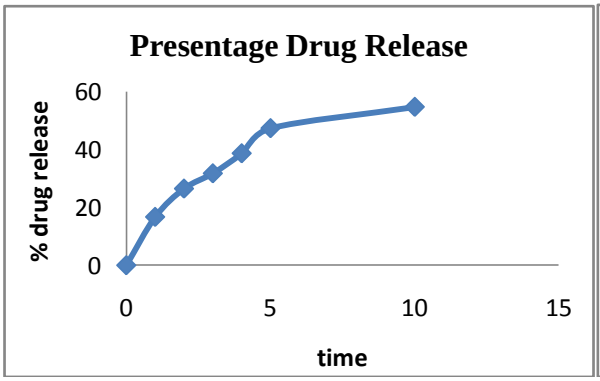

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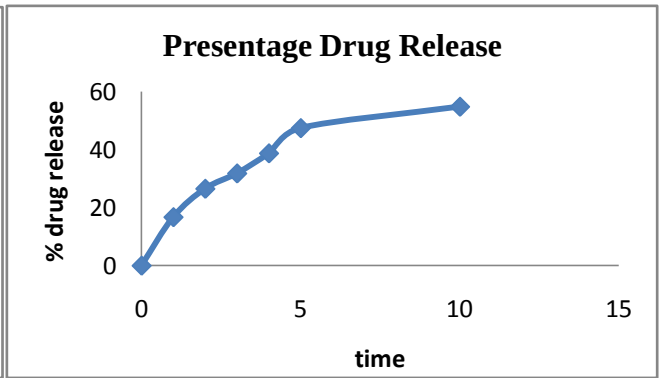

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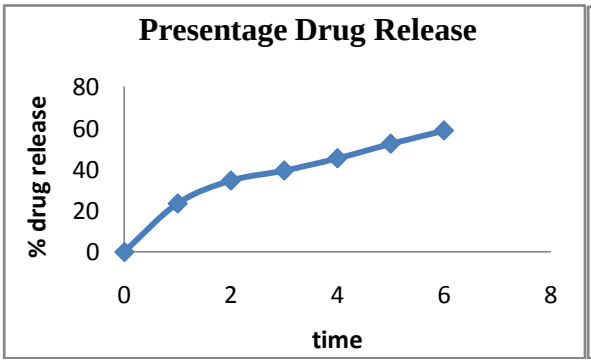

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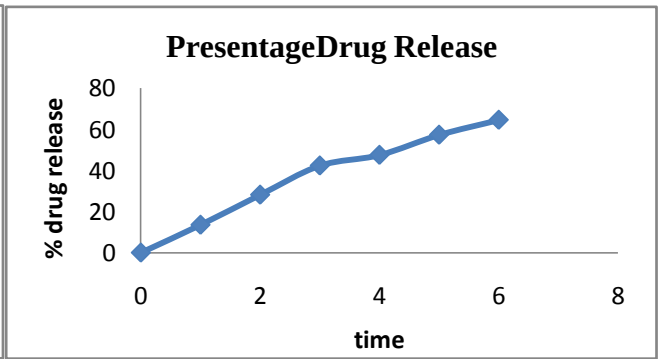

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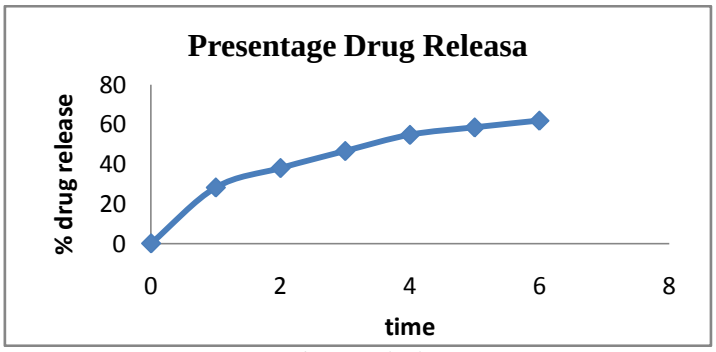

Fig no:- (F9)

Conclusion:-

In the presents study various formulation of fast dissolving tablets were prepared by direct compression method. To perform Preformulation studies like Micromeritics, melting point, partition coefficients, UV spectroscopy, % assay, thin layer chromatography, loss on drying. In direct compression method tablet was prepared by using super disintegrates (crosscarmellose and sodium starch glycolate), lubricant (magnesium stearate), diluents (lactose), surfactant (sodium lauryl sulphate), sweetening agents (sucrose), binder (starch 20%). Total nine formulations were prepared. Tablets were evaluated for various parameter like hardness, thickness, weight variation, friability, % drugs content, water absorption time, wetting time, disintegrating time, % in vitro dissolution study. The in-vitro release profile depends upon type and concentration of superdisintegrant and drug release was Increase with Superdisintegrants concentration. (40 mg) fulfilling all the parameter satisfactory and as shown fasted disintegration (55±1.2), wetting time (37±2.5) and higher % drug release (88.3%) as compared to other formulation. Over all, the results suggest that the suitably formulated fast dissolving tablet of Atenolol Containing super disintegrating (F9) can be achieved. Amongst all the formulation F9 containing superdisintegrant (sodium starch glycolate 20 mg, croscarmellose Over direct compression method, because the release of faster rate of dissolution is due to high porosity created by direct compression technique.

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