WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.421
Volume 8, Issue 4, 1352-1370 Research Article ISSN 2278 – 4357

# FORMULATION AND EVALUATION OF ORAL DISPERSIBLE TABLETS OF LORATADINE BY DIRECT COMPRESSION METHOD

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Article Received on
18 Feb. 2019,

Revised on 10 March 2019,
Accepted on 31 March 2019,

DOI: 10.20959/wjpps20194-13395

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## ABSTRACT

New era is an era of novel drug delivery system. Formulation research is oriented towards increasing safety and efficacy of existing drug molecule through novel concept of drug delivery. Oral dispersible tablet (ODT) has become one of the most widely employed commercial products. Among the various drugs that have potentiality to be formulated in ODT forms, Loratadine is one of them which at present widely applied on the formulation of ODT dosage forms. It is the second generation anti-histamine drug that is widely used in the treatment of rhinitis, hay fever and other various allergic conditions like utricaria and contact dermatitis. It forms the part of initial therapy for allergic reactions. In the present work an attempt has been made to formulate, develop and evaluate oral dispersible tablet of Loratadine by using direct compression method with various superdisintegrants like sodium starch glycolate, crosscarmellose and crosspovidone, all in different ratios with various tablet ingredients. A total 9 batch (3 batches using each superdisintegrants) were prepared and evaluated for general appearance, physical parameters, drug content and drug release. Along with this, an attempt was made to develop and validate spectrophotometric method for analysis of Loratadine. Formulation (F6) prepared by using crosspovidone in various ratios emerged as the best formulation showed rapid in-vitro disintegration time and drug release by dissolution. Finally it was concluded that oral dispersible tablet of Loratadine can be successfully formulated and will be used as a novel drug dosage form for pediatric and geriatric with improved patient compliance and enhanced bioavailability.

**KEYWORDS:** Oral Dispersible Tablet, Loratadine, Anti-histamine, Superdisintegrants, Bioavailability.

## 1. INTRODUCTION

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered as the most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance and cost effective manufacturing process.[1] Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. Orally disintegrating tablets (ODTS) are a new generation of formulations which combine the advantages of both liquid and conventional tablet formulations, and at the same time, offer added advantages over both the traditional dosage forms. This may be defined as uncoated tablets intended to be placed in the mouth where they disperse readily within 3 minutes before swallowing.[2]

According the US Food and Drug Administration's Center for Drug Evaluation and Research, Orally Disintegrating Tablet (ODT) is "A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.[3] Recently European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" and defined as uncoated tablets intended to be placed in the mouth where they disperse rapidly before being swallowed". Orally disintegrating tablets are synonyms with quick dissolving tablet, mouth dispersible tablet, melt in mouth tablet, rapid melt, porous tablet or rapidly disintegrating tablet.[4] When such tablets are placed in the oral cavity, saliva quickly penetrates into the pores to cause rapid tablet disintegration.[5]

Loratadine, a piperidine derivative related to azatadine, is a long-acting, non-sedating antihistamine with no significant antimuscarinic activity. It is used for the symptomatic relief of allergic conditions such as runny nose, itchy or watery eyes, sneezing, and nasal or throat itching and chronic urticaria.[6] They lack anti-cholinergic side effect and having non-sedating property because they do not cross the blood brain barrier.[7] Loratadine is well absorbed following oral administration with the peak plasma concentration usually attained in 1 hour. Antihistaminic effects occur within 1 hour and persist for at least 24 hours.[8,9,10] Hence, for an antihistamine drug like Loratadine, a quick disintegrating dosage form will be suitable, since the disintegration and dissolution of the dosage form occurs rapidly, thus providing the

rapid onset of action. Hence, an attempt was made for preparation of oral disintegrating tablets (ODT) of Loratadine so that the patient can ingest the dosage form anywhere and at anytime without the aid of water which would be helpful especially in cases of unavailability of water, motion sickness, sudden episodes of allergic attacks, deglutition problems. The structural formula of the drug is given below.

