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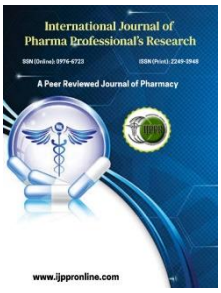

FORMULATION, DEVELOPMENT AND IN VITRO EVALUATION OF TASTE MASKING MOUTH DISSOLVING TABLET OF LEVOCETIRIZINE DIHYDROCHLORIDE

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Keywords:
Levocetirizine dihydrochloride, allergic rhinitis, superdisintigrants, Mouth dissolving tablets.

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ABSTRACT:
Levocetirizine dihydrochloride is a selective, long acting peripheral H1receptor antagonist. Allergic rhinitis is a symptomatic disorder of the nose induced by inflammation mediated by immunoglobulin E (IgE) in the membrane lining the nose after allergen exposure. Thus formulating Levocetirizine into an mouth dissolving tablet dosage form would provide fast relief. The Levocetirizine is bitter in taste so the Kyron T-114 (ion exchange resin) was used to mask the taste and to formulate an mouth dissolving tablet dosage form using drug resin complex. The tablets were evaluated for the drug content, weight variation, water absorption ratio, wetting time, in vitro disintegration, dispersion time, hardness, friability, thickness uniformity. The tablets disintegrated in vitro within 22 to 66 seconds complete drug were released from tablet within 10 minutes.

Introduction:
Taste is one of the most important parameters governing patient compliance. Undesirable taste is one of several important formulation problems that are encountered with certain drugs. Oral administration of bitter drugs with an acceptable degree of palatability is a key issue for health care providers, especially for pediatric patients. Several oral pharmaceuticals, numerous food and beverage products, and bulking agents have unpleasant, bitter-tasting components. So, any pharmaceutical formulation with a pleasing taste would definitely be preferred over a competitor's product and would translate into better compliance and therapeutic value for the patient and more business and profits for the company. The desire of improved palatability in these products has prompted the development of numerous formulations with improved performance and acceptability [**[1]**]. The methods most commonly involved for achieving taste masking include various chemical and physical

methods that prevent the drug substance from interaction with taste buds. The simplest method involves use of flavor enhancers. Where these methods fail more complex methodologies are adopted. Various techniques have been identified for taste masking which include polymer coating, inclusion complex formation with cyclodextrin, use of ion exchange resins, solubility limiting methods, liposome, multiple emulsions, use of anesthetic agents, etc. Oral drug delivery is the most favored route for the administration of various medications and tablets are the most widely accepted dosage form. Solid dosage forms are popular because of the ease of administration, accurate dosage, self-medication, pain avoidance, and most importantly patient compliance [2]. Among the major problems faced by many patients with conventional tablet dosage form is difficulty in swallowing. This problem is more apparent when drinking water is not easily available to the patient taking medicine. Dispersible tablet delivery system is characterized by fast disintegration, quick dissolving, rapid release and improved patient compliance. Dispersible tablets are either uncoated or film-coated tablets which can be dispersed within three minutes in a small amount of water or breast milk before oral administration giving a homogenous dispersion [3]. United States Food and Drug Administration (FDA) defined fast dissolving tablets as a "solid dosage forms containing medicinal substances or active ingredients which disintegrate rapidly usually within a matter of seconds when placed in water ".European pharmacopoeia also adopted the term “dispersible tablet” as a tablet that is to be placed in the water where it disperses, rapidly before swallowing [4]

AN IDEAL PROPERTIES FOR TASTE MASKING

- Involve least number of equipments and processing steps.
- Require minimum number of excipients for an optimum formulation.
- No adverse effect on drug bioavailability.
- Require excipients that are economical and easily available.
- Least manufacturing cost.
- Can be carried out at room temperature.
- Require excipients that have high margin of safety.
- Rapid and easy to prepare.

