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Effect of Combined Superdisintegrant on the Formulation of Losartan Potassium Mouth Dissolving Tablets

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ABSTRACT: Oral drug delivery remains the preferred route of drug delivery in spite of the associated disadvantage. Solid dosage forms are very popular because of ease of administration and self-medication with pain avoidance as compared to parenteral. One of such approach is to formulate mouth-dissolving tablet which are dissolves rapidly in saliva without the need of water. Within few seconds drug shown the activity due to the action of super disintegrant in the formulation. The demand for mouth dissolving tablets has been growing over the other oral dosage forms (such as tablet, capsule, dry syrups, chewing gum/chewable tablets) among pediatric, geriatric, dysphasic, psychotic and non-cooperative patients and also for travellers. We had formulated the mouth dissolving of Losartan tablets by direct compression method by using different polymers. We had formulated mouth dissolving tablets using different super disintegrants, Out of all formulations, tablets containing Ac-Di-Sol as superdisintegrant showed highest water absorption ratio than all other formulations. It was observed that disintegration time for all tablets within a fraction of second. Amongst all formulations, tablets containing Ac-Di-Sol as superdisintegrant showed faster dissolution rate as compared to other superdisintegrants.

Tablets containing single superdisintegrant like Ac-Di-Sol showed 99% drug release within 4 minutes. Tablet containing combination of two superdisintegrants Ac-Di-Sol and polyplasdone showed 99% release within 1-3 minutes respectively. It was found that as concentration of polyplasdone –XL and Ac-Di-Sol increases, the disintegration time also increases, which may be because of visco plug formation. Amongst all formulations, tablets containing Ac-Di-Sol as superdisintegrant showed faster dissolution rate as compared to other superdisintegrants.

KEYWORDS: Superdisintegrants, Ac-Di-Sol, Polyplasdone XL

I. INTRODUCTION

The demand for mouth dissolving tablets has been growing over the other oral dosage forms (such as tablet, capsule, dry syrups, chewing gum/chewable tablets) among paediatric, geriatric, dysphasic, psychotic and non-cooperative patients and travellers. The primary advantage of the fast melt dosage forms is that they do not need to be chewed because they disintegrate quickly and completely in the small amount if saliva in the mouth. This makes them easy to swallow, avoiding the need to take them with water. However hand tremors, dysphasia in case of geriatric patients, the under redeveloped muscular and nervous systems in young individuals and in case of uncooperative patients, the problem of swallowing is common phenomenon, which leads to poor patient's compliance.[1] To overcome the drawbacks, mouth dissolving tablets or orally disintegrating tablets has emerged as alternative oral dosage forms. Mostly the novel types of tablets are easily disintegrated or disperse in saliva within few seconds. The basic approach used in development of mouth dissolving tablet us the use of super disintegrates, which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. The bioavailability of some drugs may be increased

To ensure the tablet's fast dissolving attribute, water must quickly egress into the tablet matrix to cause disintegration and instantaneous dissolution of the tablets.[2-5] Maximizing the porous structure of the tablet matrix and incorporating an appropriate disintegrating agents or highly water soluble excipients in the tablet formulation are the basic approaches used in current fast dissolving tablets technologies.

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Basically, the disinterest's major function is to oppose the efficacy of the tablet binder and the physical forces that act under compression to form tablet.

The various technologies adopted to prepare mouth-dissolving tablets like Freeze drying/lyophilisation, Moulding, Sublimation, Spray drying, Mass extrusion &direct compression.

We had selected Direct Compression technique for preparing fast dissolving tablet, in this method; tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The basic approach used in the formulation of a rapidly disintegrating tablet by all technologies is to maximize the porous structure of the tablet matrix and to incorporate superdisintegrant like cross linked carboxymethyl cellulose, sodium starch glycolate, polyvinyl pyrrolidone to achieve rapid disintegration and instantaneous dissolution of drugs from the tablet.

In the present study, rapidly disintegrating tablet of Losartan potassium for pediatric and elderly patients was attempted with the aim to develop a dosage from that are easy to administer, provided rapid release of drug and also enhanced bioavailability of the drug[6]

II. MATERIALS AND METHODS

Losartan Potassium collected as gift sample from Hetero Labs limited, Raidurg, Hyderabad, India. Other excipients used in the present work were collected from SJCPS, Naharkanta Laboratory. All other excipients and Chemicals used in the present work were used as analytical grade.

