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Formultion And Evalution of Mouth Dissolving Tablet of Moexipril with A Varity of Superdisintergrant and Compare with Market Moexipril Disintegration Tablet

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ABSTRACT

OBJECTIVE

The objective of the study is to formulate of mouth dissolving Tablet of Moexipril with a variety of super disintegrants and compare with marketed Moexipril disintegration tablet.

MATERIAL AND METHOD

The direct Compression method is used to Prepare mouth dissolving tablets of Moexipril utilizing super disintegrants Crospovidone and croscarmellose sodium. Determination of post compression study of formulated tablets Solidity, Thickness, Friability, medication content uniformity, weight variation, wetting time, Water absorption ratio, Dissolution time and Stability study of best preparation at 40^0C±2/75%±5%RH for 3 month.

RESULT AND DISCUSSION

In equipped Tablets device F7very own dispersion time 13 sec, wetting time 46sec. short time period stability of method F7 has not any alternate change.in Physical appearance average weight,thickness, solidity,Friability, disintegration time in vitro dispersion time in vitro drug release at 10 min and assay stored for the three month at 40±2^0C/75%±5%RH.

CONCLUSION

This study demonstrated that fast disintegrating moexipril tablets can be successfully formulated in order to control and manage hypertension.

Keywords: crospovidone croscarmellose sodium moexipril, oral dispersible tablet.

INTRODUCTION

Mouth Dissolving Tablets (MDT[s]): These be the pills which melt and crumble unexpectedly inside the spit to produce their activities in a small number of seconds exclusive of the help of Distilled water. It takes over 15seconds-3minutes to mix into mouth for a mouth dissolving tablet. Primarily the MDT's (mouth dissolving tablets) have superb disintegrates and flavor masking agents.

For the administration of medication, the oral way was well thought-out the most frequently used way. Within it process, most normally used orally shipping of medicine, consisting of tablets and capsules.

Within this procedure consuming is the most difficulty. The swallowing problem (dysphasia) generally within the event of child's and olds patients believes mainly in compliance choose pills.

Toward solve this difficulty mouth dissolving tablets are formulated. For oral disintegration tablets preparation, the principal criterion is toward get rid of the sullenness of this drug by incorporating the sweeten mediator. Toward solve that difficulty and to create the dental route is more suitable for patients that very unique and latest method is using at present time which is known as oral dissolving drug delivery technique otherwise dispersible method. These mouth dissolving tablets break up or crumble unexpectedly inside the spit under a small number of seconds without needing liquid, chewing through the assist of spit in the oral.

The fantastic disintegrates additionally to raise the disintegration of tablets. Super dissolves are extremely cooperative to improve the drug release time of medication and raise the breakdown of pill within spit.

MATERIAL AND METHOD

Preparation of mouth dissolving tablets of Moexipril through direct compression process utilizing super disintegrates such as crospovidone and Croscarmellose sodium.

carry out the stability study of best preparation at 40^0 C ±2 /75% ±5%RH for 3months.

List of materials obtained from different andsources.

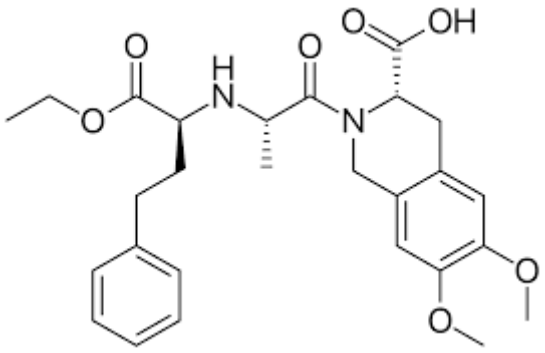
Drug profile:

Drug name: Moexipril

Moexipril an angiotensin converting enzyme inhibitor used for the treatment of hypertension and congestive heart failure. Moexipril can be administered alone or with other antihypertensive or diuretics. It works by inhibiting the conversion of angiotensin I to angiotensin II

Chemical Name: (3S)-2-[(2S)-2-[[(2S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl]amino]propanoyl]-6,7-dimethoxy-3,4-dihydro-1H-isoquinoline-3-carboxylic acid.

Chemical structure:



Molecular Formula: C27H34N2O7

Physical characterization of Moexipril:

Melting point: Melting peak of Moexipril hydrochlorides were performing via the capillary system is 152^0C. The documented melting point varies from 141C to 161°C.

UV Spectroscopy (examination of λ_{max}) stock alternative (100-10µg/mol) of Moexipril is prepared in methanol. This mixture has been suitably mixed with methanol to obtain a concentration of 40 µg/mL.The solution was stored at a fused silica cuvette 10 mm. The UV spectrum has been listed in

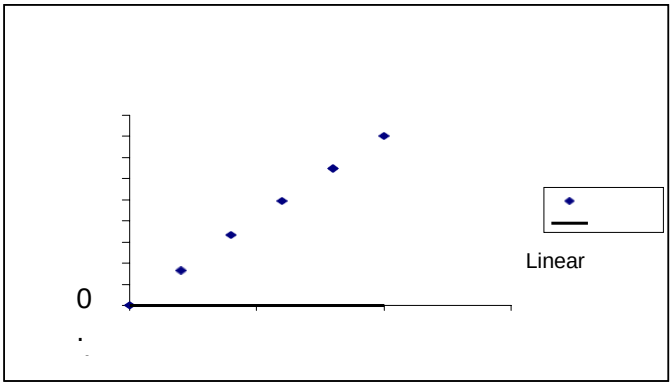
the assortment of 200- 240 nm on UV-1800, Shimadzu double ray UV-visible spectrophotometer in 1 cm, sliced width.

