International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 21s, 2025
https://www.theaspd.com/ijes.php

Formulation, Development & Characterization Of Fast Dissolving Film Of Antihistaminic Drug In Treatment Of Allergy

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Abstract

Because of their expanded consolation and versatility, rapid dissolving oral films are the most present day oral strong dose form. by means of dissolving in the oral hollow space in a depend of mins after getting into contact with less saliva than rapid-dispersing tablets, without chewing and without the requirement for water for shipping, it increases the efficacy of APIs. via the intra-gastric, sublingual, or buccal routes of management, these films have the capability to deliver the drug always. They have got additionally been hired for nearby movement. This sort of era provides a cozy technique of administering remedy not only to certain demographic organizations which includes kids, the elderly, patients who're bedridden, and patients who're mentally unwell, but additionally to the whole public. in lots of situations, including hypersensitive reaction illnesses, colds and coughs, sore throats, nausea, ache, mouth ulcers, CNS problems, and CVS problems, speedy-dissolving oral movies are tested to be appropriate. In phrases of disintegration time, folding patience, and maximal in-vitro drug launch after 30 minutes in the F3 method, the results showed that Doshion(10mg) and CCS(12mg) gave better results.

Key phrases *– FDF, Diphenhydramine Hydrochloride, CCS, Doshion, and Pectin.*

1. INTRODUCTION

Fast-dissolving drug transport structures, which aim to growth the safety and efficacy of a healing molecule by means of setting it right into a ordinary oral dosage shape for management and to obtain improved affected person compliance, have simply begun to collect popularity and popularity as revolutionary drug shipping methods. More long lasting rapid-dissolving medication transport techniques have been produced by several companies; these films are placed at the tongue's top or backside. [1] This film immediately dissolves while located on the tongue, freeing the medication, which dissolves inside the saliva. As saliva descends into the stomach, some medicines are absorbed from the mouth, pharynx, and oesophagus.[2] enhancing medicinal drug bioavailability in this situation guarantees first-rate tongue sense and removes choking chance. To get round this problem, use a quick-acting drug delivery mechanism for capsules, pills, etc. This mission gives an overview of the development of oral dosage forms and packages. Formulation attention, training technique, assessment, advertised product, and proprietary oral fast-dissolving movie technology. [3] Fig. 1 suggests the images of FDF.

Rapid-dissolving polymer film that has a medication inserted in it makes up speedy-dissolving movie. It gives instant local or systemic remedy delivery without the requirement for water when placed at the tongue or inside the oral hollow space (i.e., ducal, palatal, gingival, lingual, or sublingual). The mouth

dissolving film, speedy dissolving film, quick dissolving movie, and oral skinny movie are different names for the fast dissolving movie. the quick dissolving film is basically a postage stamp-sized, extremely-thin film that consists of an energetic substance, frequently called an lively pharmaceutical component (API), in addition to additional excipients. [4] The varieties of FDF and their attributes are displayed in desk 1.

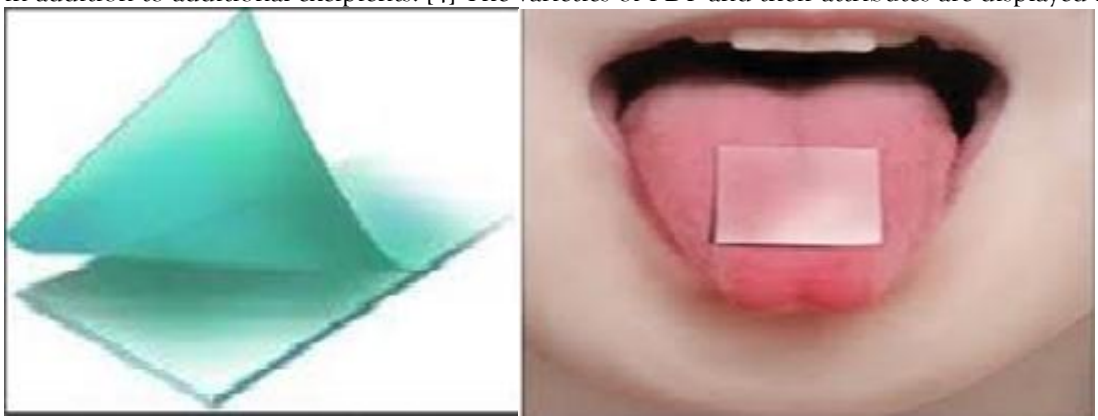


Figure 1. Images of Fast Dissolving Film

Table 1: Three Types of Oral Fast Dissolving Films Along With Their Properties

Properties	**Flash release**	**Mucoadhesive melt away wafers**	**Mucoadhesive sustained released wafers**
Area (cm^2)	2-8	2-7	2-4
Thickness (um)	20-70	50-500	50-250
Structure	Single layer	Single or multilayer	Multilayer system
Excipients	Soluble hydrophilic polymers	Soluble hydrophilic polymers	Low/ nonsoluble polymers
Drug phase	Solid solution	Solid solution or suspended drug particle	Suspension and/or solid solution
Application	Tongue (upper palate)	Gingival or buccal region	Gingival (other region in the oral cavity)
Dissolution	60 s	In few minutes forming gel	Maximum 8-10 h
Site of action	Systemic or local	Systemic or local	Systemic or local

2. MATERIALS AND TECHNIQUE

2.1 Materials

Kindly donated diphenhydramine HCL through Medicon fitness Care Pvt. Ltd. The research lab furnished pectin and sodium saccharin, and Vishal Chem provided CCS. Chemdyes employer furnished PEG, and Doshion Pvt. Ltd. furnished Doshion. Thomas Baker provided the citric acid.

2.2 Strategies

The water soluble polymers are first dissolved in water at 1,000 rpm and heated to six hundred c on this method. The ultimate excipients—colorations, flavorings, sweeteners, etc.—are all dissolved one by one. The ensuing answers are then fully mixed even as being stirred at 1,000 rpm. The API that has been dissolved in a suitable solvent is introduced to the ensuing answer. A vacuum is used to extract the trapped air. The completed aggregate is solid into a movie, allowed to dry, after which it's miles reduce into the required quantity of portions. [5]

2.2 Preformulation study

1. Coloration, odour and look

Diphenhydramine Hydrochloride became evaluated for its color, odour and appearance.