Levocetirizine (as levocetirizine hydrochloride) is a third generation non-sedative antihistamine, developed from the second–generation anti-histamine cetrizine. Chemically, levocetirizine is active enantiomers of cetrizine. It is the L-enantiomers of cetrizine race mate. Levocetirizine works by blocking histamine receptors. It does not prevent the actual release of histamine from mast cells, but prevents it binding to its receptors. The main aim of this study is to develop and characterize mouth dissolving tablets of Levocetirizine dihydrochloride which disintegrate in the oral cavity in a matter of second without need of water and also develop taste masked mouth dissolving Levocetirizine diHCl tablet using direct compression method using cationic exchange resin.This helps in easy swallowing hereby improves clinical effects through pregastric absorption, leading to an increase in bioavailability of the drug and quick onset ofpharmacological action can takes place. [5]

MATERAIL AND METHOD

Table No.1.Lists of materials used and their manufacturers/ suppliers

S.No	Materials	manufacturers/ suppliers
1.	Levocetirizine di HCl	Metrochem API Pvt. Limited Hyderabad
2.	Kyron T-114	Corel Pharma chem. Gujrat
3.	Microcrystalline Cellulose p^H (102)	N.B Enterprises ,Nagpur
4.	Aspartame	Biocon Ltd. Dehradun
5.	Colloidal silicon dioxide	GlenmarkPhrmaceutical, Baddi
6.	Magnesium stearate	Amishi Drug & Chemicals Ahmedabad

7.	Mannitol	Classic Enterprises,Delhi
8.	NaCl I.P	Vintage Enterprises,Delhi
9.	Talcum I.P	OrgaChemiagencies,Delhi
10.	Sodium starch glycolate	OrgaChemiagencies,Delhi
11.	Crosscarmellose sodium	Shreeji Chemicals ,Mumbai
12.	Crosspovidone	Shreeji Chemicals ,Mumbai
13.	Flavour Vanilla dry	Shakti Trading company,Thane

METHODS

DIRECT COMPRESSION TECHNIQUE

Activation of Resin[6]

Batch method was used to prepare drug resin complex. Ion exchange resins Kyron-114 was swelled with deionised water for an hour and then washed with 1N hydrochloric acid and 1N NaOH in order to remove impurities (alkali and acidic impurities). The treated resin was washed several times with freshly prepared deionized water to remove the traces of acid or alkali. This treated resin was kept in oven for 12 h at 50^0C. The dried activated resin was kept in desiccator until in use.

Preparation of Drug- Resin Complex:[7]

- Drug-resinates were prepared using batch method
- The resins were first washed with distilled water.
- Take purified water add potassium hydroxide to it.
- Added required amount of drug in the ratio 1:3 (Drug: Polymer) in this slurry under stirred condition.
- After the complete addition, kept stirring for around 4 hours so that most of the drug gets complexed with the resin.
- Sifted the mass threw mess 10# & allow to dry in tray drier at 50-55^0 C for 1 hr. The drug content in the filtrate was analyzed by ultraviolet (UV) spectroscopy at 230.1nm.

PREPARATION OF LEVOCETIRIZINE DIHYDROCHLORIDE MOUTH DISSOLVING TABLET FROM DRUG RESIN COMPLEX BY USING SUPERDISINTEGRANTS: [8,9,10]

Granules of drug-resinate earlier obtained were mixed/blended with super disintergrants sodium starch glycolate, crosscarmellosesodium, crosspovidone which are already sifted threw mesh no.80#and MCC(P^H-102) as diluent, spray dried mannitol as mouth feel enhancer, Mg.stearate as lubricant,Talcum as glidant and anti adherent and colloidal silicon dioxide as glidant which are already sifted threw mesh no.40#.and also lubricated with sodium chloride as taste inhancer ,flav.cherry,flav.vannila dry, aspartame as sweetner and menthol as flavouring and cooling agent which are already sifted threw mesh no.80#. Before compression, hardness was adjusted. Drug-resinate equivalent to 5mg of Levocetirizine, dihydrochloride were compressed on 10- station rotary punching machine to get tablets, each weighing 185 mg.

TABLE No.2. COMPOSITION OF MOUTH DISSOLVING TABLET OF LEVOCETIRIZINE DIHYDROCHLORIDE

Ingredients	Formulation Code & Quantity (mgs)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Levocetirizine Dihychloride: Kyron T-114 (1:3)	25	25	25	25	25	25	25	25	25
Microcrystalline cellulose (PH-102)	80	79.8	75.6	80	85.8	80	82.1	84.1	78.1
Mannitol	60	60	60	60	60	60	60	60	60
Sodium Chloride	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Flavour Cherry	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Flavour Vanilla Dry	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250