Preparation of stock solution for calibration curve: Spectra-photometric method for estimation of Moexipril at Phosphate Buffer (pH 6.8). 100 mg of Moexipril was weighed, added with 50 ml volumetric flask disband in little amount of buffer and quantity was make using buffer to Acquire concentration of 1000 Mcg/ml. 5ml had been pipette outside and thin out to 50 ml with distilled water have the mass 100 mcg/ml. From this quantity was composed with HCl to acquire concentration of 4, 2, 8, 6, 10 mcg/ml. The absorbance was uniform at 238 nm utilizing Shimadzu-1800. Medication and excipients compatibility analysis by IR.

Table1 Standard calibration curve of Moexipril.

Concentration in (µg/mL)	**Absorbance at 248 (nm)**
0	0
2	0.084
4	0.168
6	0.250
8	0.332
10	0.403
Slopes	0.042
Correlations	0.9995

Fig 1 Standard calibration curve of Moexipril phosphate buffer PH 6.8



All Pharmaceutical dosages form an essential element for recipients. It's an important Function in all pharmaceutical formula. The effective formulation relies on Fantastic choice of excipients. They encourage the constant launch and Bioavailability of medication.

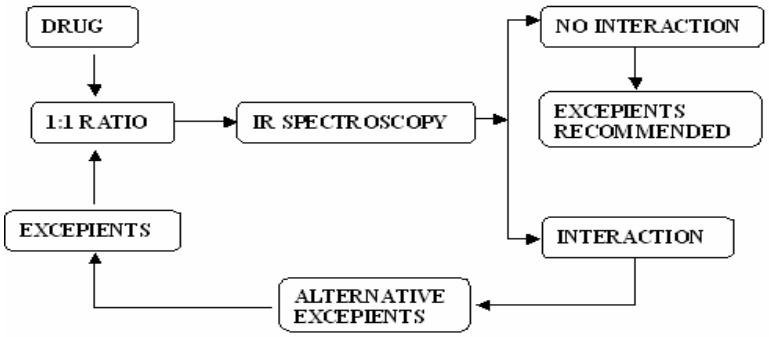


Figure 2: Schematic representation of compatibility study.

Evaluations of mouth dissolving tablets Moexipril: Organoleptic properties:

Colour: Taken the small quantity of Moexipril on the butter paper and viewed the colour of the drug.

Taste and odortaken little small amount of drug and check the taste with the assist of tongue as well as smelled to odor.

Solubility test: check the dispersible of Moexipril in water, menthol and methyl alcohol by utilize ultrasonic at area temperature. About dispersible of drugs as pe B.P. shown in list

Drug and binding agent affinity studies: the drug and excipients mixed together and make a blend and stored at $40^{O}C \pm 2^{O}C$ /75±5%RH with 30 days. The mass studies with every fifteen dayswithi change such as caking, liquefaction, discoloration and smell formulation.

FT-IR studies: any probability of chemical interactivity linking drug and excipients were evaluated by infrared spectra. Material combinations (2:2) of active and non-active are blend among an appropriate amount of potassium bromide. Concerning hundred milligram of that blend is condensed to form a visible pellet via a hydraulic force at ten plenty forces. Scan range 4000 – 5000 cm^{1} within shimadzu FT-IR spectrophotometer.

Preformulation study:

The angle of Repose:

It is measured through funnel technique. Funnel is set on a flask stand at a specific peak . A chart wrapper is put under the funnel on a table. The crush is passing slowly across the funnel, until if form a pile. The blend powder is stop when the pile touches the tip of the funnel. Circumference of the pile of powder blend is drawn with the pencil without disturbing the pile. The radius of the pile 'r' is noted. the angle of repose was calculated using the following equation (table no. 2.7).

$\tan \theta = h / r$

Hence, $\theta = \tan^{-1} h/r$

Where, θ = angle of repose

h = height of the cone

r = radius of the cone base

The results are shown in ().

Table2: Relationship between the angle of repose (θ) and flow ability

The Angle of Repose (θ)	Flow ability
Less than 20	Wonderful
20 to 30	Fine
30 to 34	Sufficient
More than 40	Very poor

The under the angle of repose, finer the move effects, when granules are placed in the hopper & allowed to slide down into the die for compression. It forms tablets. The angle of repose may be deliberate by determine the length (h) of the tablets and radius of the base (r) with the ruler. The angle of repose shows in between 30-40°C, which is considered as a passable flow of granules.

Application

Drug tablets, increase flow of granules from the hopper leads to under fill or overfills inside the die cavity. When a result, tablets will have under-weight or heavy weight; mass deviation again defected the homogeneity and doges accuracy. It too generates troubles of stability and friability throughout compression.

Bulk Density:

Mass density is the ratio of total mass of powder to the bulk volume of powder. It is evaluated via taken the weigh amount of blend crush beginning every preparation in a fifty ml test tube moreover the original quantity of the residue to calculate was written. The mass density of crush be obtained through the formula,(table no. 3.7)

$$P_b = M/ V_b$$

Where.