2. Melting point willpower

Melting point of the drug pattern turned into decided with the aid of capillary approach the usage of melting point apparatus.

3. Willpower of λ max by way of UV spectroscopy

Chlorthalidone was produced as a stock solution (one hundred g/ml) in phosphate buffer at pH 6.eight. From this inventory answer, the appropriate dilutions had been made to supply solutions with concentrations between 2 and 10 g/ml. every solution's most absorbance became measured the usage of a UV-seen Spectrophotometer (UV-1700 Shimadzu). The calibration curves had been displayed in graph 2 as absorbance at the Y-axis vs. attention on the X-axis.

4. Solubility study

The solubility of drug in Water, Chloroform, and Ethanol became decided.

5. Drug – excipients compatibility have a look at with the aid of FTIR

Drug and excipient compatibility in experimental settings changed into investigated. With the use of a KBr press and a 1 mg pattern in a hundred mg of KBr, the have a look at was completed. The resolution became 1cm-1, and the scanning variety changed into four hundred to 4000cm-1. This spectral evaluation became completed to determine whether the medicinal drugs and excipients had been compatible.

2. Three practise -

Guidance of rapid dissolving oral films

1) Calculation of drug loaded in film

The area of petri dish is calculated by using the components πr2

Diameter of Petri dish = 7 cm

Radius= diameter / 2

So, 7/2 = 3.5 cm

Then we calculate the vicinity,

$\pi r^2 = 3.14 \times 3.5 \times 3.5$

$= 38.46\ cm^2$

Now dose of Diphenhydramine HCL is 12.5 mg in 2 × 2cm movie i.e. 4 cm^2

Then the 4 cm^2 = 12.5mg drug

38. 46 cm^2 = ' X' mg of drug

X= 118.75 mg = 119 mg of drug

2) System

Solvent Casting approach-

Solvent casting becomes used to create films of diphenhydramine HCL that dissolve speedy. As said in table No. 2, Polymer Pectin was precisely weighed and dissolved in water using various formulations. Then, for numerous formulations, upload go carmellose sodium and plasticizer PEG four hundred. Blend very well until a clear answer is executed. The polymeric answer become then supplemented with the drugs. The final three substances, Doshion, Sodium Saccharine, and Citric Acid, are brought and continuously mixed for 15 mins within the magnetic stirrer. To do away with the air bubble from the method, the solution is then positioned on the ultrasonicator for half-hour. After that, a clear solution is poured right into a petri dish, which is then heated to four hundred°C for 12 hours in a warm air oven. The dried film turned into then carefully eliminated from the petri dish, tested for flaws or air bubbles, and reduces into sections of two with the aid of 2 cm, or 4 cm2. Desk 2 displays the FDF's composition.

Formulation Table of fast dissolving film

Table 2: Composition of Oral fast dissolving film

Batch	Drug (mg)	Pectin (mg)	CCS (mg)	Citric acid (mg)	Sod. Saccharin (mg)	PEG 400 (ml)	Doshion	Water(ml)
F1	119	32	6	4	8	1.5	10	10
F2	119	30	8	4	8	1.5	10	10
F3	119	26	12	4	8	1.5	10	10
F4	119	33	5	4	8	1.5	10	10
F5	119	31	7	4	8	1.5	10	10
F6	119	29	9	4	8	1.5	10	10
F7	119	34	4	4	8	1.5	10	10
F8	119	30	8	4	8	1.5	10	10
F9	119	27	11	4	8	1.5	10	10

Evaluation

Visual Inspection-

Oral fast-dissolving movies had been manually tested for transparency and air bubble presence.[6]

Determination of pH of FDOF -

Three movies of each component had been dissolved in 2 ml of distilled water to determine the pH, which became then measured the usage of pH paper. It changed into decided to maintain the surface pH as near impartial as possible because an acidic or alkaline pH can also worsen the oral mucosa. [7]

Determination of common Weight and Weight version of FDOF –

Every film from the 3 samples of every recipe turned into weighed one by one on a virtual scale. It became determined what the average weight and weight version have been.

Thickness of the movie-

The thickness of every batch becomes assessed using calibrated virtual vernier calipers. For every batch, this test turned into accomplished in triplicate. [8]

Folding staying power –

The wide variety of times the film might be folded at the equal vicinity without cracking became recorded because the folding patience after time and again folding a tiny strip of the movie in that location. The movie became folded up to a hundred instances without breaking at an perspective of 180 ranges inside the identical spot. The average mean changed into acquired speedy as soon as the research have been completed. [9]

Drug content –

The UV spectrophotometric approach becomes used to decide the drug content of every batch. From each batch, a 2 cm by using 2 cm strip was reduce, and it changed into dissolved in 50 cc of phosphate buffer, pH 6.8. The solution changed into then diluted as important before being filtered with whatman filter paper. At 258 nm, the outcome turned into measured spectrophotometrically. [10]

Dispersion test –

200 ml of 6.8 pH phosphate buffer had been added to a movie containing 12.5 mg of diphenhydramine hydrochloride, and the aggregate was agitated for 3 minutes. The very last product turned into then sent via sieve range 22. simplest while there is no residue left at the display did the movie skip the dispersion test.[11]

Percentage Moisture Absorption (PMA) –

The PMA test was run to observe the mouth-dissolving film's physical balance underneath noticeably humid situations. three movies have been taken, precisely weighed, and positioned inside desiccators that were kept at 79.5% relative humidity by means of including a saturated solution of aluminum chloride. The films had been removed, weighed, and percentaged after seventy two hours. the following formulation turned into used to compute the amount of moisture absorbed: [12]

very last weight – initial weight/ initial weight into a hundred

Percentage Moisture Loss –

The bodily balance and integrity of the films have been tested the usage of the % moisture loss technique. inside the modern investigation, the moisture loss ability of the movie was assessed with the aid of storing it in a desiccator containing anhydrous calcium chloride for three days with a recognized weight and predetermined length. The films had been taken off and reweighed, and the formula underneath became used to calculate the % moisture lack of the movies. –[12]

percent moisture loss = initial weight – final weight/ very last weight into one hundred