1. Spectrophotometric study

100 mg of drug was dissolved in 100 ml solution of 6.8 phosphate buffer and scan in the range of 200 - 400 nm, spectrum mode, and it was found 235 nm and report value was 234 nm.[7]

2. Thin layer Chromatography

Take prepared silica gel GF 254 TLC plates and a mixture of 40 volume of ethyl ether and 1 ml volume if diethylamide as mobile phase. A single drop of the Losartan potassium in 10 ml of 0.2 N sodium hydroxide and 2 ml dichloromethane was applied to the prepared TLC plates and the mobile phase allowed running up to 10 cm in height. Dry the plate in air and examine the spot by UV light (254nm) method.[8]

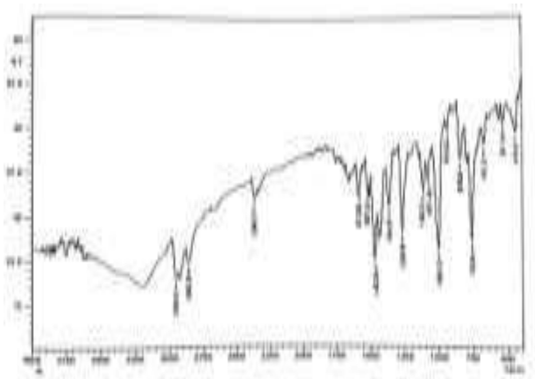
3. Melting Point Apparatus

Melting point was determined by digital auto melting point apparatus (decibel) Capillary was taken heap of Losartan potassium; so that a small plug of the powder was collected in the open end the tube was tapped gently, and the collected materials in the melting point determination apparatus. Automatically the temperature at which Losartan potassium starts to melt was shown by digital auto melting apparatus, noted and compared with literature value.[9]

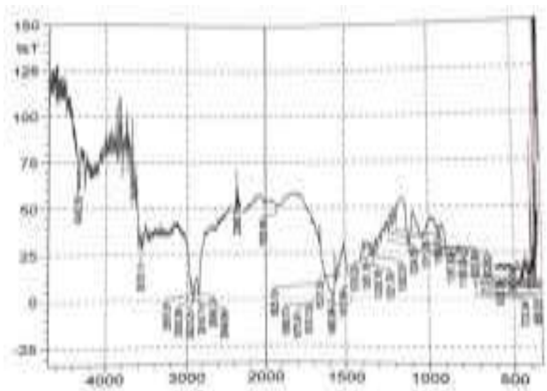
4. Drug-excipient Compatible study

The IR spectrum of Losartan potassium was determined and recorded; it was matched with literature of Losartan potassium and found that there were no any extra peaks.

All the characteristic peaks present in reference spectra of Losartan potassium are also present in drug sample indicating that drug sample is pure and authentic



IR Spectrum of Losartan Potassium



IR –Spectrum of Mannitol

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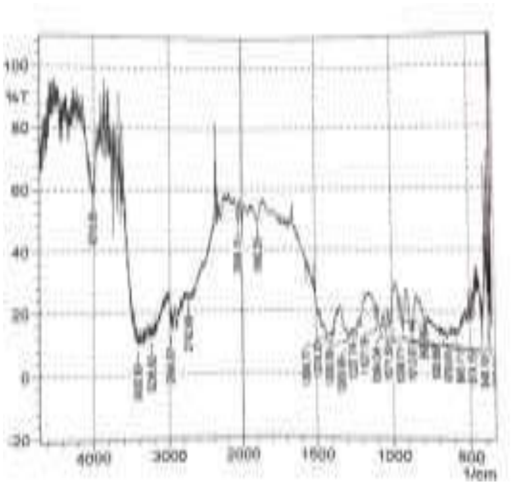
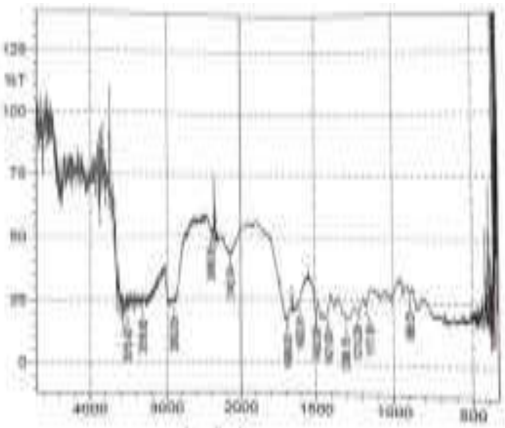
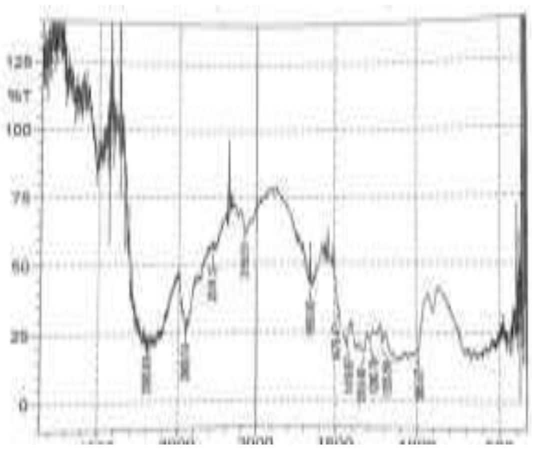


