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Development of taste masked oral formulation of Desloratadine

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Abstract
Mouth dissolving film is a Noval dosage form which disintegrates in mouth within seconds with rapid onset of action and most convenient for oral route of administration. Patient compliance will be impediment for bitter drugs become unpleasant unless taste masked. Desloratadine is an antihistaminic and often prescribed for elderly and children hence the objective of this study is to develop a pleasant, patient friendly mouth dissolving film with superior patient compliance. Taste masking of Desloratadine was done with resin indion-204 and indion-234 complexation. The taste masked complex was formulated as mouth dissolving film Superior product performance characteristics were observed in terms of Disintegration time, vitro drug release all remained stable during the stability trial a laboratory scale up was performed to ensure the feasibility of commercial manufacturing.

Keywords: Desloratadine, bitter taste, complexation, stability, antihistaminic, mouth dissolving film

Introduction

Among the different routes of administration, the oral route of administration continues to be most preferred route due to various advantages including ease of administration, avoidance of pain, versatility and most importantly patient compliance. Many patients especially geriatric and paediatric have difficulty to swallow the tablets and hard gelatin capsules [1]. Fast dissolving drug delivery systems (FDDDS) were developed as an alternative to tablet, capsule and syrups Oral fast dissolving film is relatively a new dosage form in which thin film is prepared using hydrophilic polymers, which rapidly disintegrate or dissolves on tongue or in the buccal cavity. Oral administration is the most popular route due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates), and most importantly, patient compliance. But the most evident drawback of oral dosage forms like tablets and capsules are difficulty in swallowing, leading to patient's incompliance particularly in case of pediatric and geriatric, bedridden, nauseous patients. Fast dissolving drug delivery systems (FDDDS) were developed as an alternative to tablet, capsule and syrups [2]. These systems consist of the solid dosage forms that disintegrate and dissolve quickly in the oral cavity without the administration of water. Rapid-dissolving oral thin film is a solid dosage form, which disintegrate or dissolve within 1 min when placed in the mouth without drinking of water or chewing. After disintegrating in mouth, enhanced the clinical effect of drug through pre-gastric absorption from mouth pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form [3].

Allergic rhinitis (AR) is allergen driven immune mediated disorder characterized by nasal congestion, nasal pruritus, rhinorrhea, and sneezing. Traditionally, AR is classified as Seasonal or Perennial. According to Allergic Rhinitis and its Impact on Asthma guidelines, AR can be broadly classified into intermittent (≤4 days/week or ≤4 weeks/year) or persistent (>4 days/week or >4 weeks/year) [4]. Exhaustive literature survey shows that about 40% of the children are suffering from AR, but still these figures seem conservative as AR is often confused with common cold by physicians. Desloratadine (DSL), a descarboethoxy derivative of loratadine, is a second generation anti histaminic drug approved by FDA for paediatric usage. It is given as dose of 1.25 mg for children aged 2-5 years, that is, preschool children and 2.5 mg for children aged 6-11 years [5].

Materials and Method

Materials: Desloratadine was obtained as Zydus Cadila Health Care Pvt. Ltd., Indion 204, Indion 234, HPMC E-5, PVA, Sodium CMC, PEG-400, and Sodium saccharin, Citric acid, Indion 204 Indion 234 was obtained from loba chemicals.

Preparation of Reagent

Preparation of 0.1 N Hydrochloric Acid Solution (HCL)

To make 0.1N HCL, we took 8.5 ml of concentrated HCL and diluted it with 1000 ml of distilled water.

Preparation of Buffer 6.8 pH

An appropriate amount of distilled water (1000 ml) was added to a solution containing 8 gm of sodium chloride, 0.19 gm of potassium dihydrogen phosphate, and 2.38 gm of disodium hydrogen phosphate to create a saline buffer [6].

Calibration Curve

Calibration curve of Desloratadine by UV-Spectrophotometry in 0.1N Hydrochloric Acid Solution (HCL)

Desloratadine (10 mg) was dissolved in 0.1 N hydrochloric acid solution (HCL) to make a 100 g/ml standard stock solution. Different concentrations were generated from the stock solution (100 g/ml) by diluting appropriate quantities of stock solutions to

100 ml with 01 N HCL, yielding final concentrations of 2, 4, 6, 8, 10, 12, 14, and 16 g/ml. at 241 nm, we found that the absorption was maximum. The relationship between concentration and absorbance was represented as a calibration curve [7].