In vitro disintegration time –

The USP disintegration take a look at equipment become used for the disintegration test. The medium became a phosphate buffer with a pH of 6.8. The disk turned into placed on top and the films had been inserted into the box's tubes. three films from every method batch were measured for the common time till they disintegrated. [13]

In Vitro wetting time-

The petriplate blanketed a circular piece of paper. The petriplate was filled with 6ml of a 0.1% W/V amaranth dye solution as soon as it were prepared. The tissue paper surface changed into covered with the film strip (2 x 2 cm2). the amount of time wished for the dye to show up on the film's floor changed into recorded because the wetting time. [14]

In vitro drug dissolution examine –

Drug release assessments were achieved on each method the usage of USP kind-II equipment. The dissolution check turned into performed the use of 900 ml of phosphate buffer (pH 6.eight) as the dissolution media at 100 rpm and 370c0.50. five millilitre aliquots were periodically extracted even as the pattern extent changed into constantly refilled with an equivalent extent of sparkling dissolving media. The samples had been subjected to spectrophotometric examination at 258 nm, and drug launch percentages have been calculated. [15]

Stability Study–

The rapid dissolving movies are located in appropriate packaging and stored in a temperature- and humidity-controlled environment in the course of stability studies as specified by using ICH pointers. After 15, 30, forty five, 60, and 90 days, the movies had been taken out and tested for folding resistance, time till disintegration, drug content, and time till drug launch.[16]

End result and discussion :

Using the solvent casting technique and numerous concentrations of CCS and Doshion (superdisintegrants), a quick-dissolving film of diphenhydramine HCL changed into created. We discovered the drug's maximal solubility in water and its 167oC melting factor during the preformulation investigation. All formulation batches had been decided to have neutral pH values, or values among 6 and eight. The average weight of the film is between 54.05 and sixty four.10 grams, and its thickness is among 0.11 and 0.20 microns. All formula batches from F1 to F9 passed the dispersion test, and the variety of folding persistence changed into fifty two to ninety five.8. 91.40-1.17 to ninety seven.20-1.15 turned into discovered to be the maximum drug content material. The in vitro wetting time become located to be within the range of a hundred and ten.five to 330.2 and the disintegration time changed into observed to be below 1 min, or 60 sec within the range of 20.030.15 to forty three.170.18. the proportion of moisture loss was observed to variety from 1.270.496 to 1.420.537, and the share of moisture absorption became discovered to be between 1.270.031 and 1.570.572. The created rapid dissolving film turned into subjected to in vitro drug launch the usage of a USP Dissolution apparatus type II in a pH 6.eight setting.

1. Preformulation Study

1.1 API Characterization-

API was subjected to evaluation parameter as listed in the table no. 13 the API passed the test as per specification given in Pharmacopeia.

Table No. 3 API characterization evaluation parameters

Test	Specification	Observation
Colour	White	Passed
Odour	Odourless	Passed
Appearance	Crystalline	Passed

1.2 Melting Point determination –

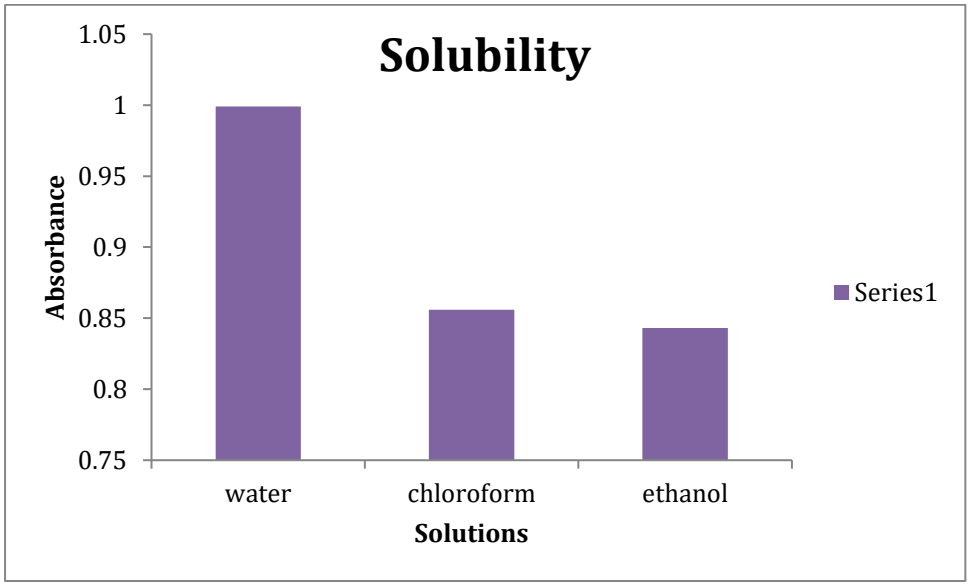
The Melting Point of the drug was found to be **167^{0}c .**