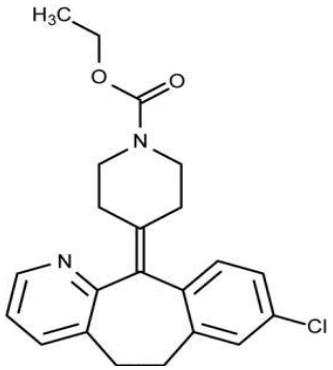


**Figure 1: Chemical Structure of Loratadine.**

Various processes employed in formulating ODTs include Freeze-Drying or Lyophilization, cotton candy process, molding, spray drying, mass extrusion and compaction (wet granulation, dry granulation, and direct compression).[11] The direct compression method is one of the widely accepted methods to manufacture the ODT tablets, since it is very simple and does not require any sophisticated equipments. This method represents the simplest and most cost effective tablet manufacturing technique.[12]

In view of the above facts, in the present investigation, an attempt was made to develop and validate new spectrophotometric method for analysis of Loratadine along with formulation and evaluation of oral dispersible tablet of Loratadine by direct compression method to improve the oral bioavailability using suitable polymers like superdisintegrants like Crosscarmellose sodium, Sodium starch glycolate, Crosspovidone, directly compressible diluents, lubricants, sweeteners and flavoring agents.

### 1.1 Advantages of ODTs

- ODT can be administered to the patients who cannot swallow tablets/cap., such as the elderly, stroke victims, bedridden patients, patients with esophageal problems & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients and thus improves patient compliance.[13]

- It contains the certain studies which concluded increased bioavailability and proved rapid absorption of drugs through pregastric absorption of drugs from mouth, pharynx & esophagus as saliva passes down.[14]
- ODT is the most convenient for disabled, bedridden patients, travelers and busy people, who do not always have access to water.[14]
- Good mouth feel property of ODT helps to change the perception of medication.[15]
- As bitter pill particularly in pediatric patients.[13]
- The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.[16]
- ODT opened new business opportunity like product differentiation, product promotion, patent extension and life cycle management.[13]
- Suitable during traveling where water may not be available.[14]
- No specific packaging required can be packaged in push through blisters.[17]
- Conventional manufacturing equipment.[17]
- Cost effective.[13]
- Good chemical stability as conventional oral solid dosage form.[15]
- Allow high drug loading.[14]
- Provides rapid drug delivery from dosage forms.[15]
- Provide advantage of liquid medication in form of solid preparation.[18]
- Rapid drug therapy intervention.[13]
- No chewing needed.[14]
- Adaptable and amenable to existing processing and packaging machinery.[13]
- Rapid onset of action.[19]

Although, ODTs show more advantages than disadvantages, still there are some challenges that have to be encountered in formulating ODTs. The challenges in formulating ODTs are related to various concerns such as Palatability[20,21], Mechanical Strength[22,23,24], Hygroscopicity[25], Amount of Drug[26], Aqueous Solubility[27,28] and Size of Tablets.[29]

## 2. MATERIAL AND METHODS

### 2.1 Materials

Loratadine (API) as well as other excipients like Crosscarmellose Sodium, Crosspovidone, Sodium Starch Glycolate, Maize Starch, Mannitol, Colloidal Silicon Dioxide, Aspartame, Microcrystalline Cellulose Powder, Magnesium Stearate, Purified Talc and PVP K30 were

provided by Asian Pharmaceuticals Pvt. Ltd, Omsatiya-1, Rupandehi, Nepal as a gift sample for our research work. The marketed sample of the Loratadine drug i.e. Alora 10 was procured from the local retail pharmacy. All other chemicals used were of analytical grade.

**2.2 Equipments/ Instruments**

UV-visible spectrophotometer (Shimadzu Corporation), Hot air oven (Indosati), Electronic balance (Shimadzu Corporation), Tablet compression machine, Tablet hardness tester (Monsanto), Roche friabilator (Excel enterprises), Vernier caliper, Tablet dissolution tester USP (PLC), Tablet disintegrator (Excel enterprises), Sieve (Bent), Glass wares (Borosilicate, India), $P^H$ meter (Emtech), Bulk density apparatus (Excel enterprises), Sonicator (Indosati), Aluminium foil, Whatman's filter paper (Whatman International Ltd., England) were employed during the course of present research work.

**2.3 METHODS**

**2.3.1 Preparation of standard calibration curve**

An accurately weighed 100 mg of Loratadine was dissolved in 100ml of Methanol ($CH_3OH$) to get a concentration of 1000 µg/ml. From this stock solution, aliquots of sample were pipetted out ranging from volume 0.25 ml, 0.5 ml, 1 ml, 1.25 ml, 1.5 ml and 1.75 ml in a 50 ml volumetric flask to produce concentration of 2.5, 5, 10, 12.5, 15, and 17.5 µg/ml respectively. The absorbance was measured at 248 nm using UV spectrophotometer against as $CH_3OH$ blank. The standard curve was obtained by plotting absorbance V/s. concentration in µg/ml.

**2.3.2. Analytical method validation:**

**2.3.2.1 Accuracy**

The accuracy of an analytical method is the closeness of the test results obtained by that method to the true value.[30] This is sometimes termed trueness. The accuracy test was carried out on various sample solution of Loratadine by using the assay method. It is indicated by recovery of analytical method.

