



FORMULATION AND CHARACTERIZATION OF SUGAR FREE FAST DISSOLVING ANTIALLERGIC TABLET

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Abstract: Allergic disorders are most common worldwide. It also affects the quality of life. Due to these reasons, there is a requirement to develop rapid action producing formulation to treat these allergic conditions.

Purpose- The Purpose of the study was Formulation and characterization of sugar free fast dissolving anti allergic tablet.

Method- Formulation was done by using direct compression method with the aid of Super disintegrants addition. Twelve formulations were developed using three different super disintegrants in varying concentrations in such a way that total weight of the tablet remains the same.

Results- Based on the results, formulation (PF-9) containing 2% Ac di sol and 5% Polyplasdone XL-10 was identified as ideal and best formulation among all formulations. In vitro release of optimized formulation (PF-9) was found to be 98.80% and drug release within 10 min and *in vitro* dispersion time was found to be 25sec.

Conclusion- Levocetirizine Dihydrochloride was successfully formulated by direct compression method the tablets were evaluated for Pre-compression parameters. As a result, this introduced the good flow and compressibility property of the bulk powder. Post compression parameters such as Physical parameter and chemical parameter was performed on punched tablets and found all the parameters within limit specified by Indian Pharmacopoeia.

Keywords: Levocetirizine dihydrochloride, Direct compression, superdisintegrant, *INVITRO* dissolution, anti allergic tablet, Formulations.

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Introduction: The Conventional dosage form establishes drug administration systems. The most commonly used and conventional route is the oral route of drug administrations. Comparison to other dosage form these oral dosage forms are easy for self administration and most commonly used and having low cost.¹

On the other hand these dosage form related with some drawbacks such as dysphagia i.e. difficulty in swallowing, low bioavailability and late onset of action. In order to overcome these problems, researchers have long explored the "oral cavity" to control its drawback to enhance the drug's permeability as well as bioavailability. The "oral cavity" has a good permeability because of mucosal lining being relatively less keratinized in the buccal mucosa.²

Drug administrations via oral route have more acceptances up to 50-60% of total dosage forms. Because of the easy administration, exact dosage, self-medication, and pain avoidance these Solid dosage forms are popular. And most importantly these solid dosage form are also popular due to the patient compliance. Tablets and capsules are the most popular solid dosage forms. Although these dosage form having some important drawback i.e. the difficulty to swallow. For swallowing of these oral dosage forms Drinking water plays an important role. Most of the times people occurrence the inconvenience for swallowing these conventional dosage forms such as tablet when water is not available specially in the case of motion sickness (kinetosis), allergic condition, sudden episodes of coughing during the common cold, and bronchitis. For these reason, for overcome these problem researcher explore the tablets that can rapidly dissolve or disintegrate in the oral cavity. These dispersible tablets are ideal not only for people who have swallowing difficulties, but also ideal for the active people.³ Fast dissolving tablets are also called as quick dissolving ,mouth-dissolving tablets, Or dispersible tablets, rapimelts, porous tablets, melt-in mouth tablets, etc. when put on tongue these Fast dissolving tablets disintegrate directly and releasing the drug which dissolve or disperses in the saliva.⁴The faster the drug into solution, quicker the absorption and onset of clinical effect. Most of the drugs are absorbed from the mouth then pharynx and esophagus as the saliva passes down into the

stomach. Bioavailability of drug which is obtained from conventional tablet dosage form is lesser than the bioavailability observed from these dosage form.

The advantage of fast dissolving dosage forms are progressively more being recognized in both, industry and academics.⁵ Their rising importance was underlined newly when European pharmacopoeia adopted the term "Or dispersible tablet" as a tablet that to be placed in the mouth where it disperses rapidly before swallowing and According to the European pharmacopoeia, the FDT should disperse/disintegrate in less than three minutes. The basic which is important in development of FDT is the use of superdisintegrants like cross linked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrrolidone (polyplasdone) etc, which provide rapidly disintegration of tablet after putting on tongue and release the drug in saliva.⁶ due to absorption of drug in oral cavity and also due to pregastric absorption of saliva which having dispersed drugs that pass down into the stomach, The bioavailability of some drugs may be increased. More ever, as compared to standard tablet, the amount of drug that is introduced to first pass metabolism is reduced. For the manufacturing of fast dissolving tablets some of the technologies have been used i.e freeze-drying, spray-drying, tablet molding, sublimation, sugar-based excipients, tablet compression, and disintegration addition. As a result of increased life expectancy, the elderly constitute a large portion of the worldwide population today. These people ultimately practice deterioration of their physiological and physical abilities.⁷ (levocetirizinehydrochloride)2-[4-[(R)-(4-Chloro phenyl)phenylmethyl]-1piperazinyl]ethoxy] acetic acid hydrochloride, is a third-generation non-sedative antihistamine which is developed from the second-generation antihistamine cetirizine. levocetirizine is the active enantiomer of cetirizine.⁸ It is the L-enantiomer of the cetirizine racemate. Levocetirizine Is