1.3 Solubility :

The solubility of Diphenhydramine HCL is given in table no. 14

Table No. 4 Solubility of Diphenhydramine HCL in different solvents

Sr. No.	Specification	Result
1.	Water	0.999
2.	Chloroform	0.856
3	Ethanol	0.843



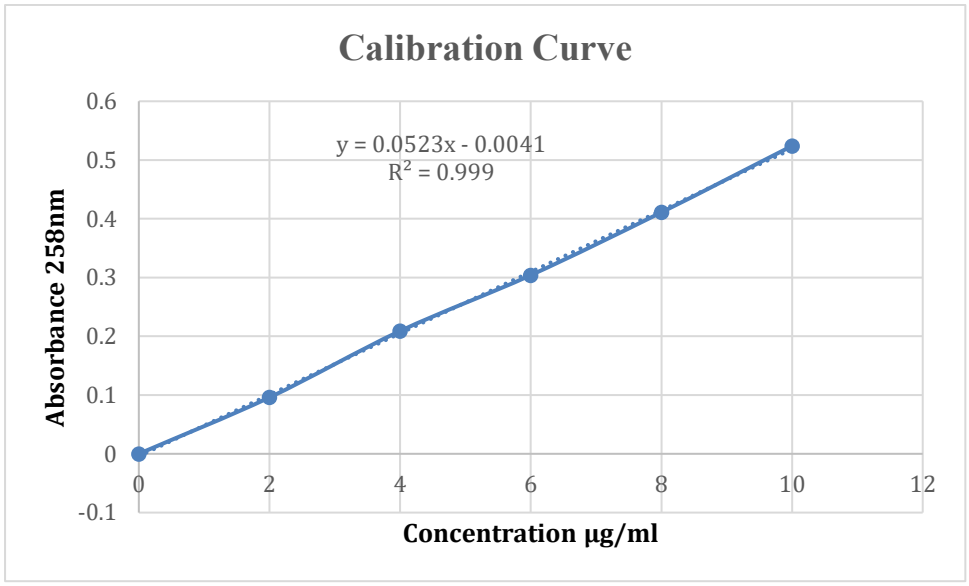
Graph 1. Solubility Profile

1.4 Determination of λ max by UV spectroscopy –

The absorbance versus concentration calibration curve for diphenhydramine HCL was plotted. The pH 6.8 phosphate buffer in which these values were taken. Diphenhydramine HCL's calibration curve displays a correlation value of 0.999. At 258 nm, the curve was discovered to be linear in the Beers range of 2–10 g/ml. The varied absorbance values at various concentrations are displayed in Table No. 15.

Table No. 5 Calibration curve readings by UV Spectroscopy

Sr.No.	Concentration (µg/ml)	Absorbance
1.	0	0
2.	2	0.096
3.	4	0.209
4.	6	0.304
5.	8	0.411
6.	10	0.524



Graph 2. Calibration Curve of Diphenhydramine HCl

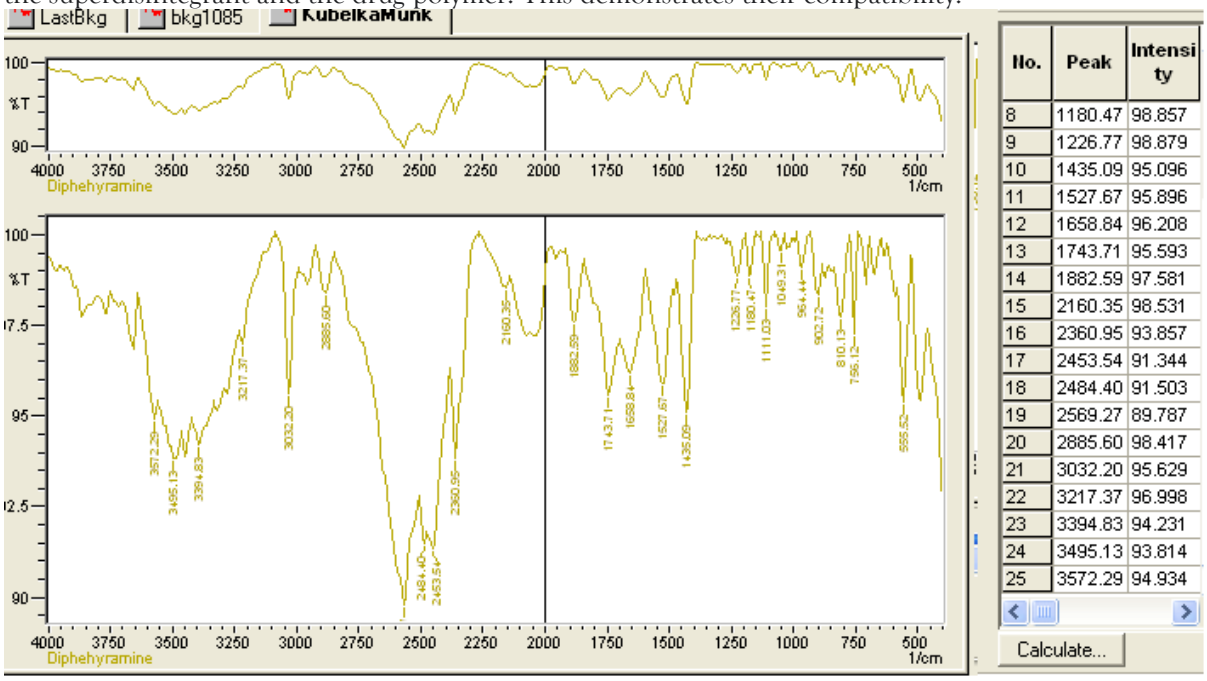
Table No. 6 Data from calibration curve in phosphate buffer pH 6.8