Magnisium Stearate	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Talcum	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2
Colloidal silicon dioxide	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Aspartame	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Sodium starch glycolate	4.1	6.3	8.5	4.1	6.3	8.5			
Cross Carmellose Sodium				6	2	6	6	2	6
Cross Povidone	5	7	9				5	7	9
Menthol	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05

Table No. 3. Lists of used equipments

S.No	Name of equipments	Manufacturers
1.	UV Visible Spectrophotometer	Shimadzu Corporation,japan
2.	FTIR Spectrophotometer	Shimadzu FTIR-8400S Kyoto, Japan
3.	Digital Electronic balance	Mettler Toledo AB204-S, Switzerland, India
4.	Digital p^HMeter	Digisunelectronics,Hyderabad
5.	Hot air oven	Universal
6.	Tablet Punching Machine	Shakti,Ahemdabad
7.	Roche Friabilator	Biological Museum,Agra
8.	Tablet Hardness tester	Pfizer
9.	Vernier Caliper	Mitutoyo, Japan
10	Dissolution Test Apparatus USP Std.	Electrolab TDL-08L
11.	HPLC	Waters 2965, Milford, US
12.	Disintegration test apparatus	Electrolab

EVALUTION PARAMETER OF MOUTH DISSOLVING TABLETS:

Precompression parameters: [11]

1.Angle of repose (θ):

Table.no.4 shows the results obtained for angle of repose of all the formulations. The values were found to be in the range of $18^0.00$' to $21^0.67$'. All formulations showed the angle of repose with in 21.67^0. It indicates that all formulations showed good flow properties.

2.Bulk Density:

Bothloose bulk density (LBD) and tapped bulk density results are shown in Table 4 The loose bulk density and tapped bulk density for all the formulations varied from 0.46gm/cm^3 to 0.59 gm/cm^3 and 0.53 gm/m^3 to 0.69 gm/cm^3 respectively. The values obtained lies within the acceptable range and not large difference found between loose bulk density and tapped bulk density. This result helps in calculating the % compressibility and hausner's ratio of the tablet blend.

3.Percentage Compressibility:

This percent compressibility of tablet blend was determined by carr's Index. Table 4 shows result obtained for percentage compressibility. The percentage compressibility for all the nine formulations lies within the range of 11.53 to 15.38%. All the formulations showing good compressibility.

4.Hausner's Ratio:

Thishausner's ratio of tablet blend was determined . Table 4 shows result obtained for percentage compressibility. The hausner's ratio for all the nine formulations lies within the range of 1.13 to 1.18. All the formulations showing good flow property.

Table no.4 : Angle of repose, Loose bulk Density, Tapped bulk Density, Carr's Compressibility Index &Hausner's Ratio –

Formulation Code	Angle Of Repose (θ)	Loose Bulk Density (gm/cm^3)	Tapped Bulk Density (gm/cm^3)	% Compressibility	Hausner's Ratio
F_1	18.56	0.46	0.53	13.20	1.15

F_2	21.17	0.47	0.54	12.96	1.14
F_3	20.54	0.46	0.52	11.53	1.13
F_4	21.17	0.59	o.69	14.00	1.16
F_5	18.26	0.57	o.66	13.63	1.15
F_6	20.29	0.54	0.62	12.90	1.14
F_7	20.59	0.55	0.65	15.38	1.18
F_8	21.67	0.53	0.62	14.51	1.17
F_9	20.50	0.52	0.60	13.33	1.15

Post – Compression Parameters:-[12,13,14]

All the tablet formulations were subjected for organoleptic, physical and chemical evaluations. Shape, thickness, hardness, friability, weight variation, in vitro disintegration time, wetting time, water absorption ratio, drug content, in vitro dissolution studies were carried out.

1.Genral Appearance:

Randomdly picked tablets from each formulation batch examine under lens for shape and in the presence of light for colour. Tablets shows flat , circular biconvex and white in colour.

2.Thickness test:

The thickness of tablets measured by using vernier calipers by picking the tablets randomly .The mean value shown in table no.5.The values are almost uniform in all formulations. Thickness was found in the range from 2.91±0.01 mm to 2.97±0.01 mm respectively.

3. Uniformity of weight:

The % weight variation for all the formulations tabulated in Table no.5 All the tablet pass weight variation test and% weight variation was in the Pharmacopoeial limit of ±10%.It was found to be from 184.95 to190.25 mg. This is due to good flow property and compressibility in all formulations.

