Formulation and Evaluation of Medicated Chewable Tablets of Triamterene

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Abstract*— Chewable tablets are required to broken & chewed in between teeth before ingestion. These are usually uncoated. These are intended to be chewed in the mouth before swallowing and not intended to be swallowed directly. Chewable tablets are designed for use by the children and those persons who may have difficulty in swallowing the tablets. The objective is to develop efficient formulation of Triamterene chewable tablet. Triamterene is potassium-sparing diuretic used for the treatment of hypertension. Triamterene medicated chewable tablets are prepared by Wet Granulation method using two super-disintegrants i.e Crospovidone and Sodium Starch Glycolate. Total 6 formulations are prepared and the blend is evaluated for pre-compression parameters i.e angle of repose, bulk & tapped density, compressibility index & Hausner's ratio. These formulated tablets are evaluated for Thickness, Diameter, Hardness, Weight Variation, Disintegration, Friability and Drug Content. The result showed that all the physical parameters are within acceptable limits. From 6 formulations, formulation F4 is selected as promising formulation on the basis of In-Vitro drug release & In-Vitro dispersion time which is found to be 24.54±1.202 sec and 95.26±2.57 % respectively.

Indexed Terms*— Triamterene, Chewable tablets, Crospovidone and Sodium starch glycolate

I. INTRODUCTION

a) Tablets –

Tablets are defined as solid dosage forms each containing a single dose of one or more active ingredients, obtained by compressing uniform volumes of particles. They are intended for the oral administration, some are swallowed whole, some after being chewed. Some are dissolved or dispersed in aqueous phase before being administered andsome are retained in the mouth, when the active ingredients are "liberated". Tablets are used not only for systemic drug delivery but also for local drug action. For systemic use drug must be released from tablet that is dissolved in the fluids of mouth, stomach and intestine and then absorbed into systemic circulation by which it reaches its site of action.The tablet is composed of the Active Pharmaceutical Ingredient (active drug) together with various excipients.

Chewable tablet: -

Chewable tablets are tablets which are required to be broken and chewed in between the teeth before ingestion. These are given to the children who have difficulty in swallowing& to adults who don't like swallowing. These tablets are intended to disintegrate in mouth at a moderate rate with or without actual chewing, substantially chewable tablets have a smooth texture with pleasant taste and leaving no bitter or unpleasant taste. Tablet formulation development involves the careful selection of ingredients in order to manufacture solid dosage form. Choose the correct excipients to perform a specific function in a tablet formulation that are disintegration or lubrication can be critical. Sweeteners, both natural and synthetic are one type of functional excipient most commonly used in chewable tablet formulations to mask the unpleasant tastes and promote pediatric dosage. Generally on chewing, tablets are broken down in the mouth and release their ingredients in the process so, don't have much lagging time as required for the disintegration before absorption from stomach. Chewable tablet are used when the active ingredient is intended for action in a localized manner rather than systemic. Chewable tablet is appetizing & can be chewed and ingested with little or without water.

TRIAMTERENE-
Triamterene (trade name Dyrenium) is a potassium-sparing diuretic used in the treatment of hypertension and edema. In combination with hydrochlorothiazide, it is marketed under the names Maxzideand Dyazide.
Accession Number: DB00384 (APRD00079) Type: Small Molecule
Synonyms: 6-phenylpteridine-2,4,7-triamine, Teridin, Triamteren, triamterena. Weight Average: 253.2626
Chemical Formula: C12H11N7 Bioavailability: 30-70%
Protein binding: 67%
Metabolism: hydroxylation to para-hydroxytriamterene Half-life: 3 hours
Excretion: renal <50%, 21% unchanged Categories

- Agents causing hyperkalemia
- Cardiovascular Agents
- Cytochrome P-450 CYP1A2 Substrates
- Decreased Renal K+ Excretion
- Diuretics
- Diuretics, Potassium Sparing
- Epithelial Sodium Channel Blockers
- Hypotensive Agents

II. MATERIALS AND METHODS

2.1 Materials –
Triamterene Cadila Healthcare Ltd. Matoda, Ahmedabad Sodium starch glycolate Sd Fine Chemicals, Mumbai.
Crospovidone Sd Fine Chemicals, Mumbai. Mannitol Sd Fine Chemicals, Mumbai.