The recovery is determined by the given equation;

% recovery = (Analytical result/True value) ×100 %

#### 2.3.2.2 Precision

The precision of the analytical method describes the closeness of repeated individual measures of analyte.[31] The precision of an analytical procedure is usually expressed as the standard deviation or relative standard deviation (coefficient of variation) of a series of measurements. It is indicated by Relative Standard Deviation, RSD, by analyzing various sample of Loratadine which is determined by the given equation.

RSD = (SD/Mean) ×100 %.

#### 2.3.2.3 Linearity

Linearity is the ability of the method to elicit test results that are directly, or by a well defined mathematical transformation, proportional to analyte concentration within a given range.[32] Various concentration of Loratadine was prepared of the standard and sample one and their absorbance was determined. Absorbance versus concentration was plotted and value of correlation coefficient ($R^2$) was determined.

#### 2.3.2.4 Limit of detection

The Detection Limit is defined as the lowest concentration of an analyte in a sample that can be detected, not quantified.[33] Various concentrations of Loratadine was prepared and limit of detection was calculated by using given equation.

LOD = (3.3/S) ×SD

Where S = slope of the standard calibration curve.

#### 2.3.2.5 Limit of quantitation

The Quantitation Limit is the lowest concentration of an analyte in a sample that can be determined with acceptable precision and accuracy under the stated operational conditions of the analytical procedures.[33]

Limit of quantitation was calculated by using given equation;

LOQ = (10/S) ×SD

Where S = slope of the standard calibration curve.

### 2.3.3 Formulation of ODT of Loratadine

ODT tablets were prepared using super disintegrants by direct compression method. Loratadine tablet each weighing 200 mg containing 10 mg of Loratadine was formulated as follows:

- All the ingredients including Loratadine, MCCP, Colloidal Silicon Dioxide, Magnesium stearate, PVP K-30, Purified Talc, Mannitol, Aspartame, Starch, Sodium Starch Glycolate, Crosspovidone & Crosscarmellose Sodium were accurately weighed and passed via 80 # sieve and kept in hot air oven to make them anhydrous.
- Since, formulation was done via direct compression method so initially starch and Loratadine were homogenously mixed to form a uniform mixture following doubling up technique.
- Then, remaining excipients like Mannitol, Aspartame, MCCP, Colloidal Silicon Dioxide, Purified Talc, Magnesium Stearate, PVPK-30, Sodium Starch Glycolate (super disintegrants) were step wise added to the uniform mixture of powder as prepared above to form formulations $F_1$, $F_2$ and $F_3$.
- Similarly, the formulations F4, $F_5$ and $F_6$ were formed by adding Crosspovidone as superdisintegrants whereas for formulations $F_7$, $F_8$ and $F_9$, Crosscarmellose Sodium was added as superdisintegrants to the powder mixture on specified ratios for each formulation.
- Then, each of the formulation was compressed into tablet using the single punch tablet compression machine with 8.2 mm punches. The prepared tablets were packed in an aluminium foil pouch.
- Using Direct Compression method, 9 batch of ODT of Loratadine (2250 nos.) was formulated varying types of superdisintegrants for every 3 batches as shown in table 1.

**Table 1: Formulation of trial batches using different concentration of excipients by Direct Compression method.**

| **Batch No. (→)** | **$F_1$** | **$F_2$** | **$F_3$** | **$F_4$** | **$F_5$** | **$F_6$** | **$F_7$** | **$F_8$** | **$F_9$** |
|---|---|---|---|---|---|---|---|---|---|
| **Ingredients (↓)** | mg/tab | mg/tab | mg/tab | mg/tab | mg/tab | mg/tab | mg/tab | mg/tab | mg/tab |
| Loratadine | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| MCCP | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 | 44 |
| Aerosil 200 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Magnesium Stearate | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| PVP K-30 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Purified talc | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Mannitol | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Aspartame | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Sodium starch glycolate | 10 | 20 | 30 | - | - | - | - | - | - |
| Crosspovidone | - | - | - | 10 | 20 | 30 | - | - | - |
| Crosscarmellose Sodium | - | - | - | - | - | - | 10 | 20 | 30 |
| Starch | 71.5 | 61.5 | 51.5 | 71.5 | 61.5 | 51.5 | 71.5 | 61.5 | 51.5 |
| **Total** | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 | 200 |

### 2.4 Evaluation of ODT of Loratadine

#### 2.4.1 Pre-compression studies

##### 2.4.1.1 Angle of repose

The frictional forces in a loose powder or granules can be measured by the angle of repose. This is the maximum angle possible between the surface of a pile of powder or granules and the horizontal plane.[34] The granules were allowed to flow through the funnel fixed to a stand at definite height. The angle of repose was then calculated by measuring the height and radius of the heap of granules formed as given equation,

$\tan \theta = h/r$

$\text{Or } \theta = \tan^{-1}(h/r)$

Where, θ = angle of repose, h = height, r = radius of heap of powder. The relationship between Angle of Repose and flow properties is shown in table 2.