4.Hardness test:

The result of hardness was given in Table no.5 .Hardness test was performed by Pfizer hardness tester. Hardness was maintained to be 2.2kg/cm^2 to 2.5 kg/cm^2 .The hardness of all formulations were uniform and have sufficient mechanical strength.

5.Friability test:

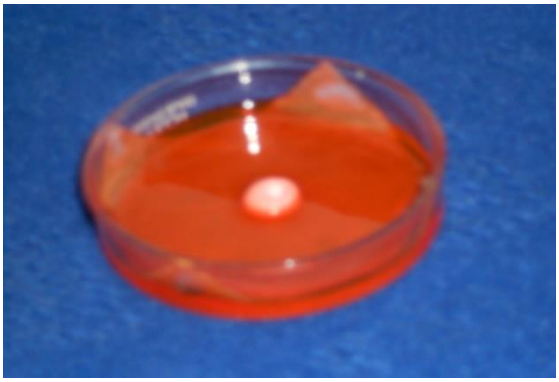
The study result was tabulated in Table no.5. was found in well approved range (<1%) in all the formulations. Result revealed that the tablets posses good mechanical strength.

Table.no.5 Result of Thickness,Hardness,Friability and Weight Variation of Levocetirizinedihydrochloride tablets

Formulation code	**Thickness (mm) (n=3)**	**Hardness (kg/cm^2) (n=3)**	**Friability (%) (n=10)**	**Weight Variation (n=20)**
F_1	2.93±0.02	2.32±0.25	0.40±0.05	185.05±1.15
F_2	2.94±0.02	2.33±0.27	0.39±0.05	186.0±1.77
F_3	2.94±0.01	2.32±0.25	0.39±0.02	185.04±1.23
F_4	2.95±0.01	2.20±0.25	0.41±0.04	190.25±1.50
F5	2.96±0.01	2.21±0.25	0.42±0.04	184.00±1.80
F_6	2.97±0.01	2.22±0.27	0.41±0.03	185.05±1.00
F_7	2.93±0.02	2.47±0.25	0.38±0.07	184.95±1.12
F_8	2.92±0.01	2.50±0.25	0.38±0.05	184.95±1.01
F_9	2.91±0.01	2.50±0.25	0.38±0.03	184.95±1.00

6.Wetting Time:

Wetting time depend upon inner structure of tablet and hydrophilicity of excipients. The record of wetting time was shown in Table no. 6.The wetting time in all the formulations is very fast.



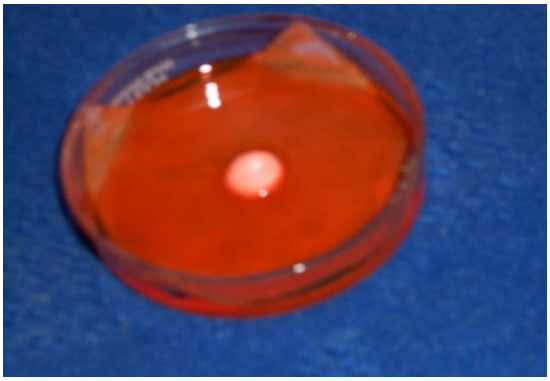


Fig no 1. Showing wetting time of Levocetirizine dihydrochloride tablets

7.Water Absorption Ratio:

The water absorption ratio for all the formulations tabulated in Table no.6. The ratio values of formulations found in the range of 86.30 to 119.53.

8.*In vitro* Disintegration time:

The internal structure of tablet that is pore size distribution, water penetration into the tablet and swelling of disintegrating substance are suggested to be the mechanism of disintegration. The result shown in Table no6 This was determined as per I.P for all the formulations. All the formulation showed disintegration time less than 48 sec. Disintegration time was observed in the order of sodium starch glycolate>crosscarmellose sodium > crosspovidone.