ρ_b= mass density

m= Total mass of residue

v_b = mass volume of residue

Tapped density:

It is defined as whole mass of the dust is divided by tapped quantity of the dust. It is calculated by taken the grind in measuring cylinder and tapping the dust with seven thundered fifty count. The tapped level be marked. The difference b/w tow tapping less than two presents, if the difference > 2%, the tapping continued with 1250 times and the tapped volume is marked. The drumming regular when the difference b/w two tapping successive volume is less than 2%. It is calculated by the following formula, (table no. 3.7).

$$p_t = m/ v_t$$

P_t = Tapped density

M = total mass of powder

V_t = tapped volume of powder

CompressibilityIndex:

The compressibility of the grind was calculated through Carr's Compressibility Index.

Carr's compressibility index (%) = [(TBD-LBD) X 100]/TBD

Or it can be expressed as Carr's Index relates the poured density of the material to the tapped density and was calculated by using the following relationship:

Compressibility Index= $\frac{\text{Tapped density – bulk density}}{\text{Density Tapped}}$ X 100

Carr's Index values for pure drug, crosspovidone, and granule be evaluated with measuring the primary volume (Vp) and finishing volume (Vt) of celebrated mass (W) of substance after introduce to hundred

pushing in a graduated test tube. Since this dimension, the poured density (W/Vp) and the tapped density (W/Vt) assessment were considered and were substitute within the above equation to evaluate Carr's Index (Table 3.7).

Hausner's ratio: this is the ratio of tapped density to bulk density. It is calculated by the following formula,

Hausner's ratio = tapped density / bulk density.

Table.3: Relationships b/w hausner ratio and flow properties.

Hausner'sratio	**Type of glide**
> 1.25	superior
1.25-1.5	Fair
< 1.5	Pours

Preparation of ODT^S through direct compression process:

Exactly weigh amount of Moexipril, crospovidone, Croscarmellose sodium, other ingredient and passed in 44 mesh sieves. The drug and microcrystalline cellulose be taken in a mortar and mixed and combine this, to produce a consistent combination and pigeonholed. After this procedure, the additional ingredient was variegated in symmetrical odour. Go across 44 mesh strainers. A tablet was press by a mechanical pressure. And the calibrated compacting forces of equipment to acquire solidity within range 3- 4 kg/cm^2 for total preparation. The mess of tablets of the formulation was 150 mg mention in (table 3).

Evaluations of post formulation studies of tablets: Psycho-Chemical studies of formulated tablets:

Thickness:

The thickness of tablets was determined through using venire caliper. There have been handiest five pills in every formula which are worn, and regular values existed measured. The thickness was denoted in millimeter. The result is proven in.

Test for the weigh variation:

To study weigh deviation 20 tablets was taken among each formulation and firstly individual tablet were weighed, after that total 20 tablets be weigh by an electronic balance (AW-220 shimadzu), the deviation not more than ± 7% and the experiment be carryout as maintained by bureaucrat system .

Table4:disclaimerfortabletsaspharmacopoeiaofIndia.

The average weightof a **Tablet**	**%Deviation**
80mg or below	Ten
Greater >80mg but below to 250mg	7.5
250mg or>	5

Drug content:

Four tablets were daintily crushed; quantity equivalent toward 50mg of Moexipril be appropriately weigh and shift to 100ml measurement piston containing 50ml of methanol. This becomes allowable

toward be set with six hours to make sure the whole solubility of the drugs. Answers had been making as much as quantity, strain, suitably diluted, and expected for Moexipril contents at 238 nm, the use of an UV spectrophotometer the usage of methanol as blank.

Hardness:

Every Chose the five tablets from every formulation, determine the hardness with Monsanto hardness tester (cadaman). The tablets were place beside its oblong axis inside between 2 jaws of tester on this peak; analysis must be 3-4 kg/cm^2. After that constant presser were appeal, noted the point at which tablets was breakup.

Friability:

It is measure of tablets strength. It is related to tablets ability to with stand both shook and abration with crumbling during the handling of manufacture, packing and consumer use.

Method: 6 tablets have been weighing and introduce inside Roche's friabilator wherever the tablets was showing to rolling at 25 rpm, and repeated shocks are resulting for free falls inside the equipment. After hundred revolutions, the pills were de-dusted and weight once more. The friability is known through the loss of percent of the weight of the tablet. Best less than 1 percent losses are relevant.

***In-vitro* test of finished formulated tablets of Moexipril:**

Determination of swelling index:

The swelling index of drugs have been decided within phosphate buffer (pH 6.8), at room temperature till eight hours. Bloated burden of this tablet has been ascertained via as soon as intervals15. The swelling equation may be determined without difficulty through using this equation:

Percentage of water uptake polymer swelling = $\frac{(Ws - Wi)}{WI} \times 100$

Ws define the Wight of matrix at time t, W is the initial mass of the Matrix.

***In Vitro* drugRelease Studies (Dissolution study):**

Invitro drug release look at for the ready mold pills become performed with 10-12 hours the use of six station USP type II (paddle) equipment at 37ºc ± 0.5 ºC and 50 rpm speed. The disintegration analysis has been done in triplicate for 2 hours in phosphate buffer P^H 6.8. Eight under spout condition, first of all half an hour one hour after which in line with one hour length forms of 5ml was pulled from dissolving slight and substituted among a new mixture to hold the quantity continual. Right dilution is there at once afterward filtration, the pattern solution changed into analyzed at 248 nm for Moexipril by means of a UV-spectrophotometer for determining its cumulative % drug release or amount gift within the pattern (table no. 3.9).