Aspartame Sd Fine Chemicals, Mumbai. PVP-K30 Sd Fine Chemicals, Mumbai.
Microcrystalline cellulose Sd Fine Chemicals, Mumbai. Mg. stearate Sd Fine Chemicals, Mumbai.
Talc Sd Fine Chemicals, Mumbai.
Orange flavor Sd Fine Chemicals, Mumbai.
Potassium dihydrogen orthophosphate Sd Fine Chem Limited, Mumbai. Methanol Sd Fine Chemicals, Mumbai.
Hydrochloric acid Sd Fine Chemicals, Mumbai.

2.2 Equipments –
1. UVSpectrophotometer (UV-1800) Shimadzu, Japan.
2. Electronic weighing balance (BL-220H) Japan Shimadzu, Japan.
3. Disintegration test apparatus ED-2L Electrolab, Mumbai.
4. Dissolution test apparatus TDT-08L Electrolab, Mumbai.
5. Digital pH meter Micropro labmate.
6. Test sieve (No.60) Sethi.
7. Hot air oven Sisca thana, east Maharashtra.
8. Stability chamber Lab Control Equipment Co. Mumbai.
9. Friabilator USP EF-2 Electrolab, Mumbai.
10. Station rotary tablet punching Machine Clit, Ahmedabad. 11. Digital hardness tester Electrolab, Mumbai.

2.3 Methods –
PREPARATION OF CALIBRATION CURVE OF TRIAMTERENE

Standard calibration curve of Triamterene in methanol -

- Standard solution:

Accurately weighed 100 mg of Triamterene was dissolved in 100 ml of methanol to get a solution containing 1000 mcg/ml.

- Stock solution:

From the standard stock, a stock solution was prepared to give a concentration of 20 mcg/ml in methanol. Aliquots of 1, 2, 3, 4 and 5 ml of stock solution were pipetted out into 10 ml volumetric flasks. The volume was made up to the mark with methanol. These dilutions give 2, 4, 6, 8 and 10 mcg/ml concentration of Triamterene respectively. The absorbance of prepared solution of Triamterene in methanol was prepared at 225.6 nm in Shimadzu UV-1700 spectrophotometer against an appropriate blank (methanol). The absorbance data for standard calibration curves are given in table-10. The standard

Calibration curve yields a straight line, which shows that the drug follows Beer's law in the concentration of 2-10 mcg/ml.

Standard calibration curve of Triamterene in 0.1 N HCl (pH 1.2):

- Standard solution-:

Accurately weighed 100 mg of Triamterene was dissolved in 100ml of methanol to get a solution containing 1000 mcg/ml.

- Stock solution:

From the standard stock, a stock solution was prepared to give a concentration of 20 mcg/ml in methanol. Aliquots of 1, 2, 3, 4 and 5 ml of stock solution were pipetted out into 10 ml volumetric flasks. The volume was made up to the mark with 0.1 N HCl (pH 1.2). These dilutions give 2, 4, 6, 8 and 10 mcg/ml concentration of Triamterene respectively. The absorbance of prepared solution of Triamterene in 0.1 N HCl (pH 1.2) was prepared at 225.7 nm in Shimadzu UV-1700 spectrophotometer against an appropriate blank 0.1 N HCl (pH 1.2).

The absorbance data for standard calibration curves are given in table-11. The standard calibration curve yields a straight line, which shows that the drug follows Beer's law in the concentration of 2-10 mcg/ml.

Method of Preparation of chewable tablets of Triamterene:

Preparation: Direct compression method has been employed to prepare chewable tablets of Triamterene using crospovidone and Sodium starch glycolate as superdisintegrants. Procedure: All the ingredients including drug, polymer and excipients were weighed accurately according to the batch formulae (Table-4) and passed through a standard sieve (sieve no 60). The drug is thoroughly mixed with diluent on a butter paper with the help of a stainless steel spatula. Then all the ingredients except lubricants were mixed in the order of ascending weights and thoroughly blended for 10 min in an inflated polyethylene pouch. After uniform mixing of ingredients, lubricant was added and again mixed for 2 min and evaluated for bulk density, tapped density, compressibility index (Carr's index), Housner ratio and angle of repose. Before compression hardness was adjusted. Finally the blends were compressed into tablets (250 mg) using 8 mm flat face punch set using a 10 station tablet press.