completely absorbed and extensively metabolized to its pharmacologically active enantiomer. The drug having half-life of 6-10 h. Levocetirizine works by preventing its binding to the receptor by blocking histamine receptors. It does not prevent the actual release of histamine from mast cells. As like that it provides aid from the typical symptoms of hay fever by preventing the release of other allergic chemicals and increased blood supply to the area. Allergic patients have sudden emergency of dosage regimen, MDTs will avoid missing out of dose even during traveling or other situations where there is no access to water.⁹

Materials and Methods

Materials: Levocetirizine dihydrochloride and all ingredients were supplied by Shri Ram Murti Smarak College of Engineering & Technology, Bareilly (U.P).

Method: Levocetirizine dihydrochloride is prepared by direct compression Method. The Levocetirizine dihydrochloride tablets are available in 5mg-10mg doses in the market. Dose of 5 mg is selected for the present study. Development of the formulation was mainly

based on the type and concentration of Superdisintegrant and the properties of the drug. Various polymers in different concentrations (2 to 7%, 2 to 5% and 2 to 3.5%) were used so as to get tablets with good physical properties.

Preparation of Levocetirizine dihydrochloride fast dissolving Tablets

Fast dissolving tablets of Levocetirizine dihydrochloride were prepared in Twelve formulations i.e. PF1 to PF12 via using the ingredients mention in the Table. Each tablet containing 5mg of Levocetirizine dihydrochloride. Superdisintegrant like Primogel, Polyplasdone XL-10 and Ac di sol were used in different ratios. All the ingredients with drug except Lubricant i.e. Magnesium stearate were taken in the mortar. by using mortar and pestle The powder blend was then mixed well for 15 to 30 minutes, and then each mixture was passed through sieve no 80. Finally Magnesium stearate was added as a lubricant and mixed thoroughly. The powder blend was compressed using 12 stations tablet compression machine equipped with 8mm punch.^{10,11,12}

Table 1: Composition of fast Dissolving tablet of Levocetirizine dihydrochloride

Sr.No	Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	Levocetirizine diHydrochloride	5	5	5	5	5	5	5	5	5	5	5	5
2	Primogel	14	14	4	4	14	14	4	4	-	-	-	-
3	Polyplasdone XL-10	10	4	10	4	-	-	-	-	10	10	4	4
4	Ac di sol	-	-	-	-	7	4	7	4	7	4	7	4
5	Mannitol	20	20	20	20	20	20	20	20	20	20	20	20
6	Microcrystalline cellulose 102	133	139	143	149	136	139	146	149	140	143	146	149
7	Sucralose	1	1	1	1	1	1	1	1	1	1	1	1
8	Aspartame	10	10	10	10	10	10	10	10	10	10	10	10
9	Flavour (Orange)	4	4	4	4	4	4	4	4	4	4	4	4
10	Aerosil	2	2	2	2	2	2	2	2	2	2	2	2
11	Mgnessium Stearate	1	1	1	1	1	1	1	1	1	1	1	1

Preformulation Studies

• **Identification of drug: Determination of melting point:** Melting point of pure Levocetirizine dihydrochloride was determined by open capillary method. The capillary tube was closed at one end by fusion and was filled with Levocetirizine dihydrochloride by repeated tapings. The capillary tube was placed in a digital melting point apparatus. The instrument was set to automatically increase the temperature of the heating bath at a rate of 100°C min rise of temperature per minute. The rise in temperature was viewed through magnifying lens. The temperature at which the drug started melting was recorded. This was performed thrice and the average value was calculated.

Determination of λ_{max} : For the Determination of λ_{max} ultraviolet Spectrophotometer is used. For this, A solution of Levocetirizine dihydrochloride containing conc. 10µg/ml was prepared in phosphate buffer pH 6.8. after that UV spectrum was taken using UV spectrophotometer (Shimadzu-1800). This solution was scanned in the range of 200-400nm.

Identification of Drug by FTIR: Identification of drug was done by FTIR (Agilent tech.) by taking the spectra of pure drug by Infra Red spectrophotometer and interpreting the peaks of the spectra.

Procedure- Triturates about 1-2 mg of drug with approximately 300-400 mg of fine dried powder of potassium bromide. with the help of hydraulic press Pellet was made and confirmed for thin and transparentness. Mount the pellet on the die holder in spectrophotometer with the help of tweezer and infrared spectrum was recorded over the range from 4000 cm^{-1} to 400 cm^{-1} .¹³

• **Standard calibration curve of Levocetirizine dihydrochloride:** Calibration of Levocetirizine dihydrochloride was done in phosphate buffer solution in pH 6.8 at λ_{max} 229.51.