Disintegration test

Dissolution time was considered with disintegration tests apparatus. Which have the six tube basket, the bottom surface of the basket was ready of stainless steel with steels screen (mesh no. #10). The tablets are placed in six tube of basket and distilled water was used as dissolution media. The test carries out at

37±0.5ºC in disintegration equipment and the speed was 100 rpm. When the tablet was completely disintegrated, the time was noted. The disintegration time was expressed in second (table no. 3.8).

Data Analysis (Curve fitting analysis)

Toward decide the process of medicine release charge kinetics of pills and records acquired was plotted as:

The vs. of time and cumulative percentage of drug launch (*in vitro* drug launched plots). The vs of rectangular cause of times and drug release % (Higuchi, splots). The vs of time of the log cumulative percent drug remained (first-order plots). The vs. of time of the loge percent drug launch (Pappas plots).

Higuchi released model:

It represents the equation as,

$F = K .t_{1/2}$

Whilst the facts are plots among cumulative drug release and the rectangular root of time. The direct line produces. It is indicated that the drug become launched by way of a dissemination process. The angle is identical near ‘ok'90.

***In vitro* dispersion time:**

Take 10 ml of distilled water in a measuring cylinder. Five tablets were taken from each formulation and Tablets are added in distilled water at 37 $\pm$ 0.5^0C. Determined the tablets for completes dispersion at time require (able no. 3.8).

Ratio of wetting time and absorption:

Taken 5 cm petridish. Two-piece of tissue paper is introduced to petridish. Water dissolve eosin pigment be put to petridish. The tablets are placed on the floor of tissue paper. After some time, the purple or pink shade is produced at the surface of tablet, the time is cited. It is a wetting time. The identical technique is accompanied by the water absorption ratio. It's far determined by using the subsequent equation,

$$R = \frac{W_b - W_a}{W_a} x\ 100$$

Where,

W_b = water absorption after wetting of tablets

W_a = Water absorption before wetting of tablets

Stability studies:

The selected formulation became examined for three months at the storage conditions at room temperature and 40°c at 75% RH were inspect for their remedy content. The residual drug contents of formulations had been located to be in the permissible limits, as shown in the desk. The tablets showed excellent bodily stability at room temperature and forty °c at 75% RH. No appreciable changes were determined in any of the formulations. The drugs were additionally subjected to IR studies to determine well matched the drug with the recipients used within the pills. Their studies confirmed that no interactions between the active and polymers.

RESULTSANDDISCUSSION

Melting point: The melting point of Moexipril was found to be 184^{0}C, which complies with given in the official reference.

FT-IR SPECTRAL STUDIES:

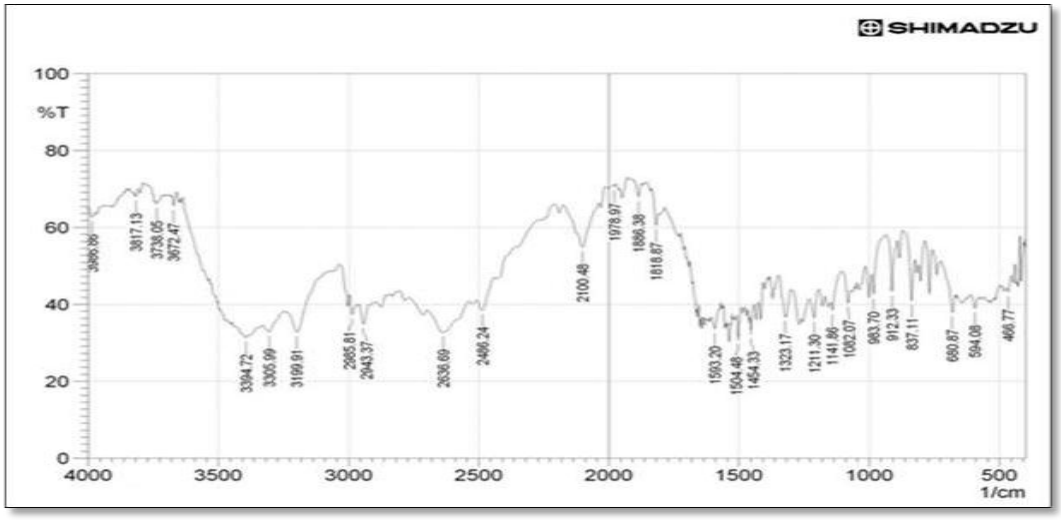


Fig.3: FTIR Spectra of Moexipril.

Evaluationof pre-compression parameters ofall formulation

Formulation	Angle of repose (θ)	Bulk density (g/cm^1)	Tapped density (g/cm^1)	Compressibility Index (%)	Hausner's ratio
F_1	31^0.15′	0.630	0.755	14.10	1.17
F_2	29^0.16′	0.405	0.368	12.99	1.15
F_3	28^0.01′	0.320	0.377	13.25	1.15
F_4	28^0.95′	0.315	0.358	13.32	1.12
F_5	26^0.32′	0.365	0.388	13.70	1.16
F_6	25^0.10′	0.388	0.398	15.90	1.14
F_7	22^0.93′	0.390	0.325	15.31	1.17

Table 5: FTIR spectral records of Moexipril.

