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FORMULATION AND EVALUATION OF LOSARTAN POTASSIUM IMMEDIATE RELEASE TABLETS

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Abstract
This study aims to develop immediate-release tablets of losartan potassium for the fast and effective management of hypertension. Losartan potassium exhibits pH-dependent solubility, requiring careful formulation optimization. Tablets were primarily prepared by the wet-granulation method using suitable excipients. Ten formulations (F1–F10) were developed and evaluated for flow and compression properties. Post-compression tests included weight variation, hardness, friability, disintegration, and in-vitro dissolution studies. Formulations F9 and F10 demonstrated the best tablet characteristics and the fastest drug release, with dissolution profiles comparable to the marketed innovator product. Stability studies conducted at 40 °C/75% RH for two months indicated no significant changes in drug content. The optimized formulations remained physically and chemically stable. Overall, a safe, effective, and stable immediate-release losartan potassium tablet was successfully developed.

Keywords: Losartan potassium, Immediate-release tablets, Wet granulation, Dissolution profile, Formulation optimization, Stability studies.

Introduction

Immediate release of pharmaceutical formulation includes any formulation in which the rate of release of drug from the formulation and/or the absorption of drug, is neither appreciably, nor intentionally, retarded by galenic manipulations.

Desired criteria for immediate release drug delivery system:

- In the case of solid dosage, it should dissolve or disintegrate in the stomach within a short period.
- In the case of liquid dosage form, it should be compatible with taste masking.
- Have a pleasing mouth feel.
- It should not leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental conditions such as humidity and temperature.
- Rapid dissolution and absorption of drug, which may produce rapid onset of action.

Advantages of Immediate Release Drug Delivery System:

An immediate release pharmaceutical preparation offers:

- Improved compliance/added convenience
- Improved stability
- Suitable for controlled/sustained release actives
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation.

Conventional Technique Used in the Preparation of Immediate Release Tablets:

- Tablet molding technique
- Direct compression technique
- Wet granulation technique
- Mass extrusion technique
- By solid dispersions

Differentiating drug delivery systems according to their mechanism of drug release:

Immediate release – drug is released immediately after administration. Modified release – drug release only occurs sometime after the administration or for a prolonged period of time or to a specific target in the body.

Modified release systems can be further classified as:

Delayed release: drug is released only at some point after the initial administration. Extended release: prolongs the release to reduce dosing frequency.

Losartan Potassium Drug Profile

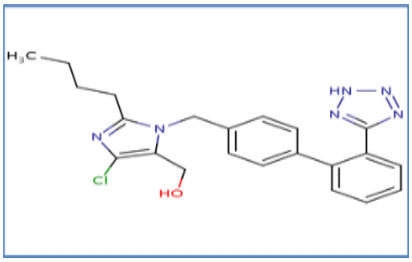

Figure 01 : structure of losartan potassium

Drug Category: Anti-HypertensiAgent

Molecular formula :C22H22ClKN6O

Solubility

Aqueous :It is freely soluble in water.

Non- aqueous :It is soluble in alcohols, and slightly soluble in common organic solvents such as acetonitrile and methyl ethyl ketone.

Site and Mode of Action

Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by blocking the binding of angiotensin II to AT1 receptor found in many tissues, (e.g.,vascular smooth muscle,adrenl gland).

Biological half life: 2 hours

Excipient Profile

Cros Carmellose Sodium -

Category: Tablet and capsule disintegrant 0.5-5%

Solubility: Insoluble in water, it swells 4–8 times its original volume on contact with water. Practically insoluble in acetone, ethanol and toluene. Applications: It is used as a disintegrant for capsules, tablets, and granules can be used up to 5% w/w as a tablet disintegrant, although normally 2% w/w is used in tablets prepared by direct compression.

Dicalcium Phosphate Dihydrate

Functional categories: Tablet and capsule diluents

Solubility: Insoluble in ethanol, ether, and water; soluble in dilute acids.

Applications:

1) It is widely used as an excipient.
2) The milled material is typically used in wet-granulated, roller-compacted or slugged formulations.

Polyvinyl Pyrrolidine (PVP)

Functional Category: Disintegrate; dissolution aid; suspending agent and tablet binder.

Solubility: Freely soluble in acids, chloroform, ethanol, ketones, methanol and water; practically insoluble in ether, hydrocarbons and mineral oils.

Applications: Polyvinylpyrrolidine (PVP) solutions are used as binders in wet granulation.

Collidal Silicone Dioxide

Functional categories: Adsorbent; anticaking agent; emulsion stabilizer; glidant; suspending agent; tablet disintegrant; thermal stabilizer; viscosity-increasing agent.