Ingredients	Formulationcode						
(mg/tablet)	F1	F2	F3	F4	F5	F6	F7
Triamterene	50	50	50	50	50	50	50
Crospovidone	---	2.5	5.0	7.5	---	---	---
Sodium starchglycolate	---	---	---	---	2.5	5.0	7.5
Mannitol	50	50	50	50	50	50	50
PVP-K30	3	3	3	3	3	3	3
Aspartame	2	2	2	2	2	2	2
Magnesium stearate	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2
Flavour (Orangeflavour)	1	1	1	1	1	1	1
MCC (Avicel PH102)	140	137.5	135	132.5	137.5	135	132.5
Total weight	250	250	250	250	250	250	250

EVALUATION OF BLEND OF TRIAMTERENE:

Tablets were made from blend and therefore evaluation of blend was important as they influence the tablet characteristics such as hardness, friability, drug content and dissolution study of tablets etc.

- Determination of Bulk Density and Tapped Density: 6 gm of the powder (W) from each formula were introduced into a 50 ml measuring cylinder, and the initial volume was observed. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 sec intervals. The tapping was continued until no further change in volume was noted.

The bulk density, and tapped density were calculated using the following formulae.Bulk density = W / VO

Tapped density = W / VF

Where,

W = weight of the granules,

VO = initial volume of the granules,

VF= final volume of the granules.

- Hausner's Ratio: It indicates the flow properties of powder and is measured by the ratio of tapped density to the bulk density.

Hausner's ratio = Tapped density/Bulk density

Sl.No.	Hausner'sratio	Property
1.	0-1.25	Free flowing
2.	1.25-1.6	Cohesive powder

- 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 flowable it is. A material having values of less than 20% has good flow property.

CI = ***Tapped density*** − ***Bulk density*** / T***apped density***

Sl. No	% Compressibilityindex	Properties
1	5-12	Free flowing
2	12-19	Good
3	19-21	Fair
4	23-35	Poor
5	33-38	Very poor
6	>40	Extremelypoor

- Determination of Angle of Repose: Angle of repose is an indication of the frictional forces existing between the blend particles. It is the maximum angle possible between the surface of the pile of blend and the horizontal plane:

$\tan \theta = h / r$

Where, θ is the angle of repose; h is the height of the heap of powder and r is theradius of the heap of the powder. Therefore $\theta = \tan^{-1}(h/r)$.

Sl.No.	Angle of repose (θ)	Type of flow
1	<25	Excellent
2	25-30	Good
3	30-40	Passable
4	>40	Very poor

- Method: Weighed quantities of the blend were poured through the funnel from the fixed height onto the graph paper. The height of the heap was measured. The circumference of the heap was marked by pencil. The area of the circle formed was calculated on the basis of large squares and small squares present inside the circle and angle of repose was then calculated on the parameter 'r' which was found out from the area of circle.

Evaluation of Tablets:

- General appearance: The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The control of general appearance involves measurement of attributes such as a tablet's size, shape, color, presence or absence of odour, taste, surface textures, physical flaws and consistency. Hence the tablets were checked for the presence of cracks, depressions, pinholes, uniformity of color, and the polish of the tablet.
- Dimensions: The shape and dimensions of compressed tablets were determined by the type of tooling during the compression process. At a constant compressiveload, tablet thickness varies with changes in die fill, particle size distribution and packing of the powder mix being compressed and with tablet weight. While with a constant die fill, thickness varies with variation in compressive load. Tablet thickness is consistent from batch to batch or within a batch only if the tablet granulation or powder blends is adequately consistent in particle size and particle size distribution, Consistent length of punch tooling, Tablet press and good working conditions Thickness and diameter of the tablets were measured using digital vernier caliper. The values of thickness were used to adjust the initial stages of compression. Tablet thickness should be controlled within a ±5% variation of a standard value. Also the thickness must be controlled to facilitate packaging.
- Weight Uniformity test: Twenty tablets were weighed individually and all together. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the

permissible limits. The percent deviation was calculated using the following formula: -

Percentage deviation = [(Individual Weight-Average weight) /Average weight] ×100

Any deviation in the weight of tablet leads to either under medication or over medication. So, every tablet in each batch should have a uniform weight. Corrections were made during the compression of tablets to get uniform weight. The USP has provided limits for the average weight of uncoated compressed tablets. These are applicable when the tablet contains 50mg or more of the drug substance or when the latter comprises 50% or more, by weight of the dosage form. Twenty tablets were weighed individually and the average weight was calculated. The individual tablet weights are then compared to the average weight. Not more than two of the tablets must differ from the average weight by not more than the percentages stated. No tablet must differ by more than double the relevant percentage.