Table.No.6 Results of Wetting time,Water Absorption Ratio and Disintegration time of Levocetirizinedihydrochloride tablets

Formulation Code	Wetting Time	Water Absorption Ratio	Disintegration Time
F_1	46±1.3416	100.00±0.60	34±1.34
F_2	32±1.5275	106.06±0.91	32±1.52
F_3	30±1.1547	109.06±0.03	30±1.15
F_4	44±1.5275	92.20±0.91	44±1.52
F_5	50±1.0000	86.30±0.03	48±1.00
F_6	48±1.3416	97.44±0.26	46±1.34
F_7	24±1.5275	115.00±0.54	24±1.52
F_8	28±1.5275	105.06±0.23	28±1.54
F_9	22±1.5235	119.53±0.31	22±1.53

9.Drug Content Uniformity:

The content uniformity for all nine formulations and result was shown in Table no.7.The mean value and standard deviation of all the formulations was calculated.The drug content of tablets was found to be between 4.775±0.120 mg to 4.912±0.135 mg of Levocetirizine dihydrochloride.And% drug content was found to be between 98.10% to 100.40% of Levocetirizine dihydrochloride tablets.

Table .No.7 Data for Drug Content& % Drug content for LevocetirizineDihydrochloride Tablets

Formulation code	Drug Content (n=3)mg	% Drug Content
F1	4.775±0.120	97.90
F2	4.825±0.011	96.72
F3	4.912±0.135	100.94
F4	4.795±0.160	99.10
F5	4.775±0.130	98.10
F6	4.800±0.110	98.20
F7	4.800±110	98.20
F8	4.875±0.104	99.58
F9	4.900±0.077	99.54

10. *In Vitro* Dissolution Time:

In vitro dissolution studies of all the formulations of Levocetrizine diHydrochloride were carried out in 6.8 pH phosphate buffer . Percentage drug release was calculated at 3, 6, 9 ,12 and 15 minutes. The variation in drug release was due to different types of superdisintegrants in different concentrations in all the formulations. Dissolution study revealed that the almost all the drug released within the 15 minutes from all the formulations.

From the dissolution data it can be observed that Formulation F9 containing CP and CCS showed the highest percentage of drug release (96.36%). This may be due to the higher concentration of superdisintegrants used in the formulation. The formulation batches containing Crospovidone + Croscarmellose sodium showed comparatively higher drug release than the other batches of formulation with corresponding concentrations of superdisintgrants. . The result was tabulated in Table no.8,9&10

***In Vitro* drug release profile of Levocetirizine dihydrochloride tablets**

Table .no.*8* *In vitro* drug release data of Levocetirizine diHCl tablets containing SSG and Crosspovidone:

Formulation code	Time(min)	Absorbance at. 231.5 nm	Conc^n in µg/ml	Cumulative drug release	% Cumulative drug release
F1	3	0.198	6.387	3.194	63.87
	6	0.209	6.742	3.435	68.69
	9	0.216	6.968	3.615	72.30
	12	0.230	7.419	3.911	78.21
	15	0.243	7.839	4.195	83.89
F2	3	0.201	6.484	3.242	64.84
	6	0.219	7.065	3.597	71.94
	9	0.229	7.387	3.829	76.58
	12	0.241	7.774	4.096	81.92
	15	0.255	8.226	4.400	88.00
F3	3	0.205	6.613	3.306	66.12
	6	0.233	7.194	3.663	73.25
	9	0.231	7.452	3.864	77.27
	12	0.247	7.968	4.196	83.92
	15	0.261	8.419	4.502	90.03

Table.no.8 *In vitro* drug release data of Levocetirizine diHCl tablets containing SSG and CSS:

Formulation code	Time(min)	Absorbance at. 231.5 nm	Conc^n in µg/ml	Cumulative drug release	% Cumulative drug release

F4	3 6 9 12 15	0.198 0.209 0.226 0.237 0.251	6.387 6.742 7.290 7.645 8.097	3.194 3.435 3.776 4.027 4.329	63.87 68.69 75.52 80.53 86.58
F5	3 6 9 12 15	0.194 0.203 0.211 0.221 0.226	6.258 6.584 6.806 7.129 7.290	3.129 3.337 3.531 3.761 3.913	62.58 66.73 70.62 75.21 78.25
F6	3 6 9 12 15	0.196 0.205 0.214 0.228 0.235	6.323 6.613 6.903 7.355 7.581	3.161 3.370 3.581 3.876 4.062	63.23 67.39 71.61 77.52 81.25
F7	9 12 15	0.232 0.244 0.262	7.013 7.532 7.922 8.506	3.902 4.172 4.544	78.04 83.44 90.87
F8	3 6 9 12 15	0.207 0.220 0.237 0.254 0.271	6.721 7.143 7.695 8.247 8.799	3.36 3.639 3.986 4.339 4.697	62.21 72.77 79.72 86.77 93.95
F9	3 6 9 12 15	0.210 0.226 0.243 0.261 0.278	6.818 7.338 7.89 8.474 9.026	3.409 3.737 4.086 4.457 4.818	68.18 74.74 81.72 89.14 96.36