Solubility: Practically insoluble in organic solvents, water, and acids, except hydrofluoric acid; soluble in hot solutions of alkali hydroxide. Forms a colloidal dispersion with water. For Aerosol, solubility in water is 150 mg/L at 258C (pH 7).

Applications: Colloidal silicon dioxide is also used to stabilize emulsions and as a thixotropic thickening and suspending agent in gels

Microcrystalline Cellulose

Functional Category: Tablet and capsule diluent, Adsorbent, suspending agent, tablet disintegrant.

Solubility: Slightly soluble in 5% w/v sodium hydroxide solution; practically insoluble in water, dilute acids, and most organic solvents.

Applications: Microcrystalline cellulose is widely used in pharmaceuticals, as a binder/diluent in oral tablet and capsule formulations.

Isopropyl Alcohol

Functional category: Disinfectant, solvent.

Solubility: Miscible with benzene, chloroform, ethanol, Soluble in acetone Insoluble in salt solutions.

Applications:

Tablets - Film forming agent & Granulating agent, 70%v/v used as disinfectant not recommended for oral use.

Table 01: Innovator table of losartan potassium

S. no	Ingredients	F1A	F1B	F2A	F2B	F3	F4	F5	F6	F7	F8	F9	F10
1	Losartan Potassium	100	100	100	100	100	100	100	100	100	100	100	100
2	Mannitol (Pear lit 25C)	24	24	24	24	24	24	24	24	24	24	24	24
3	Cellulose, microcrystalline (Avicel PH101)	157.57	157.57	157.57	157.57	157.57	233.57	181.57	171.57	171.57	167.57	151.57	143.57
4	Dicalcium phosphate dihydrate	76	76	76	76	76	-	76	76	76	76	76	76
5	Povidone (plasdone K 29/32)	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5
6	Cross carmellose sodium (Ac-di-sol)	12	12	12	12	12	12	12	6	0	8	14	14
7	Isopropyl alcohol	-	QS	QS	QS	-	QS	QS	QS	QS	QS	QS	QS
8	Purified water	QS	-	-	-	-	-	-	-	-	-	-	
9	Cross carmellose sodium (Ac-di-sol)	8	8	8	8	8	8	8	0	6	8	12	20
11	Colloidal silicon dioxide	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6

12	Magnesiu m stearate (Ferro – VG)	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Total Score													
	tablet weight	393.07	393.07	393.07	393.07	393.07	393.07	393.07	393.07	393.07	393.07	393.07	393.07
13	Coating compositi on	-		12	12	12	12	12	12	12	12	12	12
14	IPA	-		QS	-	-	-	-	-	-	-	-	-
15	Water	-		-	QS	QS	QS	QS	QS	QS	QS	QS	QS
16	Coated tablet weight	405. 07		405. 07	405. 07	405. 07	405. -7	405. 07	405. 07	405. 07	405. 07	405. 07	405. 07

Procedure for direct compression batch

Step 1: Losartan potassium with small quantities of MCC using # 30 ASTM sieve, Mix remaining MCC with other excipients except lubricants and sift through 30 ASTM sieve • Step 2: Mix all ingredients of step 1 and pass through 30 ASTM sieve.

Step 3: Blend the above sifted mass for 20 min at 16 rpm.

Step 4: Add Aerosil which was pre sifted through 40 ASTM to the above and blend for 16 rpm for 05 min.

Step 5: Add Magnesium stearate which was pre sifted through 40 ASTM to the blend of above step at 16 rpm for 03 min.

Step 6: Compress the tablets with above blend using 11 mm round shaped flat punches in Dtooling.

Wet granulation process in Rapid Mixer Granulator (RMG)

- Sifting of raw materials
- Binder preparation
- Granulation
- Drying
- Sizing of granules
- Lubrication
- Compression
- Film Coating

Table 02: Formula for all formulations.

S. no	Ingredients	F1A	F1B	F2A	F2B	F3	F4	F5	F6	F7	F8	F9	F10
1	Losartan Potassium	100	100	100	100	100	100	100	100	100	100	100	100
2	Mannitol (Pear lit 25C)	24	24	24	24	24	24	24	24	24	24	24	24
3	Cellulose, microcrystalline (Avicel PH101)	157. 57	157. 57	157. 57	157. 57	157. 57	233. 57	181. 57	171. 57	171. 57	167. 57	151. 57	143. 57