Wavenumber (cm^1)	Functional groups
1580	C=C
2545	O-H
3450	N-H
1220	C-O
2950	C-H
1770	C=O

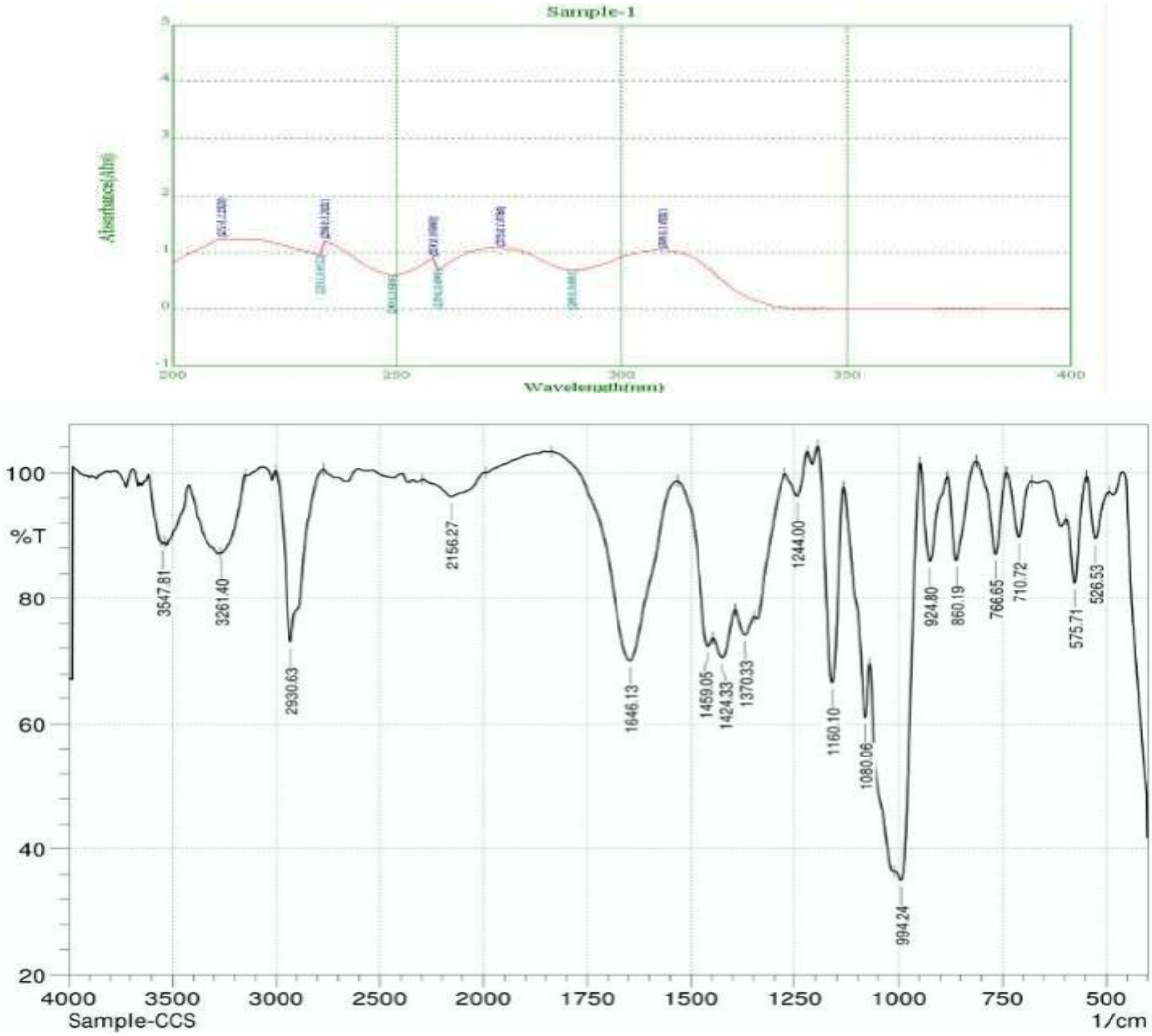


Fig.4 IR spectra ofCroscarmellose sodium

Table 6FTIR spectral statistics of Croscarmellose sodium.

Wavenumber (cm^1)	Functional group
3551	OH stretch
2932	Aliphatics C-Hstretch
1649	C=O stretch
1090	C-O stretch
995	CO-Cogroups
713	CH_2 Alkane

Table7 Evaluation of physical properties of all formulation.

Formulations	Thickness(mm)	Hardness(kg/cm^2)	Weight variant (mg)	Friability(%)
F_1	3.31±0.044	3.85 ± 0.35	143±1.22	0.25
F_2	3.35±0.012	4.16 ± 0.24	141±0.66	0.43
F_3	3.25±0.014	3.66 ± 0.32	141±0.45	0.51
F_4	3.41±0.012	4.18 ± 0.22	142±0.44	0.47
F_5	3.41±0.018	4.22 ± 0.44	143±0.97	0.33
F_6	3.22±0.055	3.60 ± 0.30	142±0.97	0.21
F_7	3.33±0.008	3.01 ± 0.25	140±0.46	0.16
Marketed sample	2.80±0.011	3.60 ± 0.32 **Sec**	€140±0.88	0.27

Table 8 Evaluation of tablets

Formulations Codes	Disintegration Test (Sec)	Wetting Time ()	Water Absorption Ratio	*In vitro* Dispersion Time (Sec)	Fineness of Dispersion
F_1	27±0.32	101±2.44	81.23±0.62	38±0.15	Accepted
F_2	23±0.22	91±1.45	86.37±0.48	39±0.13	Accepted
F_3	16±0.15	49±2.38	93.18±0.39	28±0.32	Accepted
F_4	23±0.50	87±0.81	78.26±0.20	38±0.16	Passed
F_5	24±0.62	80±0.20	88.13± 0.10	37±0.53	Passed
F_6	21±0.45	57±0.31	87.97±0.22	28±0.77	Passed
F_7	13±0.62	46±0.37	92.25±0.53	24±0.44	Passed
Marketed Sample	18±0.43	55±0.55	95.32±0.32	28±0.35	Passed

Table 9 Assay of Moexipril oral disintegration caplets.