- Hardness test: Hardness is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during handling and transportation. The hardness was tested using Monsanto tester. For determination of hardness factor, the average of the three determinations was determined and reported. The force was measured inkilograms per centimeter square.
- Friability test: Friability is the loss of weight of tablet in the container or package,due to removal of fine particles from the surface. To ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and shipment.Permitted friability limit is 1.0%.

Roche friabilator was used to measure the friability of the tablets. Ten tablets were weighed collectively and placed in the chamber of the friabilator. In the friabilator the tablets were exposed to rolling, resulting free fall of tablets (6 inches) within the chamber of the friabilator. It was rotated at a rate of 25 rpm. After 100 rotations (4 min.) the tablets were taken out from the friabilator and intact tablets were again weighed collectively. The percent friability was determined using the following formula:

Percentage Friability = [(Initial Weight – Final Weight)/Initial Weight] × 100

- Disintegration test: For a drug to be absorbed from a solid dosage form after oral administration, it must first be in solution, and the first important step toward this condition is usually the break-up of the tablet; a process known as disintegration. The disintegration test is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through a 10 mesh screen. The disintegration test is carried out using the disintegration test apparatus which consists of a basket rack holding 6 plastic tubes, open at the top and bottom, the bottom of the tube is covered by a 10-meshscreen. The basket was immersed in a bath of suitable liquid held at 37oC, preferably in a 1L beaker, the testing fluid was 0.1 N HCL.
- In-vitro dissolution test: The in vitro drug release studies were performed using USP dissolution apparatus Type II (paddle) using 900 ml of 0.1N hydrochloricacid as the dissolution medium. The temperature of the dissolution medium was maintained at 37±0.5oC and the paddle was rotated at 50 rpm. At scheduled timeintervals, the samples
- Drug content: Five tablets were powdered and the blended equivalent to 50 mgof Triamterene was weighed and dissolved in suitable quantity of methanol. The solution was filtered, suitably diluted and drug content was analysed spectrophotometrically at 363 nm. Each sample was analyzed in triplicate.

The results of in-vitro release data obtained for all formulations were fitted in one popular models of data treatments as follows:

I. Zero-order kinetic model (cumulative percent drug released versus time)

Zero Order Kinetics: A zero-order release would be predicted by the followingequation.

At = A0 – K0t …….1Where:

At = Drug release at time ‘t’ A0 = Initial drug concentration.

K0 = Zero-order rate constant (hr-1)

When the data is plotted as cumulative percent drug release versus time, if the plot is linear then the data obeys zero-order release kinetics, with a slopeequal to

K0. First Order Kinetics: A first-order release would be predicted by the following equation

Log C = Log C0 -2.303

Kt

……..2

Where:

C = Amount of drug remained at time 't'C0 = Initial amount of drug

K = First-order rate constant (hr-1)

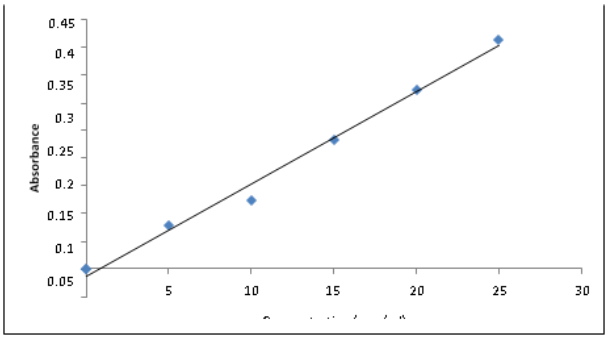
When the data is plotted as log cumulative percent drug remaining versus time yields a straight line, indicating that the release follows First-order kinetics. Theconstant 'K' can be obtained by multiplying 2.303 with slope values.

Stability studies: Accelerated stability studies were per formed at a temperatureof 40±2 oC/75±5% RH over a period of three months (90 days) on the promising formulation. Sufficient number tablets were packed in amber colored rubber stoppered vials and kept in stability chamber maintained at 40±2oC / 75± 5%.