Sr. No.	Parameters	Values
1	Absorbance Maximum	258 nm

2	Correlation coefficient	0.999
3	Equation	Y=0.0523x-0.0041

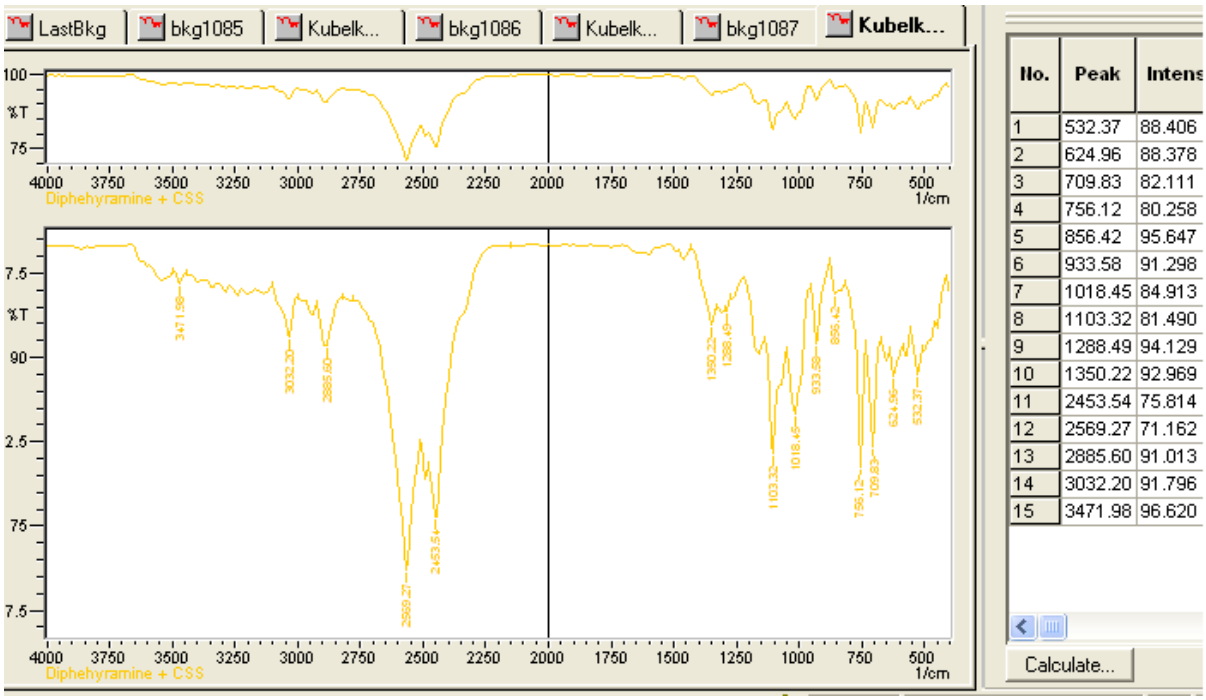
1.5 Drug – excipients compatibility study by FTIR

Diphenhydramine HCL IR spectra both alone and in combination with Superdisintegrant & Polymer are displayed. Only a minor variation in peak intensity was seen in the spectra of diphenhydramine HCL, with no discernible alteration in peak positions. The FTIR spectra of the medication with Superdisintegrant & Polymer did not exhibit any significant alterations as a result of the compatibility analysis. The outcome of the IR spectroscopy indicates that there was no chemical interaction between the superdisintegrant and the drug polymer. This demonstrates their compatibility.



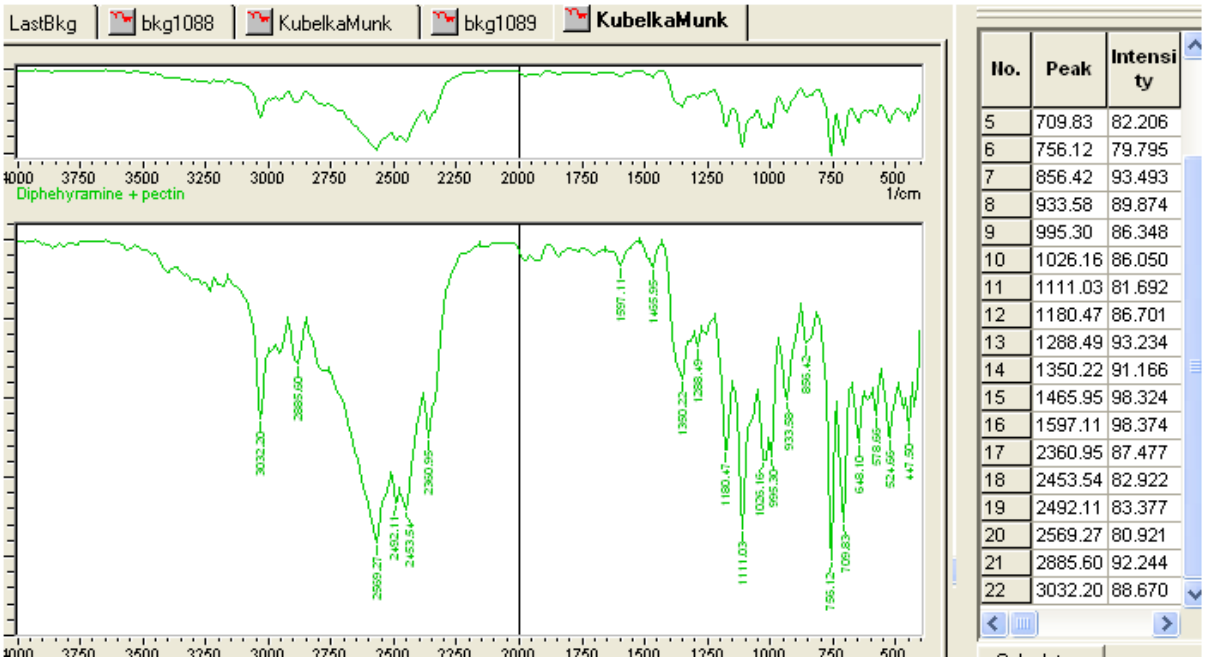
No.	Peak	Intensity
8	1180.47	98.857
9	1226.77	98.879
10	1435.09	95.096
11	1527.67	95.896
12	1658.84	96.208
13	1743.71	95.593
14	1882.59	97.581
15	2160.35	98.531
16	2360.95	93.857
17	2453.54	91.344
18	2484.40	91.503
19	2569.27	89.787
20	2885.60	98.417
21	3032.20	95.629
22	3217.37	96.998
23	3394.83	94.231
24	3495.13	93.814
25	3572.29	94.934

Figure 26. IR spectra of Diphenhydramine HCL



No.	Peak	Intens
1	532.37	88.406
2	624.96	88.378
3	709.83	82.111
4	756.12	80.258
5	856.42	95.647
6	933.58	91.298
7	1018.45	84.913
8	1103.32	81.490
9	1288.49	94.129
10	1350.22	92.969
11	2453.54	75.814
12	2569.27	71.162
13	2885.60	91.013
14	3032.20	91.796
15	3471.98	96.620