Formulation code	Limit (%)	Assay(%)
F_1		99.62
F_2		98.75
F_3		99.82

F_4	90 to 110%	99.62
F_5		99.66
F_6		98.92
F_7		99.93
Marketed sample		98.78

The assay of Moexipril mouth dissolving tablets were founded in the range between 98.75 to 99.93 %. According per IP acetableliits are 90 to 110 %, so the all formulation passed assay and have acceptable limits as per IP.

***IN-VITRO* DISSOLUTION DTUDIES:**

Table10 : drug release percentage of Moexipril ODT[s]:

Times (min)	**Drug release (%)**						
	Formulation code						
	F_1	F_2	F_3	F_4	F_5	F_6	F_7
2	21.60±0.50	25.86±0.38	31.50±0.23	18.52±0.31	22.44±0.29	30.11±0.60	35.31±1.20
4	31.24±0.69	34.75±0.59	42.59±0.56	31.18±0.30	31.55±0.50	48.51±0.49	54.16±0.60
6	42.59±0.60	49.90±0.27	61.55±0.19	48.66±0.42	46.63±0.07	59.91±0.42	72.29±0.23
8	66.99±1.24	69.62±0.58	79.55±0.45	58.95±0.69	62.80±0.30	74.18±0.68	85.62±0.53
10	72.29±0.15	76.29±0.49	84.45±0.10	70.71±0.59	73.19±0.08	81.61±0.10	99.86±0.08