Table no.10 *.In vitro* drug release data of Levocetirizine diHCl tablets containing Crosspovidone and CSS:

Formulation code	Time(min)	Absorbance at. 231.5 nm	Conc^{n} in µg/ml	Cumulative drug release	% Cumulative drug release
	3 6	0.203 0.216	6.591	3.295 3.572	65.90 71.44

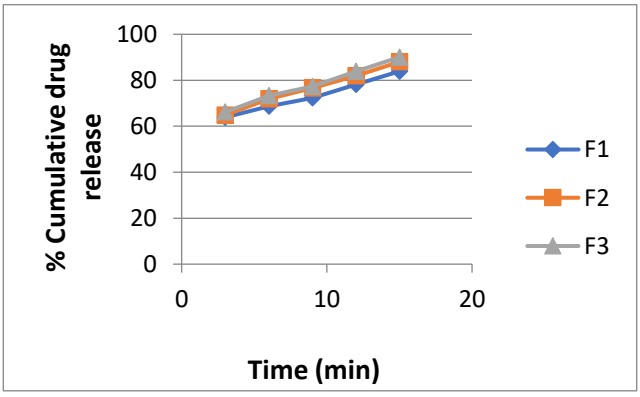


Fig.No.2 *In vitro* drug release data of Levocetirizine diHCl tablets containing SSG and Crosspovidone

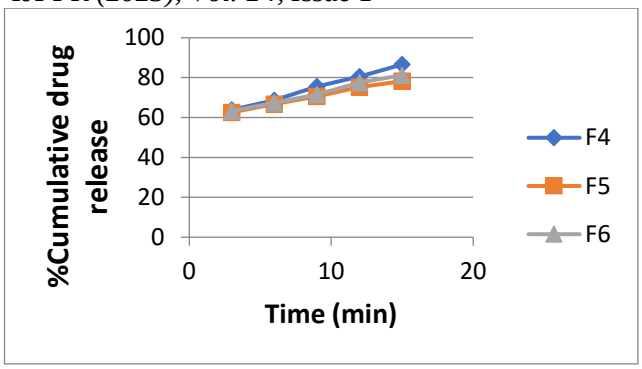


Fig no.14 *In vitro* drug release data of Levocetirizine diHCl tablets containing SSG and CSS

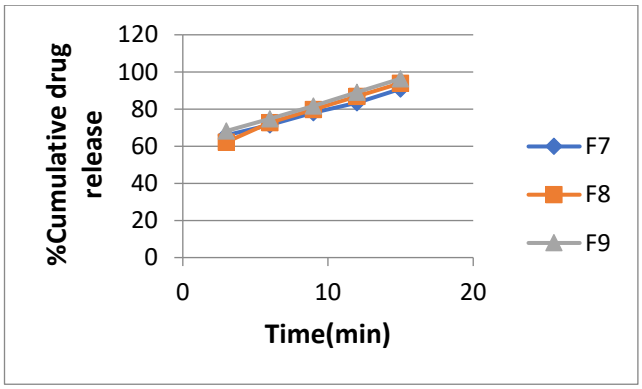


Fig.No.3 *In vitro* drug release data of Levocetirizine diHCl tablets containing Crosspovidone and CCS

RESULT & DISCUSSION

PREFORMULATION STUDIES:

UV Scanning: Preformulation studies were conducted prior to the development of mouth dissolving tablets of Levocetirizinedihydrochloride.It was found that the estimation of o Levocetirizinedihydrochloride by spectrometric method at 231.5 nm as shown in figure no.6 has good reproducibility.