III. RESULT AND DISCUSSION

Standard graph of Triamterene in methanol (λ_{max} =363 nm)

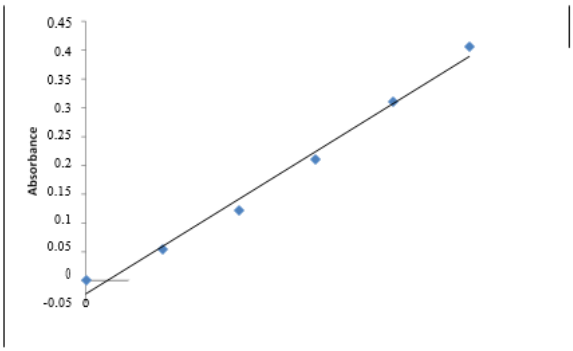
Concentration (mcg/ml)		Absorbance		
	I	II	III	Mean±SD
Blank	0.000	0.000	0.000	0.000±0.000
5	0.078	0.080	0.076	0.078±0.002
10	0.122	0.119	0.128	0.123±0.004
15	0.235	0.244	0.223	0.234±0.010
20	0.346	0.316	0.310	0.324±0.019
25	0.423	0.421	0.401	0.415±0.012



Standard calibration curve of Triamterene in Methanol

Standard graph of Triamterene in 0.1N HCL (pH 1.2) ((λmax = 363 nm)

Concentration(mcg/ml)		Absorbance		
	I	II	III	Mean±SD
Blank	0.000	0.000	0.000	0.000±0.000
5	0.051	0.053	0.056	0.053±0.002
10	0.119	0.125	0.119	0.121±0.003
15	0.215	0.204	0.209	0.209±0.005
20	0.316	0.308	0.31	0.311±0.004
25	0.411	0.401	0.402	0.405±0.005



Standard calibration curve of Triamterene in 0.1N HCL (pH 1.2)

Evaluation parameters of Triamterene chewable tablets-

Organoleptic characters- These test are performed and results are illustrated infollowing table :-

Description of Triamterene chewable tablet –

Sr. No.	Test	Description
1	Appearance	Intact and smooth

2	Odor	Orange Flavor

3	Taste	Sweet in taste

Pre compression parameters of Triamterene chewable tablet:-

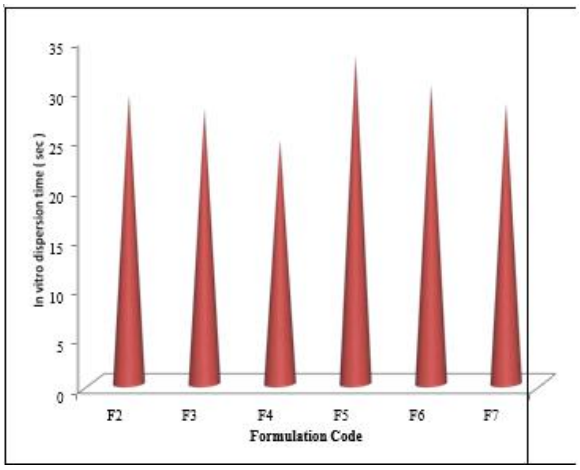
Parameters	Formulation Code					
	F1	F2	F3	F4	F5	F6
Angle of repose (θ) *	29.99±0.162	29.10±1.291	27.92±1.209	27.09±1.202	28.20±0.291	28.26±1.00
Bulk density (gm/cc)	0.41	0.38	0.38	0.37	0.39	0.40
Tappeddensity (gm/cc)	0.49	0.48	0.49	0.47	0.49	0.39
Carr's index(%)	14.19	13.21	13.10	11.12	13.89	12.17
Hausner'sratio	1.02	1.19	1.12	1.23	1.09	1.10

Evaluation result of Triamterene chewable tablets prepared using variousconcentration of Crospovidone and Sodium Starch Glycolate –

Formulation	Hardness (Kg/cm^2) ± SD*	Diameter(mm)	Thickness(mm)	Friability	Wight variation(%)	Drug Content (%)± SD*
F1	3.93 ±0.02	8 mm	3.20	0.26	< 7.5	99.51±0.21
F2	3.78±0.03	8 mm	3.22	0.47	< 7.5	98.15±1.45
F3	3.66±0.12	8 mm	3.21	0.45	< 7.5	97.48±1.56
F4	3.77±0.18	8 mm	3.23	0.55	< 7.5	100.90±1.2
F5	3.84±0.11	8 mm	3.19	0.57	< 7.5	99.48±2.10
F6	3.79±0.13	8 mm	3.22	0.56	< 7.5	99.60±1.21
F7	3.82±0.21	8 mm	3.20	0.51	< 7.5	97.48±1.29

In vitro dispersion time of Triamterene chewable tablets prepared using variousconcentration of Crospovidone and Sodium Starch Glycolate –