IR-Spectrum of MCC



IR-Spectrum of Ac-di-sol



IR-Spectrum, of Magnesium Stearate

5. Formulation of Fast dissolving tablets of Losartan Potassium

The tablets consisted of Losartan potassium (25 mg) , and Sodium saccharin, flavor (orange and mint) , magnesium stearate, talc and various concentration of microcrystalline cellulose and 1 to 5 % single superdisintegrants or combined Superdisintegrants used in the formulations as per given below in table. The weight of tablets in each batch was kept constant. We had 7 batches of tablets were prepared. All the batches of 50 tablets were prepared by direct compression using single punch machine.

Name of Ingredients	**Quantity (in mg)**						
	A1	**A2**	**A3**	**A4**	**A5**	**A6**	**A7**
Losartan potassium	25	25	25	25	25	25	25
Ac-Di-Sol	4	---	2	10	2	8	---
Poly-Plasdone XL	--	4	2	---	8	2	10
Sodium saccharin	2	2	2	2	2	2	2
Flavors	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2	2
Mannitol	105	105	105	105	105	105	105
MCC	58	58	58	52	52	52	52
Total	**200**	**200**	**200**	**200**	**200**	**200**	**200**

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6. Evaluation of the prepared tablets

Tablets was prepared by the combination of two superdisintegrants were subjected to evaluate official specifications

a) Weight Variation

We had formulate 7 veracity fast dissolving tablets by using single and combined super disintegrants in different proportions to made 50 tablets on each veracity with 200 mg tablets, from the experimental work we had found all tablets pass the weight variation test by taking their individual weight of each tablet.

b) Hardness and Friability

By using single super disintegrants i.e. Ac-Di-Sol or Poly Plasdone XL the hardness of formulations were found to be 3.5 kg/cm2 but in using high concentration of Poly Plasdone XL the hardness is 3 kg/cm2. Friability test of all formulated tablets were tests by using Roche friabilator and friability of the tablets were found to be in the range of 0.61 to 0.65% (≈0.6%) respectively [10-11]

The friability was determined using following formula.

Friability = [(Initial weight-Final Weight) / (initial weight)] x100%

c) Water absorption ratio and wetting time

The wetting time and water absorption ratio which are the important criteria for determining the capacity of disintegrates to swell in presence of little water was found have been evaluated for each batch. Using single or combined superdisintegrants the water absorption ratio and wetting time of the formulations were found to be 70.2% to 85.6 % and 10 to 20 sec. respectively. By using the combined superdisintegrant with increasing higher concentration of Ac-Di-Sol having higher value of Water absorption capacity but with increasing the concentration of Poly Plasdone water absorption capacity decreases [12]

R was determined using following equation.

R= 100 x Wa – Wb/Wa

Where, Wa = Weight of tablet after absorption, Wb = Weight of tablet before water absorption.

d) Uniformity of content:

The results indicated that the content of Losartan potassium in all the formulations i.e. A1 to A7 were found to be in the range of 97 to 99 and found to be within the pharmacopeia limits. Ten tablets from each batch were taken and their content was determined by UV spectrophotometry.[13-15]

Formulation Properties	A1	A2	A3	A4	A5	A6	A7
Weight variation	Passes	Passes	Passes	Passes	Passes	Passes	Passes
Hardness (kg/cm2)	3.5	3.5	3.5	3.5	3.5	3.5	3
Friability (%)	0.65	0.62	0.65	0.62	0.62	0.63	0.61
Uniformity of Content (%)	98.63	99.22	98.63	98.97	98.97	98.97	97.12
Water absorption ratio (%)	71.6	70.2	72.2	78.6	85.6	80.6	76.1
Wetting time (sec)	20	18	20	14	10	16	10
In-vitro Disintegration Time (sec)	36	38	24	28	20	20	30
In vivo Disintegration Time (sec)	52	55	35	37	28	28	40