**Table 2: Relationship between Angle of Repose and flow properties.**

| Angle of repose (°) | Flow Properties |
|---|---|
| ≤25 | Excellent |
| 25-30 | Good |
| 30-40 | Passable |
| >40 | Very poor |

##### 2.4.1.2 Bulk density and Tapped density

Bulk density is the ratio of total mass of powder to the bulk volume of powder. Tapped Density is the ratio of total mass of powder to the tapped volume of powder.[35] It is expressed in gm/ml.

The accurate weight amount of sample was taken in a measuring cylinder to record the volume of packing and was tapped 100 times on a plane hard wooden surface and tapped volume of packing was recorded, bulk density and tapped density was calculated as;

Bulk density = (mass of powder / volume of packing)

Tapped density = (mass of powder / tapped volume of packing).

##### 2.4.1.3 Carr's index

Percentage compressibility of powder mixture was determined by Carr's compressibility index calculated by formula as;

% Carr's index = {(tapped density – bulk density) / bulk density} x 100%.

#### 2.4.1.4 Hausner's ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granule material. The Relationship between Carr's index and Hausner's ratio is shown in table 3.

Hausner's ratio = (tapped density / bulk density)

**Table 3: Relationship of carr's index and Hausner's ratio with flow character.**

| Carr's index | Flow character | Hausner's ratio |
|---|---|---|
| ≤ 10 | Excellent | 1.00-1.11 |
| 11-15 | Good | 1.12-1.18 |
| 16-20 | Fair | 1.19-1.25 |
| 21-25 | Passable | 1.26-1.34 |
| 26-31 | Poor | 1.35-1.45 |
| 32-37 | Very poor | 1.46-1.59 |
| >38 | V. very poor | >1.60 |

### 2.4.2 Post-compression studies

The tablets were evaluated for following post-compression parameters.

#### 2.4.2.1 Thickness of tablet

The thickness of six tablets from each batch was measured using Vernier caliper and the average thickness was determined in mm. The extent of deviation from standard value was also determined.

#### 2.4.2.2 Organoleptic properties

Taste, odor and colour of ten tablets were randomly selected and evaluated.

#### 2.4.2.3 Hardness test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Monsanto hardness tester. It is expressed in kg/cm2. Six tablets from each batch were randomly picked and hardness of the same tablets from each formulation was determined. The mean and standard deviation values were also calculated.[34]

#### 2.4.2.4 Friability test

The friability of tablets was determined using Roche Friabilator. It is expressed in percentage (%). Ten tablets were initially weighed ($W_{initial}$) and transferred into friabilator. The friabilator was operated at 100 rpm. Tablets were subjected to combined effect of abrasion and shock. The tablets were re-weighed ($W_{final}$). The % friability was then calculated by,

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

% Friability of tablets less than 1%are considered acceptable.

#### 2.4.2.5 Wetting time

Wetting time of dosage form is related with the contact angle. Wetting time of the mouth dissolving tablets is another important parameter, which needs to be assessed to give an insight into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet.[34] It can be measured using the following procedure.

**Procedure:** A small piece of tissue paper folded twice was placed in small petridish containing 10ml of water and six tablets from each batch were taken and time required for complete wetting was measured.

#### 2.4.2.6 Weight variation

For weight variation, 20 tablets from each batch were taken, weighed individually & recorded and average weight was determined. To pass the test, average weight should comply with the standard requirement of USP as shown in the table 4.

**Table 4: Specification for weight variation of tablet as per USP.**

| S.N. | Average weight of tablet (mg) | Percent deviation (%) |
|---|---|---|
| **1.** | ≤130 | 10 |
| **2.** | 130-324 | 7.5 |
| **3.** | >324 | 5 |

#### 2.4.2.7 In vitro dispersion time

Ten tablets from each batch was taken and placed on beaker containing 10 ml of phosphate buffer ($PO_4^{-2}$) of $p^H$ 6.8 and time required for complete dispersion of tablet was recorded in seconds.