Formulation No.	In vitro dispersion time (sec) ± SD*
F1	450±2.192
F2	29.09±1.291
F3	27.67±0.211
F4	24.54±1.202
F5	33.10±2.862
F6	30.12±0.986
F7	28.25±0.198



Bar diagram showing In-Vitro dispersion time of Triamterene chewable tablet using various concentration of Crospovidone and Sodium Starch Glycolate

In vitro drug release data of formulation F1-

Time min	Cumulative percentdrug release
	F1
10	4.14±1.262
20	11.29±2.192
30	14.02±0.289
40	17.26±2.382
50	19.89±3.201
60	23.19±1.287
70	27.12±2.123

In vitro drug release data of formulation F2, F3 & F4-

Timemin	Cumulative percent drug release*			Log percent drug remaining		
	F2	F3	F4	F2	F3	F4
10	17.16±1.02	20.92±1.08	22.27±1.25	1.918	1.898	1.890
20	26.19±0.21	28.81±1.24	33.92±2.01	1.868	1.852	1.820
30	35.09±2.01	38.23±3.05	41.98±2.87	1.812	1.790	1.763
40	48.27±1.58	52.09±2.14	57.02±1.25	1.713	1.680	1.633
50	59.66±2.01	62.23±2.85	68.29±1.47	1.605	1.577	1.501
60	68.90±1.55	70.19±2.32	83.29±3.14	1.492	1.474	1.222
70	80.34±1.02	86.20±1.58	95.26±2.57	1.29 in3	1.139	0.675

In vitro drug release data of formulation F5 , F6 & F7

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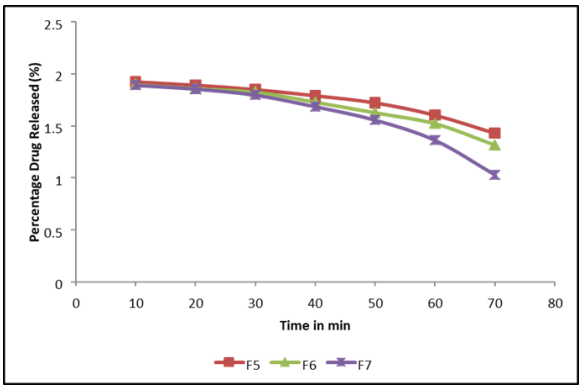
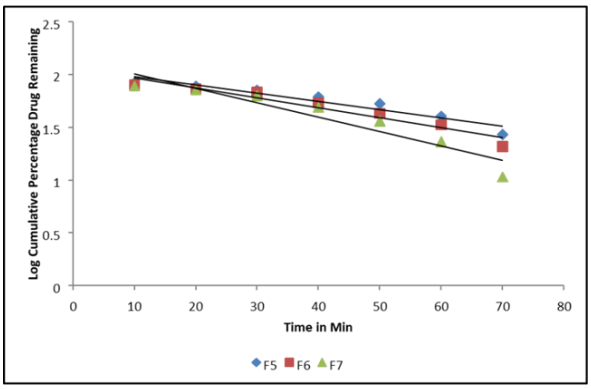
Time min	Cumulative percent drug release*			Log percent drug remaining		
	F5	F6	F7	F5	F6	F7
10	16.28±1.25	20.22±1.21	21.88±1.85	1.922	1.901	1.89
20	22.09±1.01	26.98±0.85	28.09±1.45	1.891	1.863	1.85
30	29.30±1.87	32.39±0.36	37.12±2.66	1.849	1.830	1.79

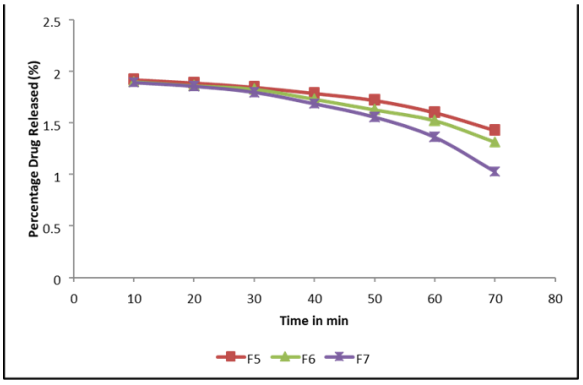
40	38.22±2.47	45.98±2.21	51.32±2.47	1.790	1.732	1.68
50	47.21±2.22	57.34±3.14	63.83±2.86	1.722	1.630	1.55
60	59.77±2.01	66.56±1.54	76.92±2.69	1.604	1.524	1.36
70	72.98±1.56	79.27±1.45	89.28±2.46	1.431	1.316	1.03