Purification of Ion-Exchange Resin: Ion exchange resin has to be purified so that the contaminants caused by production on an industrial scale could be eliminated. Under magnetic stirring, 10 grams of wet resin were rinsed with 3 to 5 milliliters of deionized water, 50 milliliters of 95% ethanol, and 50 milliliters of deionized water to purify it. Resin was recovered through vacuum filtering after being rinsed with 60 ml of 2M NaOH, 60 ml of 2M HCL, and deionized water at each step.dried after being washed in deionized water. Put through sieve 100 to get particles of the same size.

Preparation of Drug Resin Complex (RESINATE)

Complexation with ion exchange resins, such as Indion 234 and Indion 204, is used to hide the taste of Desloratadine. A batch procedure was used to make the resonates. Slurry composed of ion exchange resin and deionized water was created. The polymer structure was allowed to expand equally by stirring the mixture on a magnetic stirrer. The medication was diluted in 100 ml of distilled water and added to the resin slurry, which was then agitated constantly for 24 hours until equilibrium was reached. To eliminate any uncomplexed medication, the resulting resinate was filtered using Whatman filter paper No. 42 and rinsed with a large volume of deionized water. The drug concentration was then measured spectrophotometrically after drying at 50 °C for 1 hour in a tray drier [8, 9].

Effect of Polymer: Drug Ratio on Drug Loading

Resin was used to create four batches of drug-resin at various concentrations (1:1, 1:2, 1:3, and 1:4). Drug concentration in loading solution was evaluated by spectrophotometry at 241 nm using 0.1N HCL as a blank after 3 hours of stirring. The blank solution was filtered through Whatman filter paper No. 42.

Effect of pH on Drug Loading

We made two solutions, each with around 1 gram of medication in 100 milliliters of water. Solutions were made with a pH range of 3.5, 5.0, 6.0, 7.0, and 8.0. After adding the resin (3g), the solution was agitated for three hours using a magnetic stirrer. The residual drug content in the loading solution was measured by spectrophotometry at 241 nm after the Resinate was filtered through Whatman filter paper No. 42 using 0.1N HCL as a blank [10].

Effect of Temperature on Drug Loading

Solutions containing the drug and resin in the optimal ratio, kept at the optimal pH, and swirled on a magnetic stirrer at room temperature 30 °C, 40 °C, 50 °C, and 60 °C were used in the investigation. Using Whatman filter paper No. 42 and deionized water, resinates were filtered after 3 hours. Using 0.1N HCL as a blank, the residual drug content in the loading solution was calculated using spectrophotometry at 241 nm [11].

Determination of Drug Content in the Resinate

After carefully measuring out 100 mg of resinate, 90 minutes were spent mixing it with 100 ml of 0.1N HCL to get the drug's equivalent. After further diluting the solution with 0.1N HCL as a blank, the drug concentration was measured spectrophotometrically at 241 nm. The suspension was filtered using Whatman filter paper No. 42 [12].

Characterization of DPC

Fourier Transform Infra-Red (FTIR)

Desloratadine, Indion 234, Indion 204, and the drug-polymer complex were all analyzed utilizing an FTIR -8300 model, shimadzu, to collect their respective infrared spectra. The spectra were acquired from 4000 to 400 cm-1 after the pellets were manufactured on a KBr press. The acquired spectra were compared to reference spectra to verify the correct drug/excipient identification [13].

Differential Scanning Calorimetry (DSC)

Differential scanning calorimeter (Perkin-Elmer, Pyris-I, MA, USA) readings were captured. Aluminum pans containing 5 mg samples were sealed and heated to 250 °C at a rate of 10 °C/min. Indium was used in the equipment's calibration process. The samples were heated between 50 °C to 250 °C. If more heating to 250 degrees Celsius was needed, cooling to -10 degrees Celsius was used first [14].