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e) In-vitro Disintegration Time

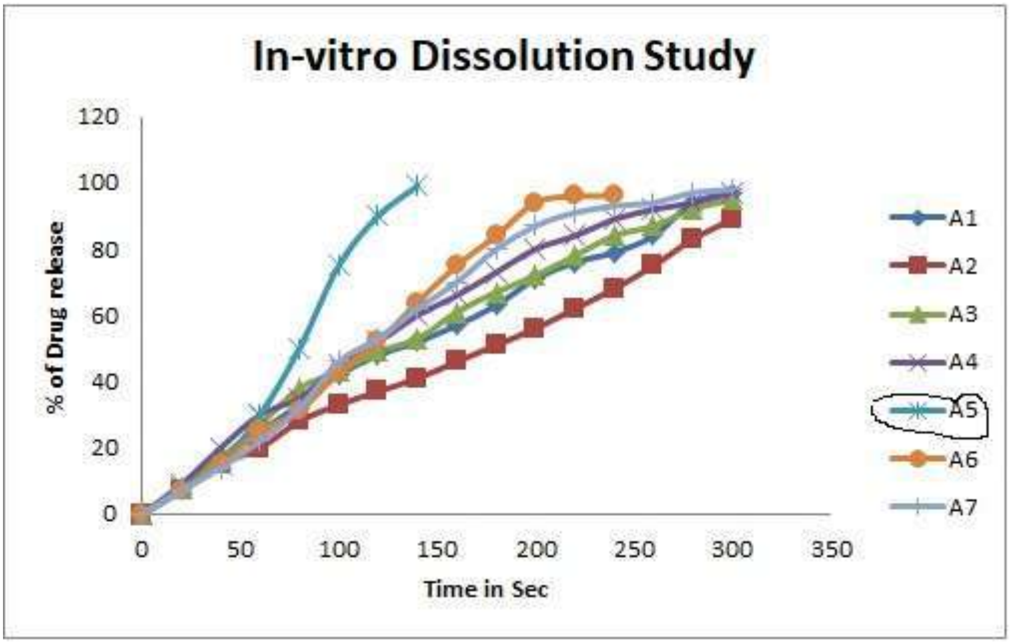
Normally the mouth dissolving tablets were disintegrated very short duration of time. Due to the use of single Superdisintegrant disintegration time in the range of 28 to 38 sec but due to use of combined superdisintegrant the disintegration time in the range of 20 to 24 sec

f) In vivo Disintegration Time

In – vivo, the mouth dissolving tablets were disintegrated very shortly. The in vivo disintegration time in the formulations from A1 to A7 were found to be 28 to 55 sec as like the in-vitro disintegration time were found [16]

g) In-vitro Dissolution Study

Dissolution rate studies showed that about 95 to 99% drug release within the 2 to 5 minutes for all formulations. When the tablet was prepared with using the combined superdisintegrants then approx. 100% of the drug released within 2 min.[17]



III. CONCLUSION

Tablets containing Ac-Di-Sol showed 99% drug release within 2-4 minute while that for tablets containing polyplasdone XL was found within 3-5 minutes. Tablet containing combination of two superdisintegrants Ac-Di-Sol and polyplasdone showed 99% release within 1-3 minutes respectively. Among the in vitro dissolution studies of all formulation i.e. A1 to A7 the best in vitro dissolution profile was found in A5, i.e 99% in one minute.

In conclusion, with increase in concentration of superdisintegrants disintegration time decrease, in the combination of two superdisintegrants tablet preparation, with increasing in the concentration of Ac-Di-Sol and on keeping the constant concentration of polyplasdone the disintegration time decreased. Faster dissolution was obtained for combination of preparation. Dissolution studies indicate, that tablets prepared by combination of two superdisintegrants showed rapid dissolution than tablet prepared by use of a single superdisintegrant.

The stability study was conduct for most satisfactory formulation, A5 at 40^0C $\pm 2^0$C/75% RH±5% for two months. From the above results, it was concluded that there was no significant change in any parameters. Hence the formulation A5 was considered to be highly stable.

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