Figure 27. IR spectra of Diphenhydramine HCL + CCS



No.	Peak	Intensity
5	709.83	82.206
6	756.12	79.795
7	856.42	93.493
8	933.58	89.874
9	995.30	86.348
10	1026.16	86.050
11	1111.03	81.692
12	1180.47	86.701
13	1288.49	93.234
14	1350.22	91.166
15	1465.95	98.324
16	1597.11	98.374
17	2360.95	87.477
18	2453.54	82.922
19	2492.11	83.377
20	2569.27	80.921
21	2885.60	92.244
22	3032.20	88.670

Figure 28. IR spectra of Diphenhydramine HCL + Pectin

2. Evaluation of Fast Dissolving Film

2.1 Visual Inspection

Fast dissolving film is observed visually and listed the specification in table no. 17

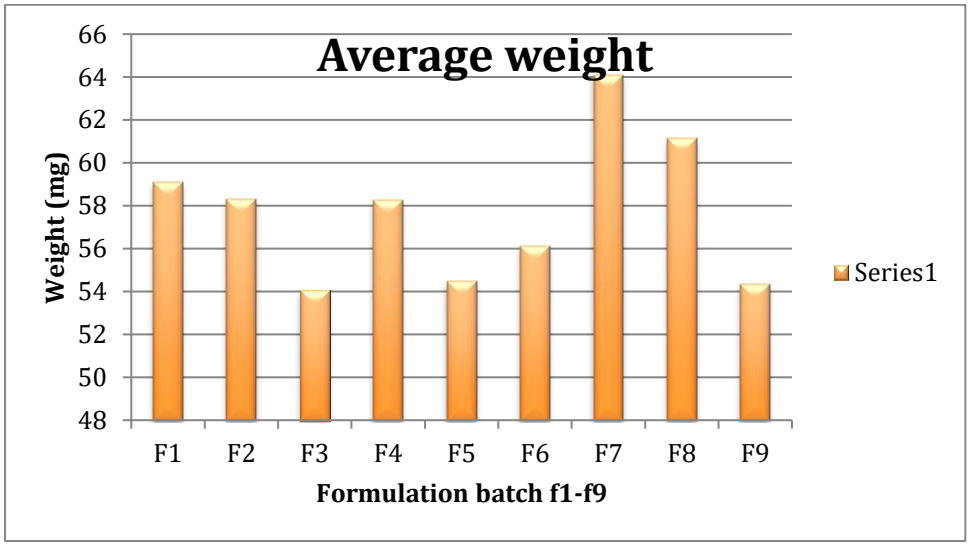
Table No. 7 Visual Inspection of Fast dissolving film

Test	Specification	Result
Description	Odourless Yellowish brown film Transparent film	Passed
Appearance	Smooth	Passed

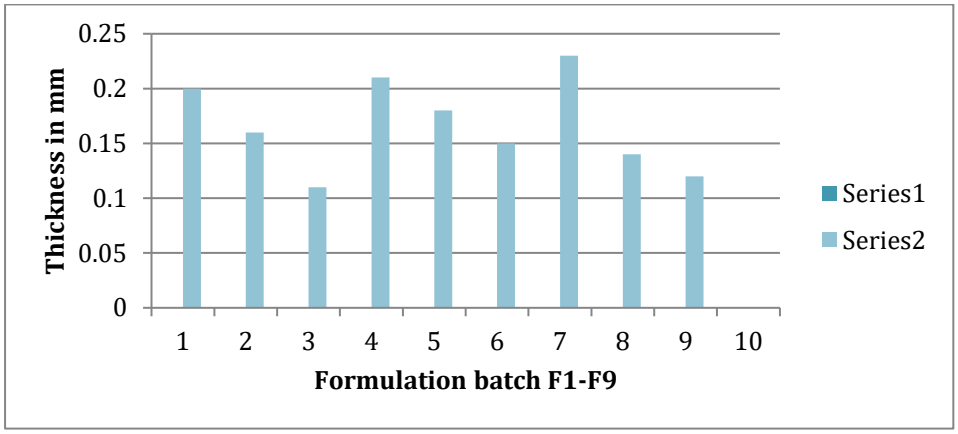
Table 8: Average weight, pH, thickness and folding endurance of formulation F1- F9

Formulation Batch	pH	Average Weight	Thickness	Folding Endurance
F1	6-7	59.11±0.5	0.20±0.005	65±0.27
F2	6-7	58.31±0.09	0.16±0.005	77±3.7
F3	6-7	54.05±0.10	0.11±0.005	95±3.6
F4	6-7	58.26±0.09	0.21±0.03	60±0.11
F5	6-7	54.45±0.08	0.18±0.011	70±1.52
F6	6-7	56.11±0.04	0.15±0.005	82±2.1
F7	6-7	64.10±0.11	0.23±0.09	52±0.08
F8	6-7	61.15±0.10	0.14±0.005	90±4.5
F9	6-7	54.33±0.08	0.12±0.01	87±2.08

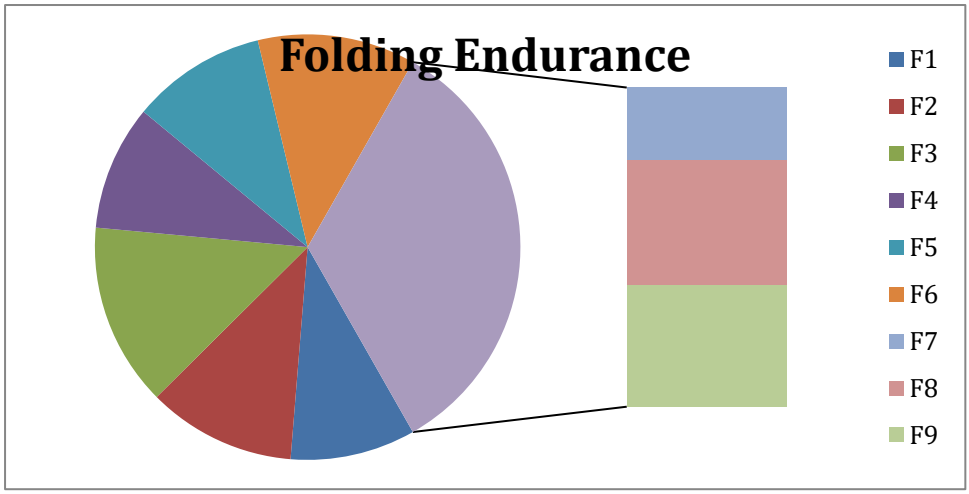
*All values are mean±SD, (n=3)