4	Dicalcium phosphate dihydrate	76	76	76	76	76	-	76	76	76	76	76	76
5	Povidone (plasdone K 29/32)	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5
6	Cross carmellose sodium (Ac-di-sol)	12	12	12	12	12	12	12	6	0	8	14	14
7	Isopropyl alcohol	-	QS	QS	QS	-	QS	QS	QS	QS	QS	QS	QS
8	Purified water	QS	-	-	-	-	-	-	-	-	-	-	
9	Cross carmellose sodium (Ac-di-sol)	8	8	8	8	8	8	8	0	6	8	12	20
11	Colloidal silicon dioxide	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6
12	Magnesiu m stearate (Ferro – VG)	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
	Total core tablet weight	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07	393. 07
13	Coating compositi on	-		12	12	12	12	12	12	12	12	12	12
14	IPA	-		QS	-	-	-	-	-	-	-	-	-
15	Water	-		-	QS	QS	QS	QS	QS	QS	QS	QS	QS
16	Coated tablet weight	405. 07		405. 07	405. 07	405. 07	405. -7	405. 07	405. 07	405. 07	405. 07	405. 07	405. 07

Evaluation Parameters

Evaluation of powder flow properties

- Bulk density
- Tapped Density
- Carr's compressibility Index Hausner's Ratio

Evaluation of Tablets

- Uniformity of weight
- Thickness
- Hardness
- Friability
- Disintegration
- *In-vitro* drug dissolution study Stability study

Stability Studies

- **Long-term Testing :** 25°C ± 2°C / 60% RH ± 5% RH for 12 Months.
- **Intermediate Testing:** 30°C ± 2°C / 65% RH ± 5% RH for 12 months.
- **Accelerated Testing :** 40°C ± 2°C / 75% RH ± 5% RH for 6 Months.

Procedure

Accelerated stability studies on the promising tablet formulations were carried out by storing 15 tablets in rubber-stoppered vials at an elevated temperature of **40 ± 2 °C / 75 ± 5% RH** (Stability Chamber, Oswald) for a period of 30 days (1 month). After storage, the tablets were visually examined for any physical changes and evaluated for drug content, disintegration time, hardness, friability, and in-vitro dissolution profile.

Table 03: Blend properties of different formulations

Formulation	B.D(gm/ml)	T.D(gm/ml)	C.I(%)	HR	Property
F1	0.710	0.873	19.714	1.251	Fair
F2	0.710	0.873	19.714	1.251	Fair
F3	0.483	0.681	29.03	1.409	Passable
F4	0.483	0.681	29.03	1.409	Passable
F5	0.461	0.714	35.385	1.548	Fair
F6	0.416	0.714	35.385	1.548	Fair
F7	0.500	0.600	23.22	1.295	Passable
F8	0.500	0.600	23.22	1.295	Passable
F9	0.541	0.691	21.62	1.276	Passable
F10	o.541	0.691	21.62	1.276	Passable

Table 04: physical evaluation of film coated tablets.

Formulation	Avg.Weight (Mean ±S.D) (n=20)	Hardness (kg/cm) (n=3)	Disintegration time (min'sec'')
F2A	414±4.43	7.6±0.2	8'54''
F2B	412±5.74	7.8±0.2	8'48''
F3	409±3.85	7.8±0.3	8'52''
F4	413±3.87	8.1±0.4	9'02''
F5	411±4.45	8.2±0.2	9'26"
F6	413±4.26	7.9±0.3	12'43''
F7	410±4.56	7.8±0.1	13'04''
F8	412±4.48	7.9±0.4	11'43''
F9	412±4.17	8.0±0.3	9'52''
F10	413±3.63	7.9±0.3	6'48''

Table 05: In-vitro Dissolution profile of Losartan potassium

Time (min)	Innovator	F2B	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	16	10	9	12	11	8	9	11	12	14
10	45	23	26	35	30	16	18	30	37	43
15	69	47	40	54	52	37	36	43	60	65
20	86	59	60	68	66	55	53	60	78	81
30	96	72	78	80	81	68	70	76	87	90
45	98	90	90	92	94	95	94	95	94	96