#### 2.4.2.8 In *vitro* Disintegration time

The process of breakdown of a tablet into smaller particles is called as disintegration. The *In vitro* disintegration time of a tablet was determined using disintegration test apparatus. Six tablets from each batch was taken and kept in each tablet chamber of the apparatus maintaining temperature 37±2ºC of the distilled water along with of pH 6.8. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

**2.4.2.9 *In vitro* dissolution studies**

In vitro dissolution study was carried out by using 6 station USP tablet dissolution test apparatus Type II (paddle type) at 50 rpm, 0.1N HCl with 900ml distilled water maintaining temperature 37±0.5ºC. Six tablets from each batch were taken and kept in apparatus and the dissolution study was performed at every 2, 4, 6, 8, 10 minutes taking 10 ml sample from each station for each tablet which was analyzed spectrophotometrically at 248 nm and % cumulative drug release was calculated.

**2.4.2.10 Assay of sample of tablet**

Ten tablets from each batch were weighed, powdered and passed via 80 # sieve. A quantity of powder equivalent to 10 mg of Loratadine was accurately weighed and was transferred to 50 ml volumetric flask and was fully dissolved with methanol ($CH_3OH$) by sonicating the solution for 20 minutes at 30°C. Then, the final volume was made up to 50 ml with $CH_3OH$. The solution was filtered using Whatman's filter paper, first 10 ml of solution was rejected and then again sample solution was taken and analyzed at UV-visible spectrophotometer at λmax 248 nm and % of Loratadine in sample was determined.

% assay = (spl abs/std abs)×(std wt/spl wt)×(spl dilution/std dilution)×{(100-LOD)/100}× purity %

Where,

Spl abs = Absorbance of the sample, Std wt = Weight of the standard

Std abs = Absorbance of the standard, Spl wt = Weight of the sample

LOD = Loss on drying

**2.5 Statstistical Evaluation:**

All the statstistical evaluations were performed by using SPSS V16 software and MS Excel 2007.

**3. RESULT AND DISCUSSION**

**3.1 Standard Calibration Curve**

Standard Calibration Curve for the standard drug was obtained by plotting the values of the concentration versus respective absorbance obtained for each of the concentrations. From the calibration curve, the correlation coefficient ($R^2$) was found to be 0.999 with slope (m) 0.029 and y-intercept 0.007(Table 5 and Figure 2).

**Table 5: Respective absorbance for different concentration of the standard drug.**

| S.N | Concentration (µg/ml) | Absorbance |
|---|---|---|
| 1 | 2.5 | 0.082 |
| 2 | 5 | 0.152 |
| 3 | 10 | 0.301 |
| 4 | 12.5 | 0.365 |
| 5 | 15 | 0.441 |
| 6 | 17.5 | 0.500 |

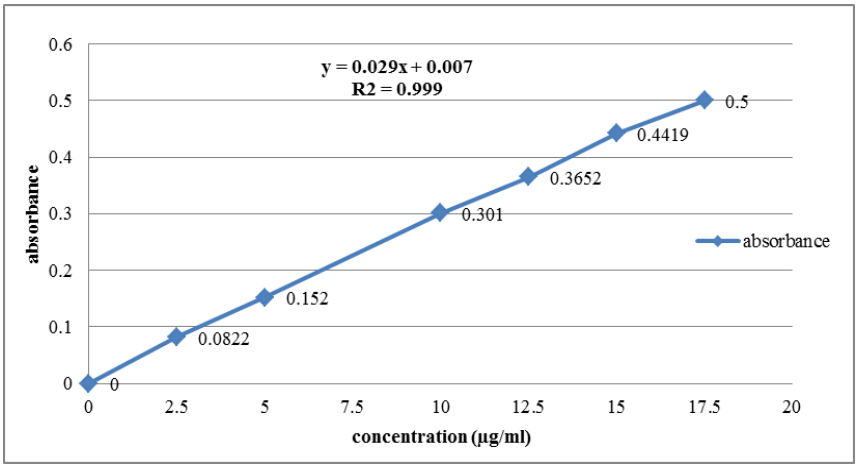


**Fig. 2: Standard calibration curve for Loratadine drug.**

### 3.2 Validation of the analytical method

Validation of the analytical method was carried on different parameters that are mentioned above. Linearity test was performed by plotting concentration vs. absorbance of the marketed sample of the Loratadine. The correlation coefficient, $R^2$ was found to be 0.999 and y-intercept 0.002. This value verifies that the analytical procedure is suitable for different concentration range (Table 6 and Figure 3). The accuracy test was performed on the concentrations 5µg/ml of the sample which showed result near to the true value (Table 7). The method performed in our work was precised since the RSD value was found to be 1.08% which is less than 2%. The LOD was calculated by taking the slope obtained from standard calibration curve of fig.2. The LOD was found 124.034 & LOQ was found 375.862.