Procedure for Calibration of Levocetirizine

dihydrochloride in phosphate buffer (pH6.8)

solution: From stock solution, suitable aliquots were pipetted into different volumetric flasks and volumes were made up to 10 ml with phosphate buffer (pH 6.8) solution, so as to get drug concentrations of 2, 4, 6, 8, 10, 12,14, 16, 18, 20 µg/ml. after that Absorbance was taken using UV spectrophotometer (Shimadzu-1800). The data are given in the Table and calibration curve constructed is shown in the Figure.^{14,15,16}

➤ Determination of Powder characteristics

• **Angle of Repose:** For the determination of Angle of repose funnel method was used. The blend was poured through funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose was calculated using the formula i.e.

$$\tan \theta = h/r$$

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

Where, θ is the angle of repose

h is height of pile

r is radius of the base of pile.

Table 2: Relationship between Angle of Repose and flow properties

Angle of repose (θ) (degrees)	Type of flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

• **Bulk Density:** Apparent bulk density (Db) was determined by pouring the blend, which is previously lightly shaken to break any agglomerates formed, into a graduated cylinder. The bulk volume (Vb) and weight of powder (M) was determined. The bulk density was calculated using the formula

$$\text{Bulk Density} = \frac{\text{Weight of the powder}}{\text{volume of the packing}}$$

• **Tapped Density:**

The measuring cylinder containing known mass of blend was tapped for a fixed time. The minimum volume (Vt) occupied in the cylinder and weight (M) of the blend was measured. The

tapped density (Dt) was calculated using the following formula

Total Bulk Density = weight of the powder / tapped volume of the packing

• **Hausner Ratio:**

Hausner ratio is an indirect index of ease of powder flow. It indicated the flow properties of the powder. And It is calculated by the following formula.

Hausner ratio= Tapped density/ Bulk density

Lower Hausner ratio (< 1.25) indicates better flow properties than higher ones (>1.25).

• **Carr's Compressibility Index:**

The simplest way of measurement of free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow is given by compressibility. The compressibility index of the granules was determined by Carr's compressibility index, which is calculated by using the following formula.¹⁷

$$\text{Carr's index (\%)} = \frac{(\text{TBD} - \text{LBD}) \times 100}{\text{TBD}}$$

Table 3: Scale of flow properties

Sr. no.	Carr's index	Hausner's ratio	Flow properties
1.	5-15	1.05 - 1.18	Excellent
2	12-16	1.14 – 1.20	Good
3	18-21	1.22 – 1.26	Fair – passable
4	23-35	1.3.-1.54	Poor
5	33-38	1.50-1.61	Very poor
6	>40	>1.67	Very, very poor

➤ **Characterization of The Tablets:**

• **Physical Parameter**

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 ($\pm 7.5\%$). The total weight of tablets formulated was 200mg.

Table 4: The percentage deviation for weight uniformity of tablets as per IP limits

Average Weight of Tablet	Percentage Deviation
80mg or less	± 10
More than 80 mg and less than 250 mg	± 7.5
250 mg or more	± 5

Any variation in the weight of tablet (for any reason) leads to either under medication or over medication. So, every tablet in each batch should have a uniform weight. Deviation within the IP permissible limit of 7.5% is allowed as the tablet weighs 200 mg.^{18,19}

Uniformity in thickness: The crown thickness of individual tablet may be measured with a **vernier calliper**, which permits accurate measurements and provides information on the variation between tablets. Other technique employed in production control involves placing 5 or 10 tablets in a holding tray, where their total crown thickness may be measured with a sliding caliper scale. The tablet thickness was measured using screw gauge.

Hardness test: Tablets require a certain amount of strength, or hardness and resistance to friability, to withstand mechanical shocks of handling in manufacture, packaging and shipping. The hardness of the tablets was determined using **Monsanto Hardness tester**. It is expressed in Kg/cm². Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

Friability test: It is the phenomenon whereby tablet surfaces are damaged and/or show evidence of lamination or breakage when subjected to mechanical shock or attrition. The friability of tablets was determined by using **Roche friabilator**. It is expressed in percentage

(%). Four tablets were initially weighed (W initial) and transferred into friabilator. The friabilator was operated at 25 rpm for 4 minutes or run up to 100 revolutions. The tablets were weighed again (W final). The percentage friability was then calculated by,

$$F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

% Friability of the tablets less than 1% is considered acceptable.

• Chemical Parameter

Wetting time: The method was applied to measure tablet wetting time. A piece of tissue paper folded twice was placed in a small petridish (i.d. = 6.5 cm) containing 10 ml of water, a tablet was placed on the paper, and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined.