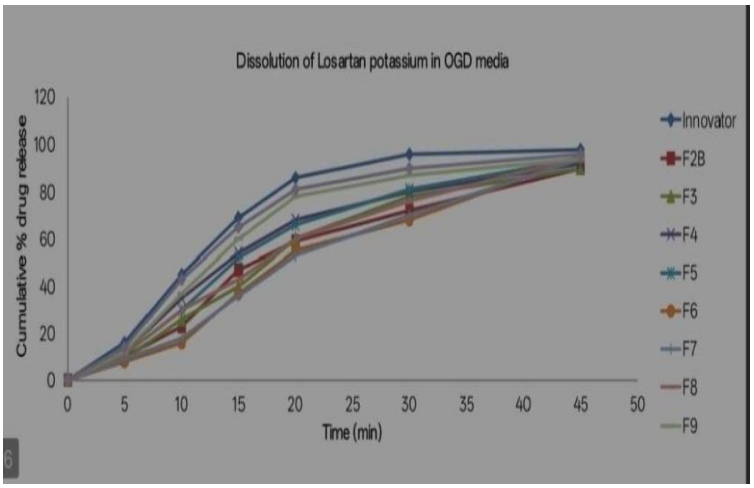

Figure 2: dissolution of losartan potassium in OGD media

Table 06: Stability condition % Assay results of F9 and F10

Stability conditions	Description	F9 Losartan potassium	F10 Losartan potassium
Room temperature initial	Light white coloured Film coated tablets	99.72	99.76
40°C/75% RH (1 month)	Light white coloured Film coated tablets	98.47	98.62
40°C/75%RH (2 months)	Light white coloured Film coated tablets	97.93	98.16

Table 07: In-vitro Dissolution profile of Losartan potassium in optimized formulation F10 at 40°C and 75% RH

Time (min)	Innovator	1 month	2 months
0	0	0	0
5	72	70	68
10	83	82	79
15	89	89	86

20	91	90	90
30	96	95	93
45	97	96	95
60	98	98	97

Discussion

The purpose of formulation of Losartan potassium Immediate release tablets 5/100 mg was to provide treatment of hypertension effectively by the synergistic effect of Calcium channel blocker i.e., Angiotensin II inhibitor i.e., Losartan potassium.

Solubility of Losartan potassium was also found to be pH dependent and increases as the pH increases. Solubility at pH 1.5 was low (0.27 mg/ml)and was maximum at pH 7.4 (477.48 mg/ml).As per BCS classification, at low dose (50 mg), Losartan can be classified as highly soluble and at high dose 100 mg it falls under low soluble category.

- In the F1 formula the wet granulation process was followed and is done by using water as a granulating agent in F1A , Isopropyl alcohol as a granulating agent in F1B.
- The best suited process is selected by analyzing the tablets for % of related substances initially and after 7 days storing in 50°C.
- Then the selected formulation was coated with opadry white dispersed in isopropyl alcohol in F2A and water in case of F2B and the tablets were analyzed for % of related substances initially and after 7 days storing in 50°C.
- The results shown that coating dispersion with water and isopropyl alcohol was similar hence it was decided to go with dispersion in with water.
- The selected F2B was compared with the direct compression batch coated with Opadry white dispersed in water and related substances were analyzed.
- Then the diluent combination was selected by comparing formulations containing soluble diluent Mannitol in F4 and insoluble diluent Dicalcium phosphate dihydrate in F5 along with microcrystalline cellulose as another diluent in common.
- Then disintegrant concentration was optimized by taking Croscaramellose sodium at intra granular or extra granularly and/or both in the F6-F10.
- Disintegrant Croscarmellose sodium was added in intra granular portion (1.5%) in F6 , and (1.5%) extra granular portion in F7,and F8 contains disintegrant in both intra granular(2%) and extra granular(2%) portions.
- Formulation F9 contains concentrations of disintegrating agent 3.5% intra granular portion and 3% extra granular portion.
- The dissolution profile Losartan potassium in F9 was near to innovator .
- F10 was taken by including Croscarmellose sodium 5% extra granular and 3.5% intra granular concentrations were used.
- All the tablets were prepared under similar conditions
- The values of pre- compression and post -compression parameters evaluated were found to be within prescribed limits.
- The stability study was performed for F9 and F10 formulations as per ICH guidelines.
- Among the all formulations the release profile of trial F10 was found to be similar to the marketed product release profile.

Summary and Conclusion

All formulations were prepared by wet granulation method by using microcrystalline cellulose, povidone, Dicalcium phosphate dihydrate, mannitol, colloidal silicon dioxide, and magnesium stearate. On direct compression batch was taken and results were compared with wet granulated batch of same composition. The tablets prepared were found to be within the official limits with respect to weight variation, thickness, hardness, friability, disintegration and dissolution. The stability study was performed for F10 formulation as per ICH guidelines. Stability study was carried out for 2 months at 40°C/75%RH. Among the all formulations the release profile of trial F10 was found to be similar to the marketed product release profile. Attempts were made in the present investigation to develop a pharmaceutically stable formulation of Losartan potassium immediate release tablets. Losartan potassium was

indicated for the treatment of hypertension. In this study, Losartan potassium immediate release tablets was formulated by wet granulation method and moisture protective film coating was given. These results clearly reflect that the prepared formulation releasing the drug immediately within the specifications. The final formulation also shows good comparative dissolution profile with marketed preparation.

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Conflict of Interest
None Declared

Author Contribution
Both Authors contributed equally

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Ethical Approval and Inform Consent
Not Applicable

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