Evaluation of Drug-Polymer Complex

% Yield

Percentage The percentage yield or efficiency of any given technique may be determined by calculating the practical yield of Desloratadine, which in turn aids in the selection of the most suitable method of production. The amount of drug polymer complex that could be recovered from each batch was used to determine the practical yield. The following equation was used to determine the yield.

$$\%\ Yield = \frac{Weight\ of\ complex\ obtained}{Theoretical\ weight\ of\ complex} \times 100$$

Taste Evaluation: *In vitro* taste sensing system: Insent TS-5000Z

For this analysis, researchers employed the TS-5000 Z taste sensing system at the lab of S. Zhaveri Pharma chem Pvt Ltd in Dombivali-Thane, Maharashtra, India.

Sensors

The TS-5000Z taste sensor equipment (Insent Inc., Japan) was used for all of the measurements. This artificial tongue had four reference electrodes and four lipid membrane sensors labeled with descriptions of various flavors. CPA1 CO0 for acidic bitterness, CPA1 AN0 for neutral bitterness, and CPA1 BT0 for sweet bitterness. Basic bitterness scores of 0 on the AN and BT scales. Astringency (CPA1 AE1) and other gustatory sensations were represented by the fourth sensor. Insent Inc., a Japanese company, created the BT0 sensor especially for this investigation. The synthetic lipid in BT0 is phosphoric acid di-n-decyl ester, while the plasticizer is Bis (1-butylphenyl) adipate. Particularly useful for hydrochloride salts, which may be some what bitter. Due to the fact that Desloratadine is not a hydrochloric salt, BT0 was not employed in the bitterness analysis. It is possible to quantify the "aftertaste" for bitterness, umami, and astringency [15, 16].

Sensors AN0, CO0, and AN1 all picked up on the bitterness. Each sensor had 0. 2 cc of the inner solution inserted into it before the studies began. One day before to the test, all sensors were

preconditioned in standard solution.

Preparation of Standard and Washing Solutions

Standard and washing solutions were prepared using experimental methods that satisfied the specifications of the Insent system. Both the positive and negative sensors need to be washed in different solutions because of their opposite charges. A 100 mmol/L Potassium chloride and 10 mmol/L Potassium hydroxide solution was used to clean the positively charged sensors. While 100 mmol/L of hydrochloric acid and 30% ethanol (diluted from absolute ethanol) make up the negatively charged sensor. Any ordinary solution will do as a cleaner. The reference solution was made by dissolving 30 mmol/L of potassium chloride and 0.3 mmol/L of tartaric acid into 1 liter of distilled water [17].

Preparation of Stock Solution

A solution of 10mM KCL and 1N HCL were both made in advance. Desloratadine (120 mg) was dissolved in a mixture of 10mM KCL and 1N HCL (1.0 ml). A final volume of 500 ml was achieved by adding 10 mM KCL. Stock Solution (240 ppm) was prepared using this solution. Table 1 shows the specifics of how the remaining linearity solutions with concentrations between 2.88 ppm and 180 ppm were made. To make them, we used a 10 mM KCL solution to dilute 100 mL of stock solution [18].

Preparation of Desloratadine Solution

Desloratadine was dissolved in distilled water to make sample solutions. All of the samples were made up in a 10 mM KCl solution with a final desired concentration of 32.44 ppm of Desloratadine. All of the samples were analyzed, and the process was repeated four times. Each sample was sonicated in an Ultrasonic bath for three minutes. UV spectroscopy at 240 nm was used for analysis, and a 0.22-micron Whatmann filter G4 was used for filtration before being sent through the electronic tongue system. According to the specifications of the Insent System, the first mV measurements were thrown away (this guarantees the conditioning of sensors). The statistical analysis of all the collected data for each sample was performed by the system's own software [19].

Table 1: Sample preparation for linearity evaluation of Desloratadine

Desloratadine concentrations (ppm)	Amount of Stock solution added (ml)
2.88	1.2 ml
12	5.0 ml
60	25 ml
120	50 ml
180	75 ml

Procedure of Mouth dissolving film Preparation

Solvent casting is the preferred process for creating mouth dissolving films because it allows for the dissolution of water-soluble components into a clear, viscous solution. A suitable solvent is used to dissolve the medication and any excipients. The two solutions are combined, agitated, and then cast onto the prepared Petri dish, which is then dried Solvent casting was used to create the optimal mouth dissolving dosage form of Desloratadine the excipients were dissolved in distilled water and then put into the Petri dish after being well mixed.