Water absorption ratio: A piece of tissue paper folded twice was placed in a small petridish containing 6ml of water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using following equation.

$$R = \frac{100 (W_a - W_b)}{W_b}$$

Where, W_b = weight of tablet before absorption

W_a = weight of tablet after absorption Three tablets from each formulation were performed and standard deviation was also determined.²⁰

In vitro dispersion Time: *In vitro* dispersion time was measured by dropping a tablet into a petridish containing 10 ml of phosphate buffer pH 6.8 solution (simulated saliva fluid). Three tablets from each formulation were randomly selected and tested. *In vitro* dispersion time was found and expressed in seconds.²¹

Drug content determination:

Procedure for determining drug content: Three uncoated tablets were selected randomly and average weight was calculated. Tablets were crushed in a mortar and accurately weighed amount of tablet powder was taken from the crushed blend. Then the samples were transferred to three 100 ml volumetric flasks

and were diluted up to the mark with phosphate buffer (pH 6.8) solution. The contents were shaken periodically and kept for 24 hours for solvation of drug completely. The mixtures were filtered, appropriately diluted, and absorbences were measured at λ_{max} 229.51 nm against blank reference. The drug content in each tablet was calculated using the standard calibration curve of Levocetirizine dihydrochloride in phosphate buffer pH 6.8 solution.

In vitro drug release

Procedure for determining In vitro drug release studies: *In vitro* drug release of the samples was carried out using USP – type II dissolution apparatus (paddle type). The dissolution medium, 900 ml of phosphate buffer (pH 6.8) solution, was placed into the dissolution flask maintaining the temperature of $37 \pm 0.5^\circ\text{C}$ and rpm of 50. One tablet was placed in each flask of dissolution apparatus. The apparatus was allowed to run for 10 min. Samples measuring 5 ml were withdrawn after every 2,4,6,8,10,12 min. Samples were filtered through 10 μm filter. The fresh dissolution medium was replaced every time to maintain sink condition. The collected samples were analyzed at 229.51 nm using dissolution medium as blank. The cumulative percentage drug release was calculated.²²

Table 5: The following procedure was employed throughout the study to determine the *in vitro* dissolution rate for all the formulations.

PARAMETERS	CONDITIONS
Dissolution medium	900 ml of (pH 6.8) phosphate buffer solution
Temperature	$37 \pm 0.5^\circ\text{C}$
RPM	50 rpm
Tablet taken	One tablet (known drug content)
Volume withdrawn	5ml every 2 min
λ_{max}	229.51nm
Beer's range	2-16 $\mu\text{g/ml}$
Time duration of the study	12 minutes

Result and Discussion: Preformulation studies

Determination of melting point: The melting point of Levocetirizine diHCl was found to be in the range of $215 \pm 220^\circ\text{C}$.

Determination of λ_{max} : Wavelength of maximum absorption of Levocetirizine diHCl in phosphate buffer pH 6.8.

SR. No.	Solvent	λ_{max}
1	Phosphate buffer pH 6.8	229.51

Data for Standard calibration curve

Table 6: Data for calibration curve of Levocetirizine di HCl at 229.51 nm

SR. No.	Concentration ($\mu\text{g/ml}$)	Absorbance at 229.51 nm
1	2	0.074
2	4	0.145
3	6	0.214
4	8	0.291
5	10	0.364