Fig5.In-vitro release studies of batch F_1 in pH 6.8 buffer

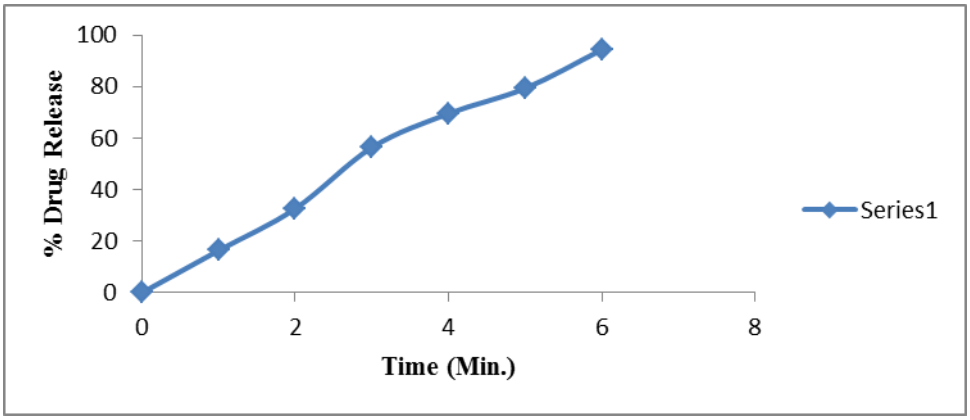


Fig6.In-vitro release studies of batch F_2 in pH 6.8 buffer

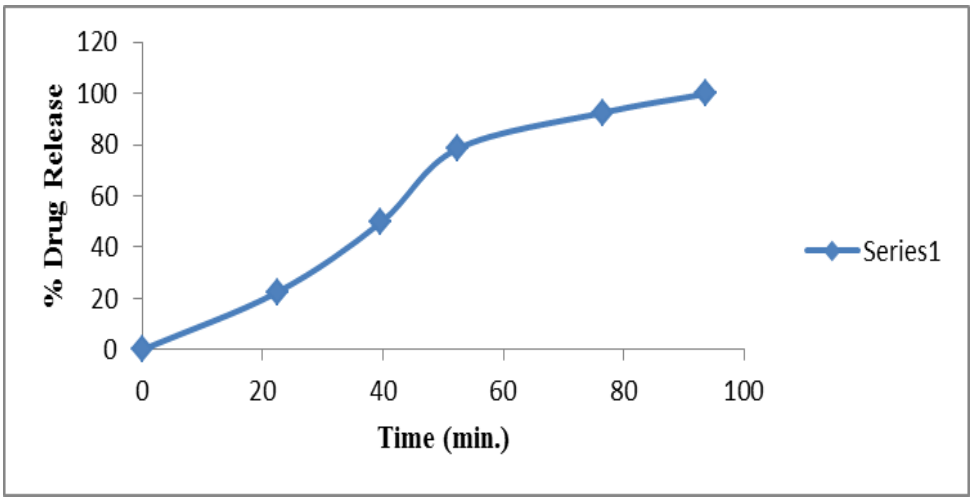


Fig 7. In-vitro release studies of batch F_3 in pH 6.8 buffer

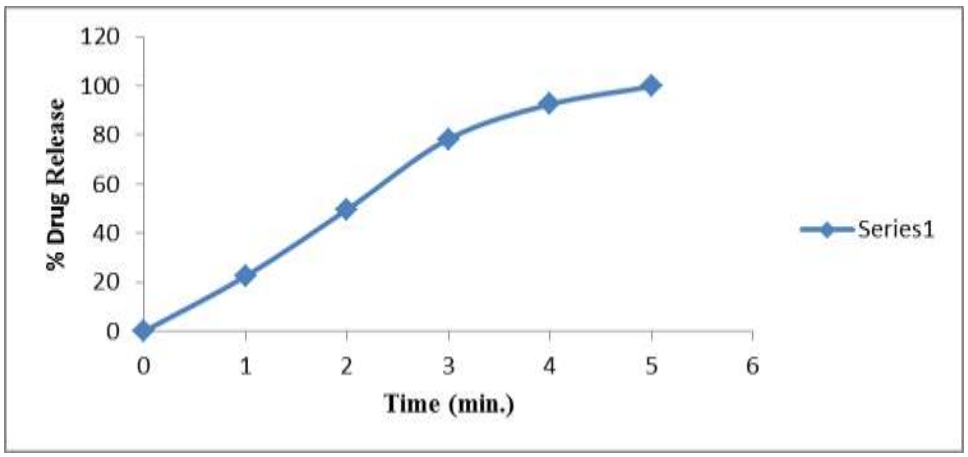


Fig 8. In-vitro release studies of batch F_4 in pH 6.8 buffer

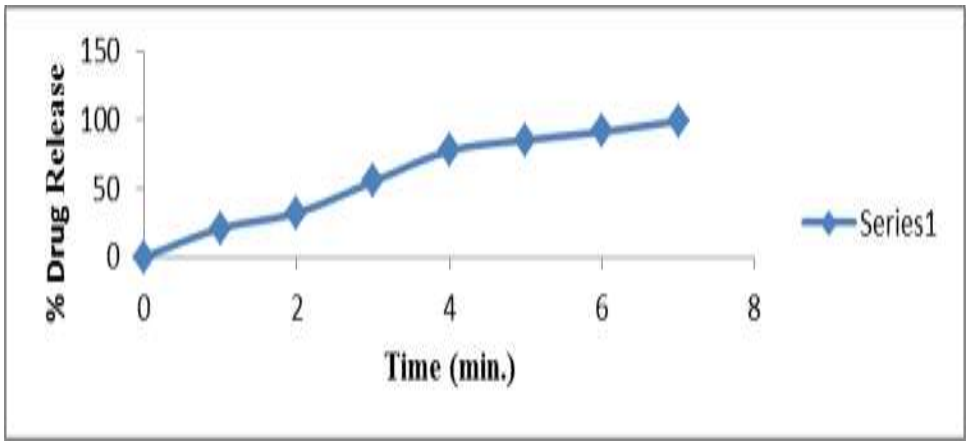


Fig. 9 In-vitro release studies of batch F_5 in pH 6.8 buffer

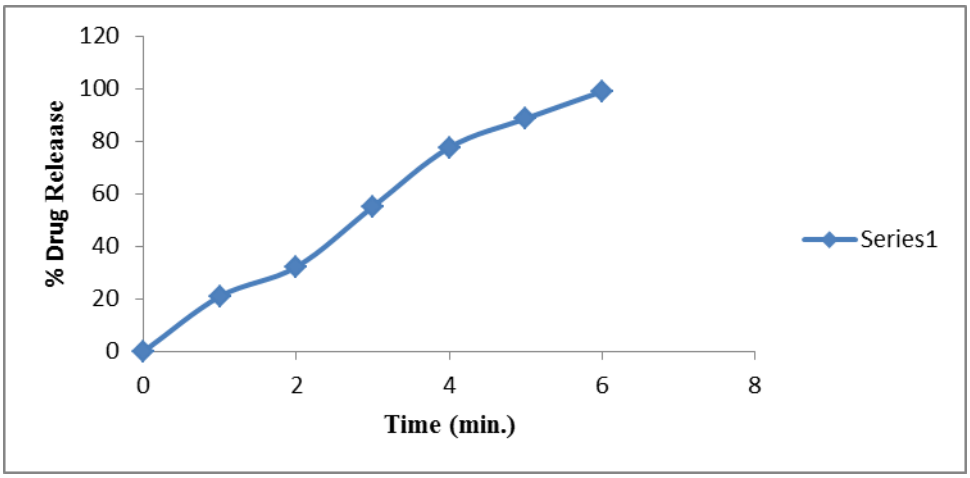


Fig.10 In-vitro release studies of batch F_6 in pH 6.8 buffer

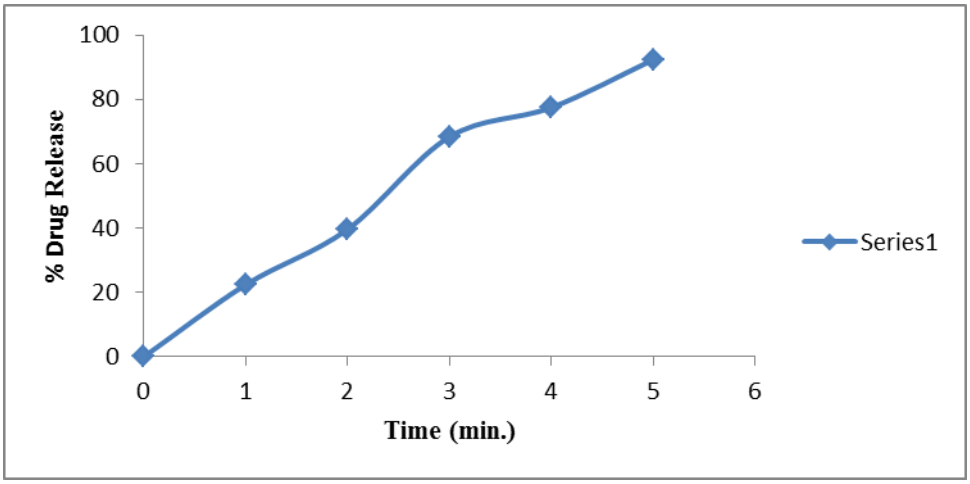
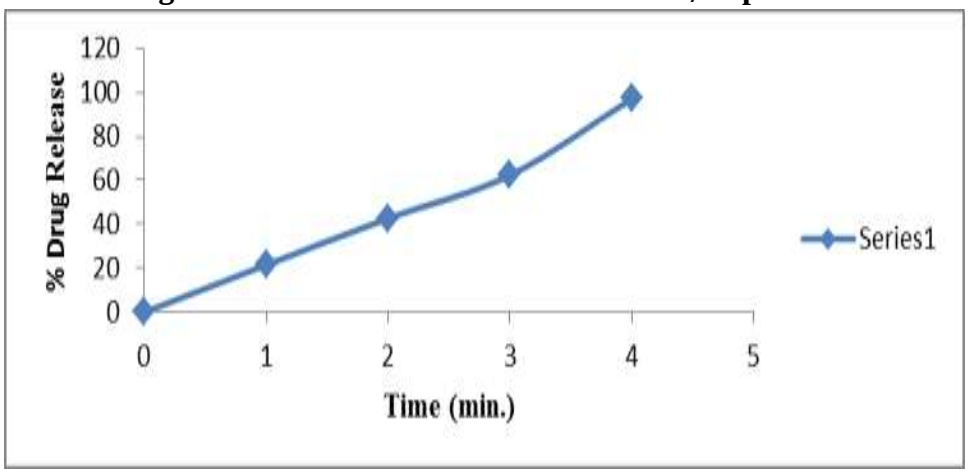


Fig.11 In-vitro release studies of batch F_7 in pH 6.8 buffer



The formulation F_1, F_2, F_3 has the drug release 72.29±0.15, 76.29±0.49, 84.45±0.10 respectively at ten min. The drug release (%) of formula F_4, F_5 and F_6 was found to be 70.71±0.59, 73.19±0.08, and 81.61±0.10 at ten min. The formulation F_7 has drug release 99.86±0.08 at ten min. expectable *invitro* melt curb was NLT80% of remedy discharge at ten min. So the formulation F_3, F_6 and F_7 passed in the in vitro dissolution test.

Table11 : Comparative dissolution studies of formulated formulation F_7 and marketed tablet.

Time(min)	drug release (%)	
	Formulation code	
	F_7	Marketed sample
2.0	36.31±1.20	21.30± 0.27
4.0	53.16±0.60	33.18± 1.03
6.0	73.29±0.23	55.59± 0.95
8.0	84.62±0.53	71.60± 0.49
10.0	99.86±0.08	83.53± 0.44

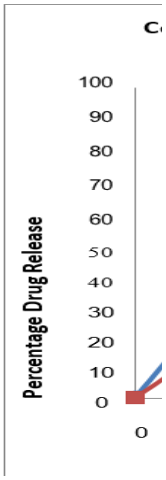


Fig.12: Relative studies of invitro drug release data of Moexipril as well as marketed sample.

The drugs release% of marketed drug and formulated preparation F_7be originate to 83.53± .44 and 99.86±.08. so it is prove that the formulated formulation F_7 have best drug release percentage according to marketed sample.