Table 2: Formulation of Mouth dissolving film Using HPMC E5

Ingredients	Formulation code			
	A1	A2	A3	A4
Drug: resin complex Desloratadine: Indion-204 (Equivalent to 5 mg Desloratadine) gm)	0.960	0.960	0.960	0.960
HPMC E-5 (%)	1	2	3	4
PEG-400 (ml)	0.12	0.24	0.36	0.48
Citric acid (gm)	0.31	0.31	0.31	0.31
Sodium saccharin (gm)	0.11	0.11	0.11	0.11
Water (ml)	QS	QS	QS	QS

Evaluation of mouth dissolving film of Desloratadine

Determination of Weight Variation

The films were measured and sliced into (2x2 cm^2) Electronic balance was used to figure out the difference in weight.

Thickness

A micrometer screw gauge may be used to precisely measure it at several predetermined points. This is crucial for ensuring consistent dosing in the strip by measuring film thickness uniformly.

Folding Endurance

To test the strip's folding durability, fold it over and over again at the same spot until it snaps. The folding endurance of a film is measured by counting the number of folds it can withstand before tearing.

***In-vitro* Disintegration Studies**

The film's disintegration and dissolution properties might be inferred from its disintegration time. The film used in this experiment measured exactly (2x2 cm^2) and was put in a beaker containing 10 milliliters of artificial saliva. The *in vitro* disintegration time was recorded as the amount of time the film took to shatter.

Determination of Drug Content

Desloratadine concentration was calculated by dissolving sheets of known area (2x2 cm2) in 0.1 N HCL. Absorbance at 241 nm (using a UV-VIS double beam spectro-photometer) was used to quantify the concentration of Desloratadine in the sample. An R2 = 0.997 standard calibration curve of 0.1N HCL was used to calculate the drug concentration

***In-vitro* Dissolution Studies:** 0.1N HCL was also used in the dissolving test. After that, we put each film sample (equal to 5mg of medication) into the dissolving medium. 37±0.5ºC At, 50 rpm, and with 900 ml of each dissolving media, a dissolution study was conducted using a tablet dissolution USP (XXI)/(XXII), (Electrolab). Using a spectrophotometer set at 241 nm (UV-VIS) [20].

Results and Discussion

Taste Masking

Scanning of Desloratadine by UV Spectrophotometry:

Desloratadine was scanned using the approach outlined in Section of the methodology.