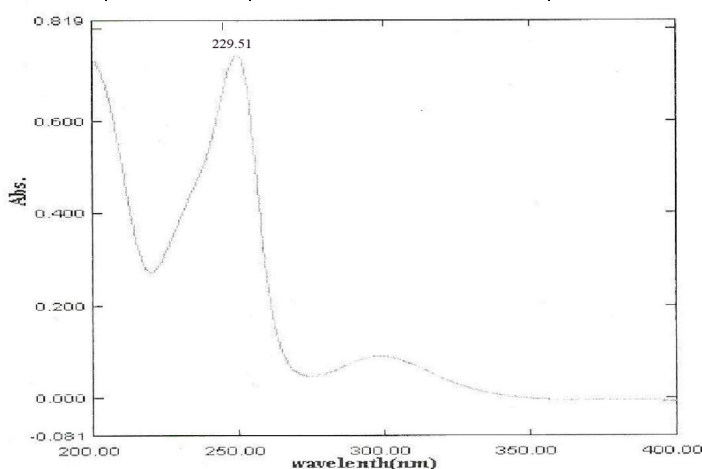


Figure 1: UV spectra of Levocetirizine di HCl in phosphate buffer pH 6.8

Identification of Drug by FTIR

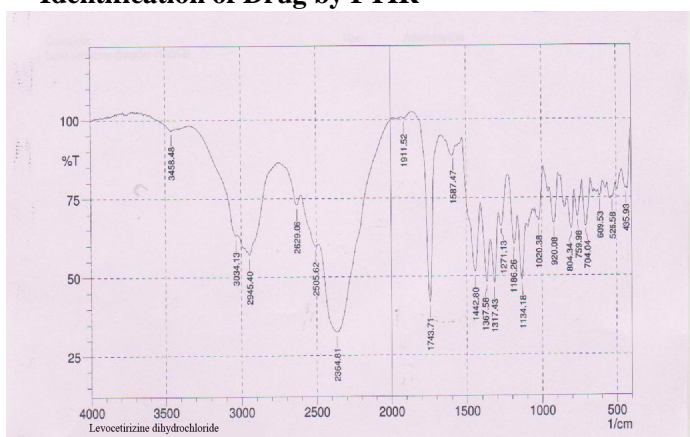


Figure 2: IR spectra of Levocetirizine diHCl

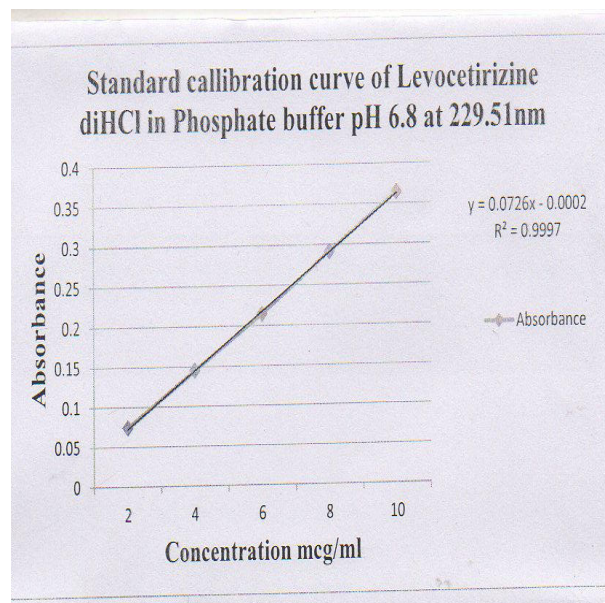


Figure 3: Standard calibration curve of Levocetirizine di HCl in phosphate buffer pH at 229.51nm

Table 7: Results of Powder characteristics

Drug/Superdisintegrant	Bulk density (g/cc)	Tapped density(g/cc)	Angle of repose	Carr'Index	Hausner Ratio
Levocetirizine di HCl	0.53	0.43	22° 70	19.53	1.26
Primogel	0.52	0.41	24° 22	18.32	1.25
Ac-di-sol	0.50	0.44	23° 65	16.65	1.17
PolyplasdoneXL-10	0.54	0.43	20° 58	19.21	1.24

Table 8: Results of formulated tablet (Levocetirizine diHCl) Batches

Formulation Code	Angle of Repose(Θ)	Bulk Density(g/cc)	Tapped Density(g/cc)	Carr's Index	Haunser Ratio
PF1	21.44±0.201	0.65±0.004	0.723±0.002	10.21±0.01	1.10±0.001
PF2	20.54±0.475	0.65±0.002	0.734±0.001	11.55±0.05	1.12±0.001
PF3	21.31±0.560	0.64±0.001	0.724±0.001	10.33±0.04	1.10±0.002
PF4	22.28±0.205	0.64±0.002	0.733±0.007	12.79±0.06	1.13±0.002
PF5	21.42±0.108	0.65±0.004	0.731±0.005	11.21±0.06	1.10±0.001
PF6	20.81±0.116	0.64±0.004	0.721±0.006	11.34±0.01	1.10±0.002
PF7	20.44±0.221	0.65±0.004	0.733±0.006	11.43±0.01	1.11±0.004
PF8	21.44±0.475	0.65±0.002	0.733±0.001	12.81±0.21	1.13±0.004
PF9	20.66±0.501	0.64±0.001	0.731±0.004	11.21±0.06	1.11±0.003
PF10	20.83±0.781	0.64±0.001	0.733±0.001	12.79±0.01	1.13±0.003
PF11	21.24±0.542	0.65±0.004	0.721±0.004	9.95±0.01	1.10±0.004
PF12	21.26±0.471	0.64±0.001	0.733±0.004	11.42±0.07	1.11±0.001

*Value expressed as mean±SD, n=3

Result of characterization of Levocetirizine dihydrochloride Tablets (Post compression parameter)