Graph 3. Average weight of Batch F1-F9



Graph 4. Thickness of Formulation batch f1- f9



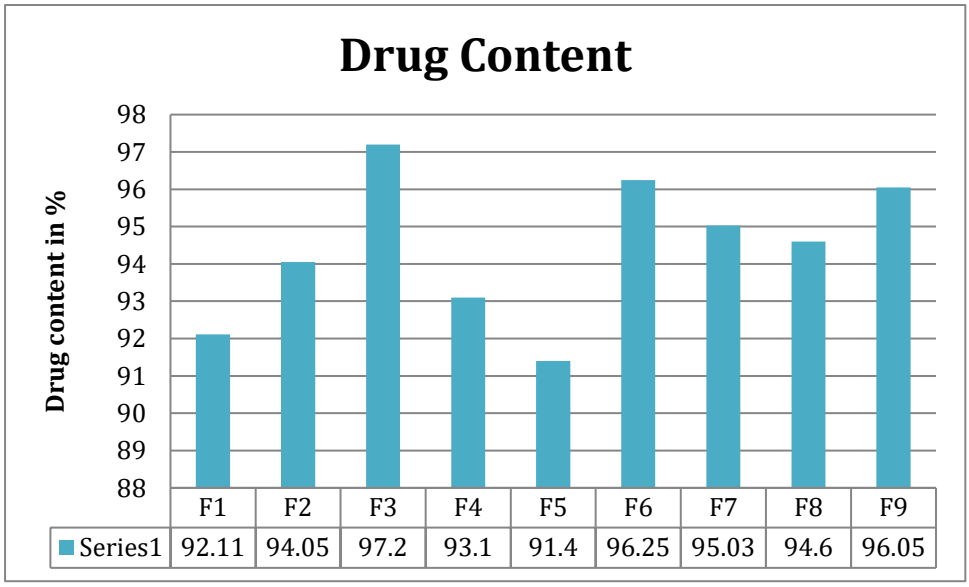
Graph 5. Pie chart of folding endurance of batch F1-F9

Table 9: Drug content, dispersion test, % moisture absorption and % moisture loss of formulation F1-F9

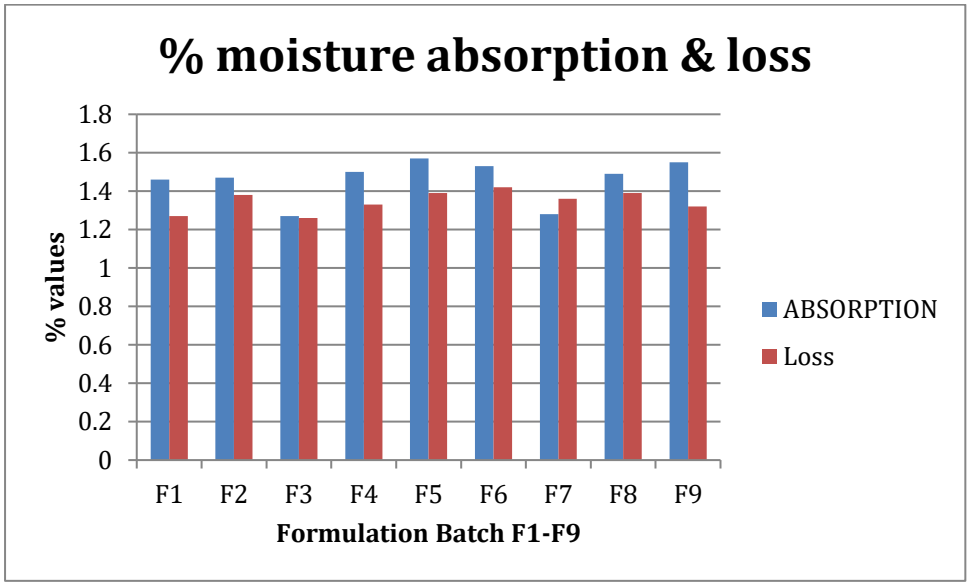
Formulation Batch	Drug Content	Dispersion Test	% Moisture aborption	% Moisture loss
F1	92.11±1.95	Passed	1.46±0.590	1.27±0.496

F2	94.05±1.10	Passed	1.47±0.930	1.38± 0.592
F3	97.20±1.15	Passed	1.27±0.031	1.26±0.598
F4	93.10±0.94	Passed	1.50±0.554	1.33±0.015
F5	91.40±1.17	Passed	1.57±0.572	1.39±0.019
F6	96.25±1.05	Passed	1.53±0.025	1.42±0.537
F7	95.03±1.01	Passed	1.28±0.549	1.36±0.525
F8	94.60±0.62	Passed	1.49±0.528	1.39±0.517
F9	96.05±0.85	Passed	1.55±0.509	1.32±0.514

*All values are mean±SD, (n=3)