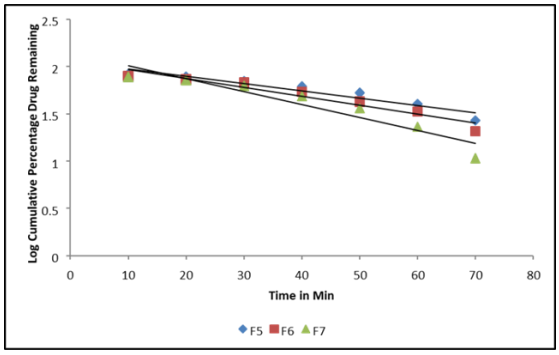
Cumulative % drug released vs time plots of formulation F2,F3 & F4



Log Cumulative % drug remaining vs time plots of formulation F5, F6 & F7



Cumulative % drug released vs time plots offormulation F5, F6 & F7



Log Cumulative % drug remaining vs time plots of formulation F2, F3 & F4

Kinetic Data-

Batch		Zero-Order	First-Order
F1	r	0.977	0.953
	A	2.608	2.076
	B	0.352	-0.010
F2	r	0997	0.901
	A	5.254	2.093
	B	1.069	-0.011
F3	r	0.992	0.846
	A	8.010	2.229
	B	1.080	-0.018
F4	r	0.995	0.915
	A	8.287	2.055
	B	1.228	-0.007
	r	0.980	0.929
	A	3.211	2.061
	B	0.940	-0.009
	r	0.986	0.894
	A	6.782	2.143
	B	1.004	-0.013
	r	0.989	0.984
	A	5.981	1.992

		B	1.166	-0.001

IV. DISCUSSION

Chewable tablets are intend to be chewed in the mouth prior to swallowing and are not intended to be swallowed intact.

The purpose of chewable tablet is to provide a unit dosage form of medication which can be easily administered to children or to the elderly, who may have problem in swallowing a tablet intact. It is also recommended to achieve rapid onset of action.

Triamterene (potassium-sparing diuretic), is a drug used in the treatment of hypertension and edema. Rapidly absorbed, with somewhat less than 50% of the oral dose reaching the urine. Since Chewable dosage forms bypasses disintegration & increases the bioavailability, the dose of Triamterene could be reduced by 50%.

The properties of Triamterene, its suitable half-life (3 h) and bioavailability 30- 70% make it suitable candidate for chewable type of dosage form.

So, the present investigation undertaken with design and evaluation of chewable tablets of Triamterene to to enhance the patient compliance and provide a quick onset of action.

Chewable tablets of Triamterene were prepared by direct compression method using crospovidone and sodium starch glycolate as disintegrating agents in different ratios along with microcrystalline cellulose as diluent.

According to work plan, the tablets were evaluated for their pre-compression and post compression parameters like angle of repose, bulk density, tapped density, carr's index etc and appearance, thickness, hardness, friability, weight variation, drug content, in vitro release, short-term stability respectively.

V. CONCLUSION

In this work, Chewable tablets of Triamterene are prepared by direct compressionmethod using super-disintegrants such as crospovidone & sodium starch glycolate.

All the tablets of Triamterene is subjected to

- Weight variation,
- Drug content- uniformity,
- Hardness,
- Friability,
- In- Vitro dispersion time
- Dissolution studies.

Based on the above studies, following conclusions can be drawn:

- Tablets prepared by direct compression method were found to be good without any chipping, capping and sticking.
- The hardness of the prepared tablets were found to be in the range of 3.66±0.12 to 3.93 ±0.02 Kg/cm² for direct compression method.
- The friability values of the prepared batches of tablets were found to be lessthan 1%.
- The thickness of the prepared chewable tablets were found to be in the range of 3.19 to 3.23 mm.
- The average drug content of the tablets was found to be within the range of97.48±1.29 to 100.90±1.2 %
- Out of six formulations, formulation F4 was selected as promising formulationon the basis of In-vitro Dispersion time and In-Vitro drug release.
- The In-vitro Dispersion time and In-Vitro drug release of formulation F4 was found to be 24.54±1.202 sec and 95.26±2.57 % respectively.

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