Physical parameter**Table 9: Physical Parameter of Formulated Batch**

Formulation	*Thickness	*Hardness	Friability	Weight
Code	(mm)	(kg/cm ²)	(%)	Variation
PF1	2.495±0.03	3.13±0.24	0.233±0.06	199.09±0.20
PF2	2.486±0.03	3.68±0.24	0.295±0.06	201.08±0.32
PF3	2.482±0.03	3.11±0.26	0.347±0.03	200.17±0.21
PF4	2.475±0.03	3.19±0.26	0.377±0.03	200.32±0.74
PF5	2.442±0.02	3.46±0.26	0.335±0.11	198.81±0.32
PF6	2.435±0.01	3.50±0.24	0.375±0.03	199.32±0.11
PF7	2.435±0.02	3.11±0.26	0.334±0.11	198.59±0.26
PF8	2.451±0.02	3.19±0.24	0.226±0.01	201.42±0.70
PF9	2.452±0.01	3.49±0.26	0.307±0.03	200.66±1.25
PF10	2.447±0.01	3.33±0.24	0.337±0.05	198.25±0.19
PF11	2.458±0.01	3.60±0.24	0.320±0.01	199.33±0.46
PF12	2.462±0.01	3.21±0.24	0.309±0.05	199.65±1.25

*Value expressed as mean±SD, n=3

Chemical parameter**Table 10. Results of Chemical Parameter of Formulated Batch**

FORMULATION CODE	In Vitro dispersion time(Sec)	Wetting time (Sec)	Water absorption ratio	% Drug content
PF1	92±1.5274	105±1.5	108.05±0.60	99.20±0.38
PF2	99±1.5274	109±0.52	100.59±0.90	98.82±0.41
PF3	118±1.5274	131.1.62	96.37±0.48	97.52±0.40
PF4	127±1.3414	141±1.44	87.43±0.90	98.39±0.44
PF5	53±1.000	69±0.51	97.19±0.02	100.60±0.41
PF6	59±1.5274	62±1.79	91.11±0.25	98.31±0.36
PF7	64±1.5274	69±1.69	90.06±0.85	99.00±0.24
PF8	70±1.5274	79±0.81	84.63±0.12	97.55±0.86
PF9	25±1.1546	28±1.57	117.52±0.30	99.16±0.37
PF10	35±1.5274	37±1.57	114.00±0.22	98.38±0.54
PF11	39±1.5274	52±1.56	106.00±0.53	99.51±0.42
PF12	47±1.5274	58±1.56	98.25±0.02	98.15±0.43

Value expressed as mean±SD, n=3

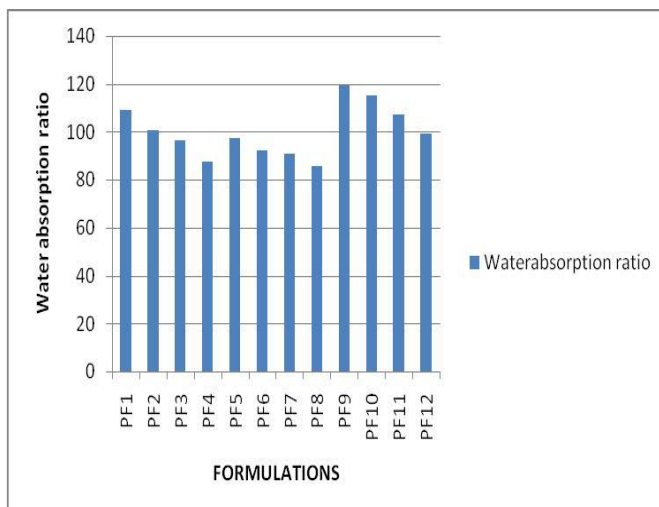


Figure 4: Water absorption ratio of Levocetirizine diHCl tablets

***In vitro* drug release profile of Levocetirizine diHCl tablets**

Table 11: *In vitro* drug release data of Levocetirizine diHCl tablets contains Primogel and Polyplasdone XL-10

SR NO	Time (mins)	%Cumulative drug release			
		PF1	PF2	PF3	PF4
1	0	0	0	0	0
2	2	48.22±0.64	38.86±0.21	41.66±0.95	37.27±0.86
3	4	65.44±1.11	56.86±1.11	61.11±0.53	49.31±1.14
4	6	76.31±1.22	68.39±1.22	70.53±0.42	60.21±0.36
5	8	87.41±0.75	76.64±0.75	80.77±0.53	71.72±0.61
6	10	97.01±0.40	88.50±0.32	91.74±0.31	80.26±0.20

Table 12: *In vitro* drug release data of Levocetirizine di HCl tablets containing Primogel and Ac-di-sol.

SR NO	Time (mins)	% cumulative drug release			
		PF5	PF6	PF7	PF8
1	0	0	0	0	0
2	2	48.85±0.44	42.66±0.95	39.16±0.21	38.27±0.86
3	4	64.44±1.11	62.11±0.53	56.86±1.11	47.21±0.36
4	6	74.31±1.2	71.53±0.42	68.39±1.22	50.21±0.36
5	8	86.41±0.75	81.77±0.53	76.64±0.75	73.72±0.61
6	10	98.61±0.20	92.14±0.43	89.50±0.32	83.29±0.41

Table 13: *In vitro* drug release data of Levocetirizine di HCl tablets containing Polyplasdone and Ac-di-sol.