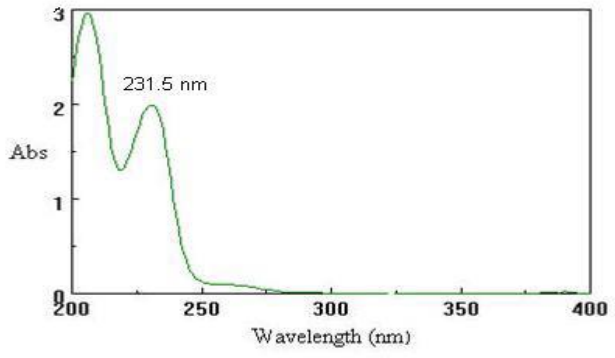


Fig no.4 U.V spectrum of Levocetrizinedihydrochloride

Standard Plot:

The calibration curve of Levocetirizinedihydrochloride also prepared in Sorenson's buffer (pH 6.8). The plot of different concentrations of Levocetirizinedihydrochloride versus absorbance was found to be linear in the concentration range of 8-24 µg/ml(Beer's range) at 231.5 nm. The absorbances at different concentrations were shown in Table no.15. The data of standard curve were linearly regressed. The correlation coefficient value was found to be 0.9996 respectively.

The calculation of drug content and *in vitro* drug release studies based on calibration curve.The calibration curve was shown in Figure.no..

Sr.no.	Concentration (ug/ml)	Absorbance(A^0)
1	0	0
2	4	0
3	8	0
4	1	0
5	1	0
6	2	0
7	2	0

Table No.11 Conc^n And Abs Of LevocetrizineDihydrochloride

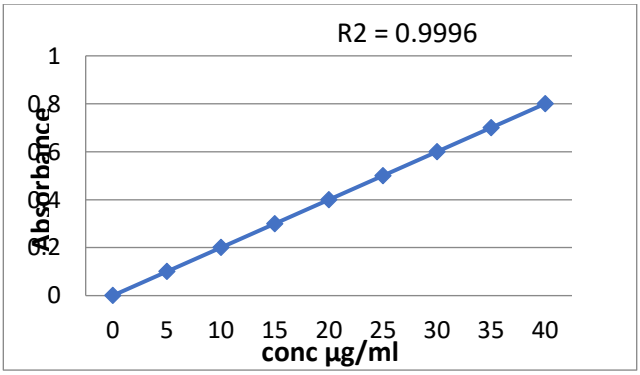


Figure no. 5 .Standard Calibaration Curve of Levocetirizinedihydrochloride

Drug excipient compatability studies:

To study the compatability study of drug with varios polymers and resin ,IR spectra of drug and formulation component were carried out.The IR spectra of drug and excipient were shown in fig..And result was shown in Table.

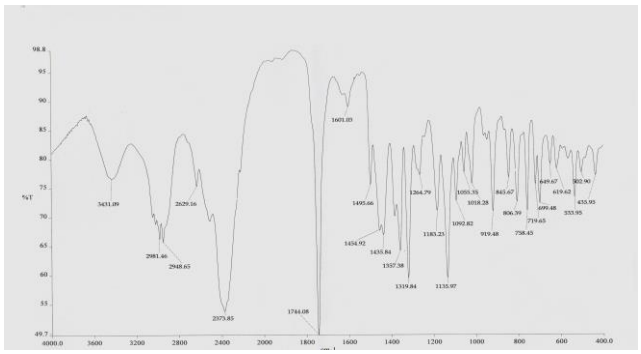


Fig no.6 -FT-IR spectrum of Levocetirizinedihydrochloride

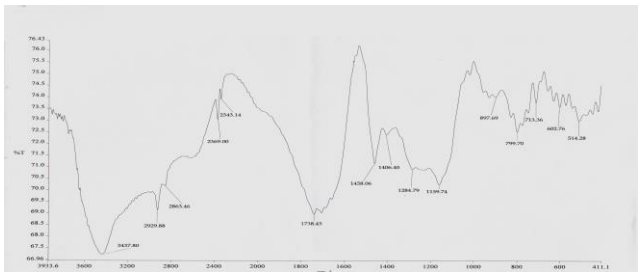


Fig no.7-FT-IR spectra of Resin(kyron T-114)