**Table 6: Respective absorbance for different concentrations of the marketed drug.**

| S.N. | Concentration (µg/ml) | Absorbance |
|---|---|---|
| 1 | 2.5 | 0.082 |
| 2 | 5 | 0.152 |
| 3 | 10 | 0.284 |
| 4 | 12.5 | 0.364 |
| 5 | 15 | 0.442 |
| 6 | 17.5 | 0.523 |

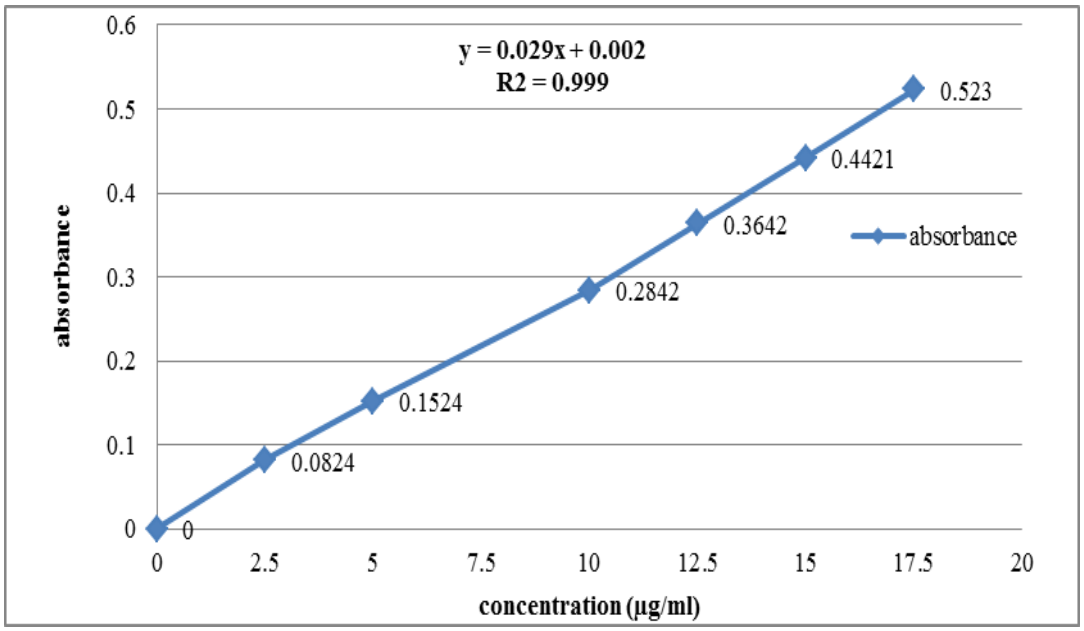


**Fig. 3: Standard calibration curve for the marketed sample drug.**

**Table 7: Accuracy test result for assay of 5µg/ml.**

| S.N | Actual drug content | Quantity found per tablet | % of content | % mean | SD | RSD |
|---|---|---|---|---|---|---|
| 1 | 113.135 | 113.063 | 100.35 | 100.59 | 1.09 | 1.08 |
| 2 | 113.143 | 113.788 | 101.78 | | | |
| 3 | 113.136 | 113.655 | 99.64 | | | |

### 3.3 Evaluation of ODT of Loratadine

### 3.3.1 Evaluation of Pre-compression parameters

#### 3.3.1.1 Angle of Repose

The data obtained for angle of repose for all the batches prepared are tabulated in Table 8. The values were found to be in the range of 26.19°- 29.74°. The maximum angle of repose was found of $F_5$ formulation whereas minimum of $F_2$ formulation. All the formulations showed the angle of repose less than 30° which reveals good to fair inherent flow property of the powder blend.

#### 3.3.1.2 Bulk density and tapped density

The maximum bulk density was found to be 0.53 for $F_9$ and minimum was found to be 0.438 for $F_6$. Similarly, maximum tapped density was found to be 0.606 for $F_9$ and minimum was found to be 0.511 for $F_6$ formulation as shown in table 8.

### 3.3.1.3 Carr's index & Hausner's ratio

The Carr's index values were found to be in the range of 13.04-14.45. Results clearly showed that flowability of all the batches is satisfactory and also the blend has good compressibility. The Hausner's ratio of all the batches prepared ranged from 1.15 to 1.16. The results obtained indicated that all the powder blends had appreciable flow property as per the Table 8.