S.R	Time	% cumulative drug release			
NO	(mins)	PF9	PF10	PF11	PF12
1	0	0	0	0	0
2	2	48.860±.0	44.75±0.11	46.71±0.12	37.15±0.86
3	4	63.120±.61	55.86±0.17	59.97±0.54	49.31±1.14
4	6	80.42±0.90	72.49±1.31	75.64±0.32	62.21±0.36
5	8	89.91±0.46	84.91±1.11	89.63±0.65	75.72±0.61
6	10	98.80±0.01	94.00±0.37	94.00±0.38	86.74±0.41

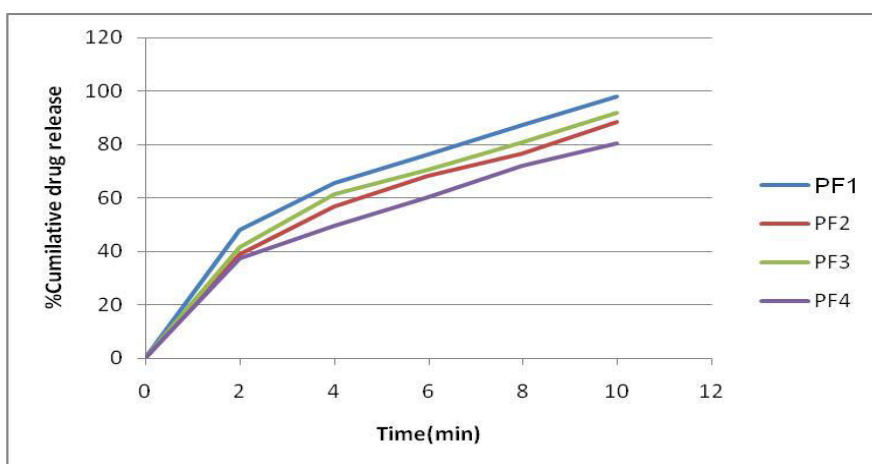


Figure 5: *In vitro* drug release profile of Levocetirizine di HCl tablets containing primogel and Polyplasdone XL-10

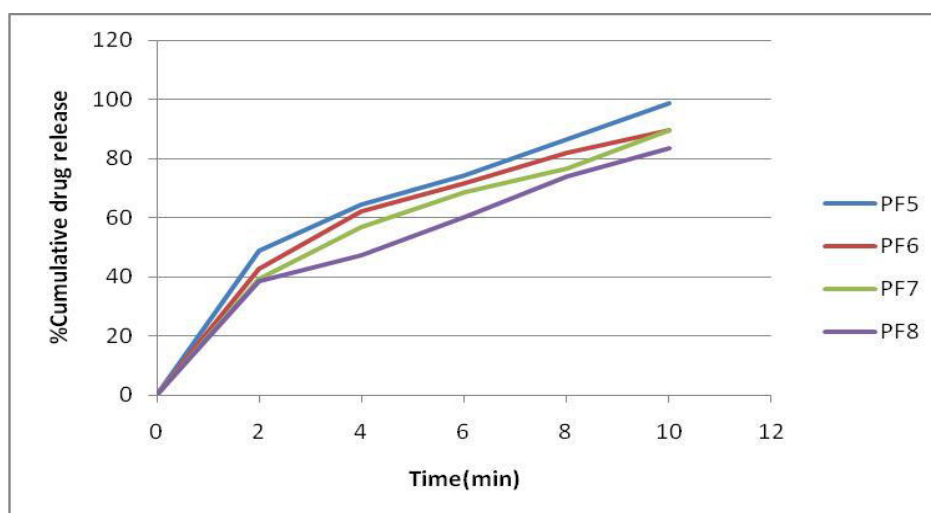


Figure6: *In vitro* drug release profile of Levocetirizine di HCl tablets containing Primogel and Ac di sol.