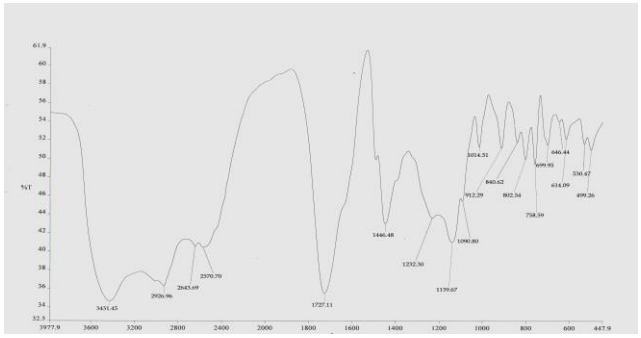


Fig no8- FT-IR spectra of DRC

CHARACTERISTICS FT-IR PEAKS OF LEVOCETIRIZINE DIHYDROCHLORIDE AND RESIN

TAB NO.12 - FT-IR PEAKS OF LEVOCETIRIZINE DIHYDROCHLORIDE

TYPEOF VIBRATION	cm^{-1}
-Cl	705,758, 804
-C-H	2944
-C-N	1359,1390
-COOar	1741
-OH	3373
-CH3	2983

TYPEOF VIBRATION	cm^{-1}
-Cl	758,804, 847
-C-Har	2890
-C-N	1362
-COOar	1742
-C-O	1134

TAB NO. 13- FT-IR PEAKS OF KYRON T-114 AND LEVOCETIRIZINE DIHYDROCHLORIDE

Formulation Design:

Mouth disssolving tablets of Levocetirizine Dihydrochloride were prepared to enhance overall bioavailability by using direct compression method. Total nine formulations were prepared in which the concentrations of the superdisintegrants is varied to evaluate the effect on thedisintegration time of LevocetirizineDihydrochloride mouth dissolving tablets. The composition of nine formulations is given in Table. The tablets prepared with drug and excipients are shown in figure.

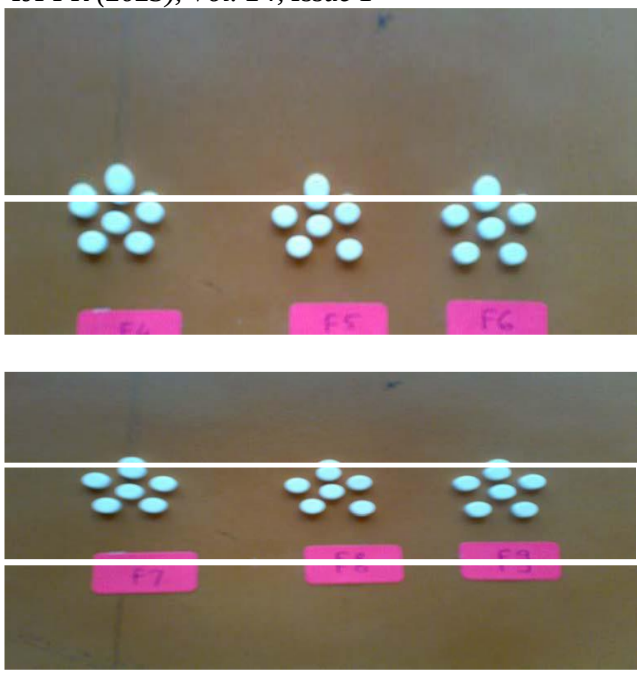


Fig9: Formulation F 1 to F 9

Conclusion

The present was an attempt to formulate and standardize mouth dissolving tablets of an antihistaminic drug Levocetirizine Dihydrochloride. Prepared tablets were evaluated for Pre-compression Parameters and Post compression parameters. Flow properties – Angle of repose, loose bulk density, tapped density and also % Carr's compressibility was determined to all the formulations which showed good flow property. The shape and color of all formulations were found to be circular and white in color. The thickness found uniform in all the formulations. Amongst all the developed formulations, Levocetirizine Dihydrochloride mouth dissolving tablets formulated by using crosscarmellose sodium and crosspovidone as superdisintegrants, having hardness (2.5Kg/cm2), Friability (0.38%), Drug Content (4.900±0.077 mg). and it is fulfilling all the parameters. It has shown good in vitro disintegration time (22 sec), compared to other superdisintegrants. Water absorption ratio showed good absorptivity in all formulations. Hardness and friability of all the formulations indicated tablets were mechanically stable and percentage weight variation and drug content uniformity found within limits. Based on the results, formulation containing 5% crosspovidone and 3% crosscarmellosesodium (F9) was identified as ideal and better formulation. *In vitro* release of optimized formulation (F9) was found to be 96.36%drug release within 15 min. The final optimized formulation (F9) was compared with marketed product of Levocetirizine dihydrochloride tablet (Xyzal) which shows 95.37% drug release in 24 min. From this observation it was concluded that the formulation tablet of Levocetirizine dihydrochloride (F9) were superior and effective in achieving patient compliance.

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