Stability studies: The formulated formulation F_7 be selected for stability studies, store at 40±2^{0}C/75%±5% RH for three month of period. The tablets are examined for following boundary as such, physical appearance, weight variation, thickness, hardness, disintegration time, excellence of dispersion, dissolution and assess. by each months gap for three month. The result be so within table 3.12.

Table12 :solidity statistics of Moexipril oral disintegration tablets keep at 40±2^{0}C/75%±5% RH.

S.NO.	Storage conditions: 40±2^{0}C/75%±5% RH				
	Test	original period	30 days	60 days	90 days
1	Physical appearance	Not change	Not change	Not change	Not change
2	Weight variation	142.49	141.99	142.29	141.30
3	Thickness (mm)	3.33	3.38	3.33	3.32
4	Hardness (kg/cm^1)	3.01	3.1	3.01	3.01
5	Friability (%)	0.16	0.21	0.18	0.20
6	Disintegration test (sec)	11	11	9	07

7	In vitro dispersion time (sec)	23	23	23	22
8	excellence of dispersion	Good	Good	Good	Good
9	*Invitro* drug release at the end of ten min (%)	99.86	99.76	99.74	99.73
10	Assess (Limit 99-110%)	99.93	99.88	99.82	99.80

On the bases of above stability studies its observed that no significance change were found in physical appearance, weight variation, thickness, solidity, friability, disintegration test, *in vitro* disintegration period, excellence of collapse, *invitro* drug release with ten min and assess, stored for the 3 months at $40\pm2^{0}C/75\%\pm5\%$ RH.

Conclusion

According to the previous work, Oro-dispersible tablets of Moexipril were invented with superb disintegrates such as crospovidone, Croscarmellose sodium independently and also mix together, tablet are prepared by direct compression technique. Moexipril is a water-soluble drug but has limited bioavailability. Bioavailability of medication is raised via this method.

Super disintegrates such as crospovidone and Croscarmellose sodium and blends reduce the dispersion period of tablets.

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