Graph 8. % drug content of batch F1-F9



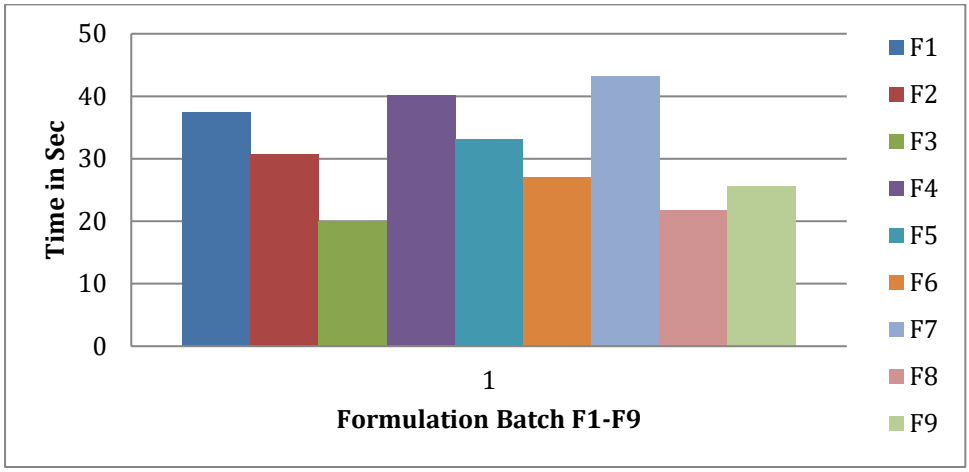
Graph 7. % moisture absorption and loss of batch F1-F9

Table 10 : In vitro drug dissolution, in vitro disintegration and in vitro wetting time

Formulation Batch	In vitro drug dissolution	In vitro disintegration	In vitro wetting time
F1	88.6±0.27	37.45±0.23	16±0.2
F2	90.04±1.02	30.77±0.49	26±0.2

F3	97.54±0.1	20.03±0.15	14±0.4
F4	94.38±0.44	40.12±0.92	20±0.2
F5	92.47±0.29	33.07±1.11	13±0.3
F6	95.5±1.13	27.08±0.29	11±0.5
F7	93.8±0.38	43.17±0.18	33±0.2
F8	96.3±0.84	21.8±0.19	16±0.2
F9	91.78±0.7	25.23±0.92	23±0.1

*All values are mean±SD, (n=3)



Graph 6. *In vitro* disintegration time

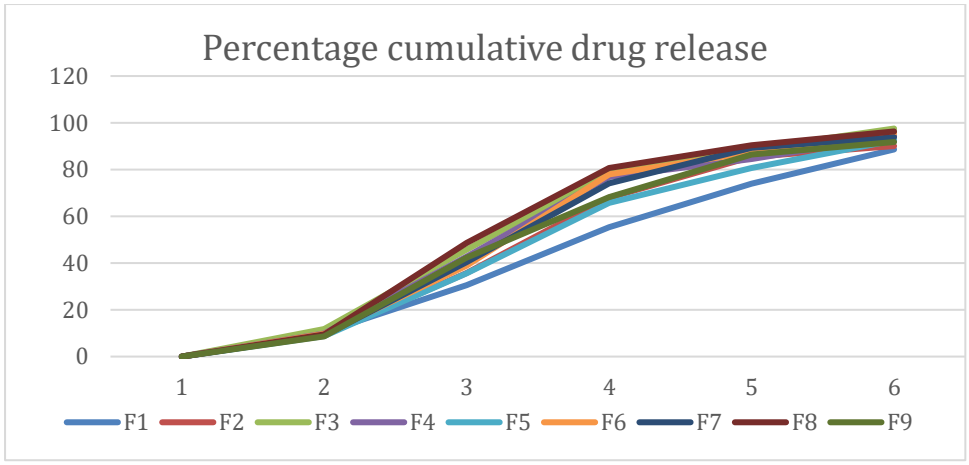
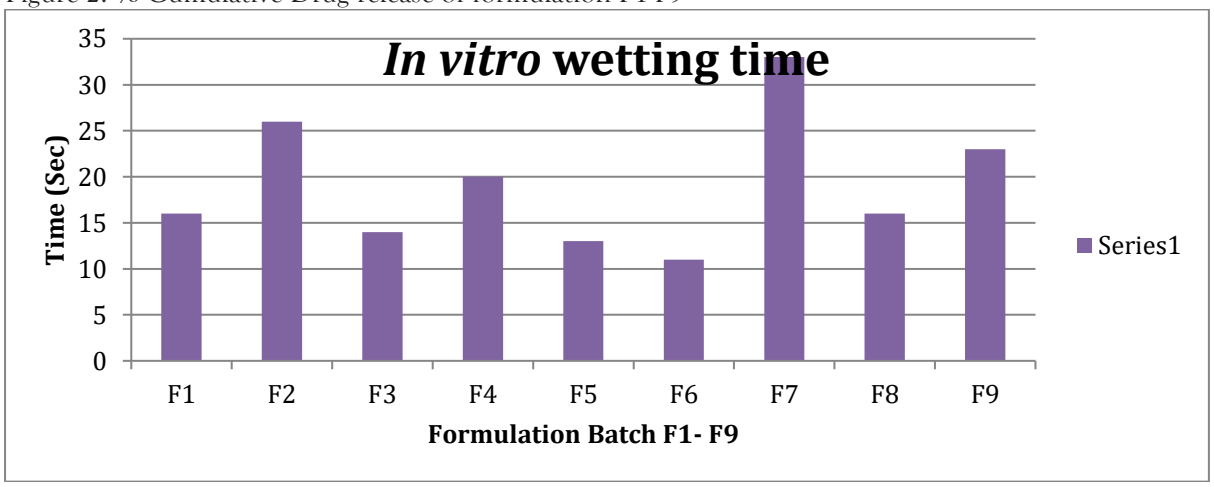


Figure 2. % Cumulative Drug release of formulation F1-F9



Graph 9. *In vitro* Wetting time

CONCLUSION-

With the aid of adjusting the concentrations of superdisintegrants such Doshion, CCS, and polymer pectin, speedy dissolving films of diphenhydramine HCL had been created. the short dissolving movie changed into created the use of the solvent casting process. Batch F3, which uses the progressive superdisintegrating agent Doshion as a fantastic disintegrant, exhibited the exceptional in vitro disintegration time and in vitro cumulative drug launch while as compared to different formulations. inside half-hour, it turned into revealed that the medication launched from formulation F3 turned into ninety seven.540.1, and the disintegration time turned into 20.030.15 sec. It was located that the folding persistence becomes 953.6. The method F3 changed into decided to be the nice formulation as a result.

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