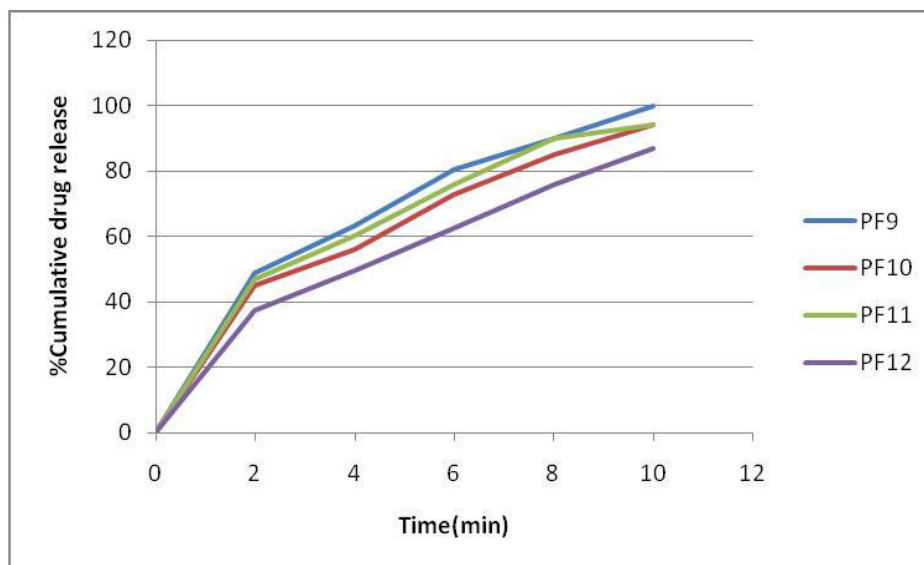


Figure 7: *In vitro* drug release profile of Levocetirizine di HCl tablets containing Polypladone XL-10 and Ac di sol.

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References:

1. Bhowmik D, Fast Dissolving Tablet: An Overview. *Chemical and Pharma. Research.*, 2009, 1(1):163-17.
2. Kumari S, Visht S, Sharma PK, Yadav RK, Fast dissolving Drug delivery system: Review Article. *J. Pharmacy Research.* 2010, 3(6): 1444-1449.
3. Lailla JK, Sharma AH, Freeze-drying and its applications. *Indian Drugs.*, 1993, 31: 503-513.
4. Seager H, Drug delivery products and zydis fast dissolving dosage form. *J. Pharm. Pharmacol.*, 1998, 50: 375-382.
5. Renon JP, Corveleyn S, Freeze-dried rapidly disintegrating tablets. US Patent No.6,010,719, 2000.
6. Masaki K, Intrabuccaly disintegrating preparation and production. US Patent No.5, 466,464, 1995.

7. Pebley WS, Jager NE, Thompson SJ, Rapidly disintegrating tablets. US Patent No.5, 298,261, 1994.
8. Shukla D, Chakraborty S, Singh S, Mishra B, An Overview of Formulation Technology of mouth dissolving tablets. *Sci Pharm.*, 2009, 309-26.
9. Dobbetti L, Fast melting tablets Development and technology. *Pharm Tech Drug Delivery.*, 2001, 44-50
10. Udupa N, Venkatesh, Mutalik S, Venugopal K, Nimesulide dispersible tablets from direct Compression method. *Ind Drugs.*, 2001, 38(4): 208-10.
11. Kuchekar BS, Badhan AC, Mahajan HS, Mouth dissolving tablets of salbutamol sulphate: A novel drug delivery system. *Ind Drugs.*, 2004, 41(10): 592-8.
12. Ugimoto M, Matsubara K, Koida Y, Kobayashi M, The preparation and evaluation of rapidly disintegrating tablets in the mouth. *Pharm Dev Tech.*, 2001, 6(4): 487-93
13. ICH topic 8 Pharmaceutical guidelines, Note for Guidance on Pharmaceutical Developments, (EMA/CHMP167068/2004).
14. Nandgude TD, Bhise KS, Shinday BN,

- Sharma DK, Mouth dissolving tablets: geriatrics and paediatrics friendly drug delivery system. *Ind Drugs.*, 2007, 4: 271-2.
15. United states Pharmacopoeia, Asian Edition. Convention Inc.
16. British Pharmacopoeia, London: Her Majesty's Stationary Office, 2003.
17. Marshall K, Lachman N, Lieberman HA, The theory and practice of industrial pharmacy, 3rd edi., Varghese Publishing House., Mumbai, 1987, 66-69.
18. Lachmann L, Liebermann HA, Kiang JL, The theory and practice of Industrial Pharmacy, 3rd edi., Varghese Publishing House., Bombay, 1998, 430-440.
19. Kaushik D, Dureja H, Saini TR, Mouth Dissolving Tablets: A review. *Indian Drugs.*, 2004, 41(4): 187-193.
20. Swamy PV, Orodispersible tablets of Carbamazepine prepared by direct compression method using 32 full factorial design. *J. Pharm Sci.*, 2008, 7 (1): 1-5.
21. Udupa N, Venkatesh, Mutalik S, Venugopal K, Nimesulide dispersible tablets from direct compression method. *Ind drugs*, 2001, 38(4): 208-210.
22. The United state pharmacopoeia. Vol 24; Asianed. Rockville, MD: United state pharmacopoeial convention Inc; 2000, 1941-3.