**Table 8: Pre-compression parameters.**

| Formulation code | Angle of repose (θ) | Bulk density (g/cc) | Tapped density (g/cc) | Carr's index (%) | Hausner's ratio |
|---|---|---|---|---|---|
| $F_1$ | 28.71 | 0.474 | 0.547 | 13.25 | 1.15 |
| $F_2$ | 26.19 | 0.440 | 0.506 | 13.04 | 1.15 |
| $F_3$ | 28.99 | 0.480 | 0.561 | 14.43 | 1.16 |
| $F_4$ | 27.52 | 0.447 | 0.521 | 14.20 | 1.16 |
| $F_5$ | 29.74 | 0.474 | 0.551 | 13.97 | 1.16 |
| $F_6$ | 27.94 | 0.438 | 0.511 | 14.28 | 1.16 |
| $F_7$ | 28.93 | 0.497 | 0.551 | 14.45 | 1.16 |
| $F_8$ | 27.84 | 0.496 | 0.571 | 13.13 | 1.15 |
| $F_9$ | 28.94 | 0.530 | 0.606 | 14.19 | 1.16 |

### 3.3.2 Evaluation of Post-compression parameters

As shown in table 9, the evaluation of taste, odor and color of various randomly selected tablets from each batch were done. All tablets were found sweet in taste, pleasant in odor and white in color. For weight variation test, 20 tablets from each batch were taken randomly and were accurately weighed on an analytical balance. Average weight with their % deviation was calculated. Maximum weight variation (201±1.38) was found in $F_2$ and minimum weight variation (194±0.42) was found in $F_4$ formulation. For thickness test, 10 tablets from each batch were taken randomly and thickness was evaluated with their average and % deviation. Maximum thickness (3.7±0.016) was found in $F_6$ whereas minimum thickness (3.58±0.053) was found in $F_3$ formulation. Similarly for hardness and friability test, the maximum hardness (2.66±0.050) was found in $F_6$ whereas minimum hardness (2.46±0.050) was found in $F_8$ formulation. Similarly, maximum friability (0.52%) was found in $F_9$ whereas minimum friability (0.10%) was found in $F_2$ formulation. For wetting time test, the maximum wetting time (35 sec) was found in $F_1$ whereas minimum wetting time (19 sec) was found in $F_6$ formulation.

Similarly for in-vitro dispersion time, disintegration time and assay of tablet, the test was carried out as per method above described. The time required for complete dispersion of tablet was evaluated and maximum dispersion time (72 sec) was found in $F_7$ whereas

minimum dispersion time (22 sec) was found in $F_6$ formulation. However, the maximum disintegration time (30-49 sec) was found in $F_7$ whereas minimum disintegration time (9-15 sec) was found in $F_6$ formulation. Similarly, the % assay was found in a range of 90.6% to 99.2% which showed good content uniformity among the prepared formulations. Formulation $F_6$ showed maximum % assay whereas formulation $F_4$ showed minimum % assay result.

**Table 9: Post-compression parameters.**

| Formulation Code | Weight±SD (mg) | Hardness±SD (kg/cm$^2$) | Thickness±SD (cm) | Friability (%) | Disintegration time (sec) | Wetting time (sec) | Dispersion time (sec) | Assay (%) |
|---|---|---|---|---|---|---|---|---|
| $F_1$ | 194±0.77 | 2.58±0.037 | 3.68±0.024 | 0.51 | 25-45 | 35 | 30 | 90.8 |
| $F_2$ | 201±1.38 | 2.60±0.031 | 3.68±0.020 | 0.10 | 25-35 | 33 | 34 | 96.4 |
| $F_3$ | 200±1.01 | 2.58±0.037 | 3.58±0.053 | 0.49 | 19-30 | 28 | 32 | 97.8 |
| $F_4$ | 194±0.42 | 2.58±0.037 | 3.67±0.021 | 0.31 | 17-25 | 27 | 26 | 90.6 |
| $F_5$ | 195±0.42 | 2.58±0.037 | 3.71±0.027 | 0.53 | 13-20 | 23 | 24 | 98.3 |
| $F_6$ | 197±0.73 | 2.66±0.050 | 3.7±0.016 | 0.20 | 9-15 | 19 | 22 | 99.2 |
| $F_7$ | 200±1.00 | 2.54±0.024 | 3.70±0.014 | 0.10 | 30-49 | 26 | 72 | 95.4 |
| $F_8$ | 200±0.82 | 2.46±0.050 | 3.50±0.014 | 0.10 | 22-37 | 24 | 68 | 96.7 |
| $F_9$ | 202±0.80 | 2.60±0.031 | 3.52±0.020 | 0.52 | 18-27 | 22 | 70 | 98.1 |

As per method described above, the in-vitro dissolution test was carried out (Table 10). The % cumulative drug release for each of the formulations was also determined and is shown in respective figures for respective formulations (Figure 4).

**Table 10: Dissolution profile for various formulations.**

| Time (min) | % cumulative drug release | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | $F_1$ | $F_2$ | $F_3$ | $F_4$ | $F_5$ | $F_6$ | $F_7$ | $F_8$ | $F_9$ |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 72 | 73 | 75 | 76 | 71 | 76 | 70 | 77 | 75 |
| 4 | 75 | 76 | 78 | 80 | 78 | 81 | 76 | 84 | 85 |
| 6 | 86 | 86 | 88 | 87 | 85 | 89 | 84 | 89 | 89 |
| 8 | 89 | 90 | 91 | 90 | 92 | 93 | 92 | 93 | 91 |
| 10 | 92 | 93 | 95 | 94 | 95 | 96 | 94 | 95 | 95 |

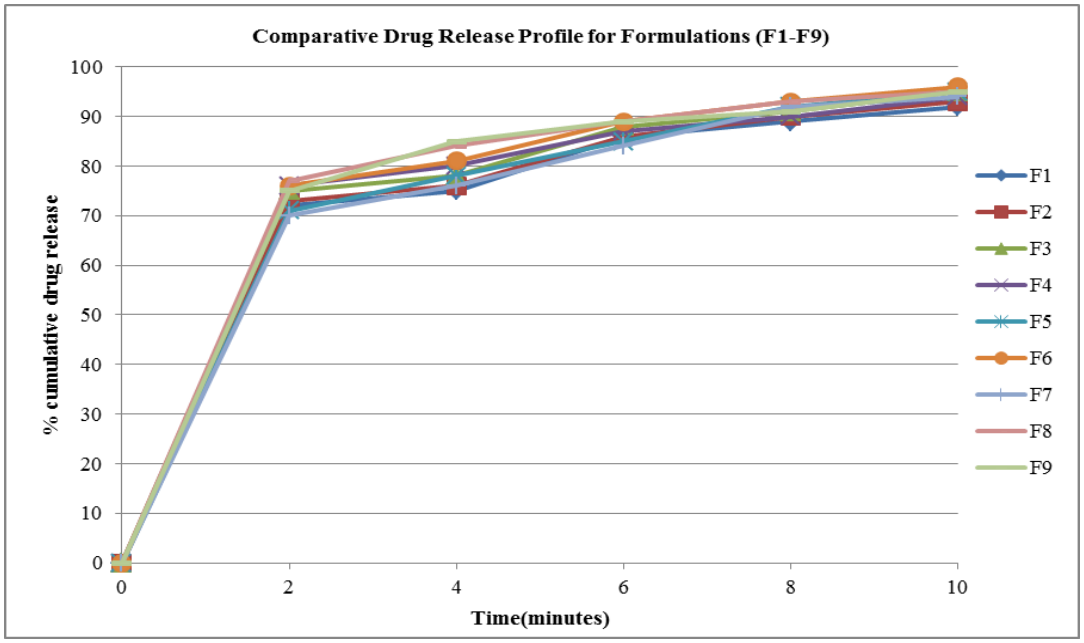


**Fig. 4: In-Vitro Drug Release Profile of formulation codes F1 to F9.**

## 4. CONCLUSION

From the above results and discussion, it was concluded that the new spectrophotometric method for analysis of Loratadine was developed and validated and the formulation and evaluation of oral dispersible tablet of Loratadine by direct compression method was successful to improve the oral bioavailability using suitable polymers. Amongst all the formulations, formulation containing crosspovidone (F6) as optimized formulation is fulfilling all the parameters satisfactorily. It has shown excellent *in vitro* disintegration, wetting time, *in vitro* dispersion time, in vitro dissolution and assay value compared to other formulations containing superdisintegrants such as sodium starch glycolate, cross carmellose sodium. The present research work could therefore provide the opportunity and form the basis as suitable platform technology to further pursue & own the research using other potent drugs.

## 5. ACKNOWLEDGEMENT

The author is thankful to Asian Pharmaceuticals Pvt. Ltd, Omsatiya-1, Rupandehi, Nepal who provide necessary raw materials as a gift sample and also to the management team of Siddhartha pharmaceuticals Pvt. Ltd, Rupandehi, Nepal for providing and arranging necessary facilities to pursue our research work.

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