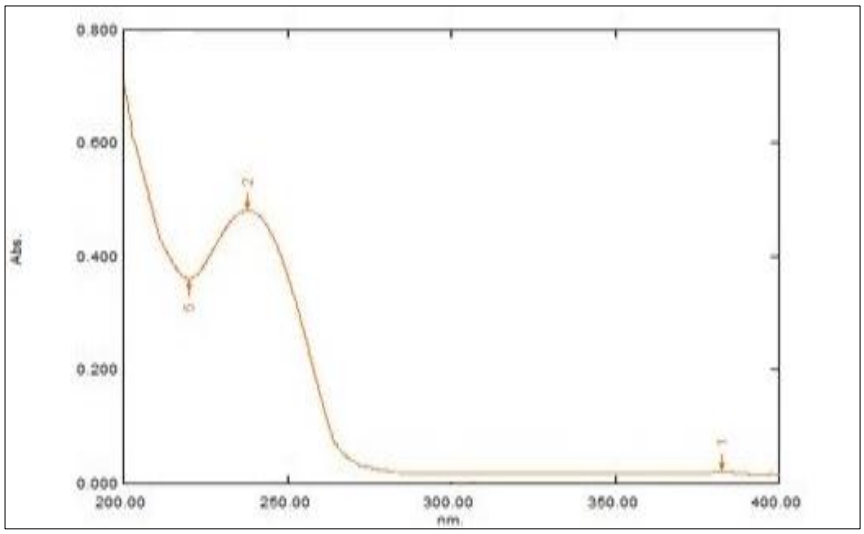

Fig 1: UV Spectra of Desloratadine in 0.1 N HCL at 241nm

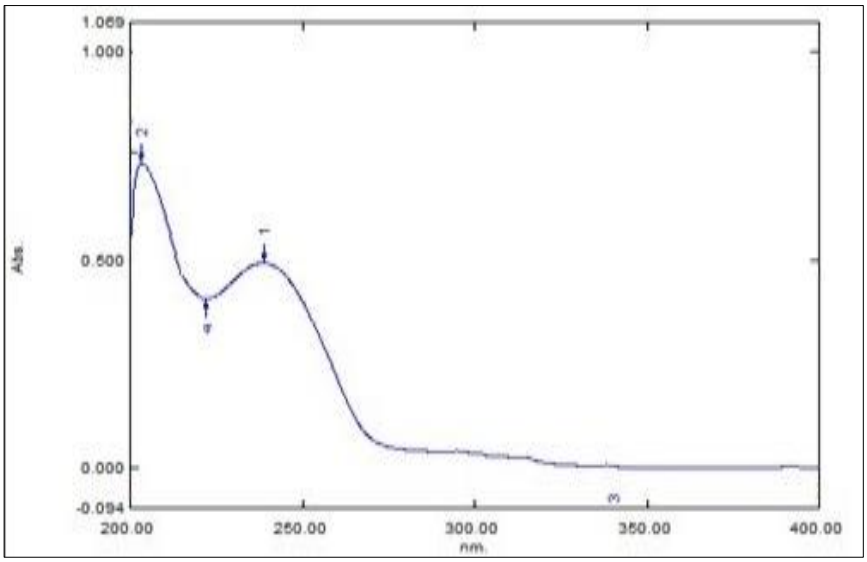

Fig 2: UV Spectra of Desloratadine in methanol at 241nm

Calibration Curve

Desloratadine calibration curves were generated using the approach outlined in the methodology section.

Calibration Curve of Desloratadine by UV Spectrophotometry in 0.1 N HCL

Table 3: Calibration Curve of Desloratadine in 0.1 N HCL

Concentration (µg/ml)	Absorbance (mean±SD)
0	0.000±0.000
2	0.102±0.0032
4	0.162±0.0005
6	0.251±0.0040
8	0.327±0.0015
10	0.410±0.001
12	0.515±0.002
14	0.581±0.0015
16	0.642±0.0015

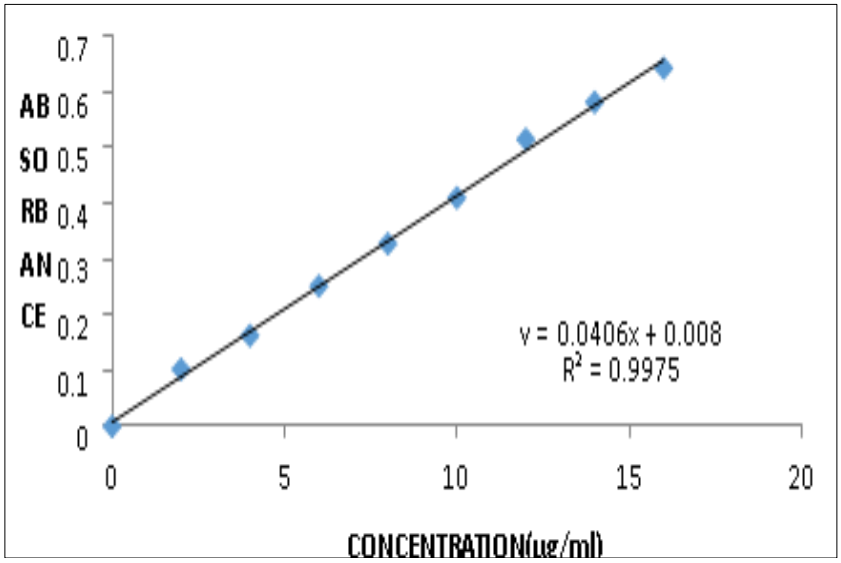

Fig 3: Calibration curve of Desloratadine in 0.1 N HCL

Characterization of Drug and resins

FTIR of Drug, Resins and Resinate

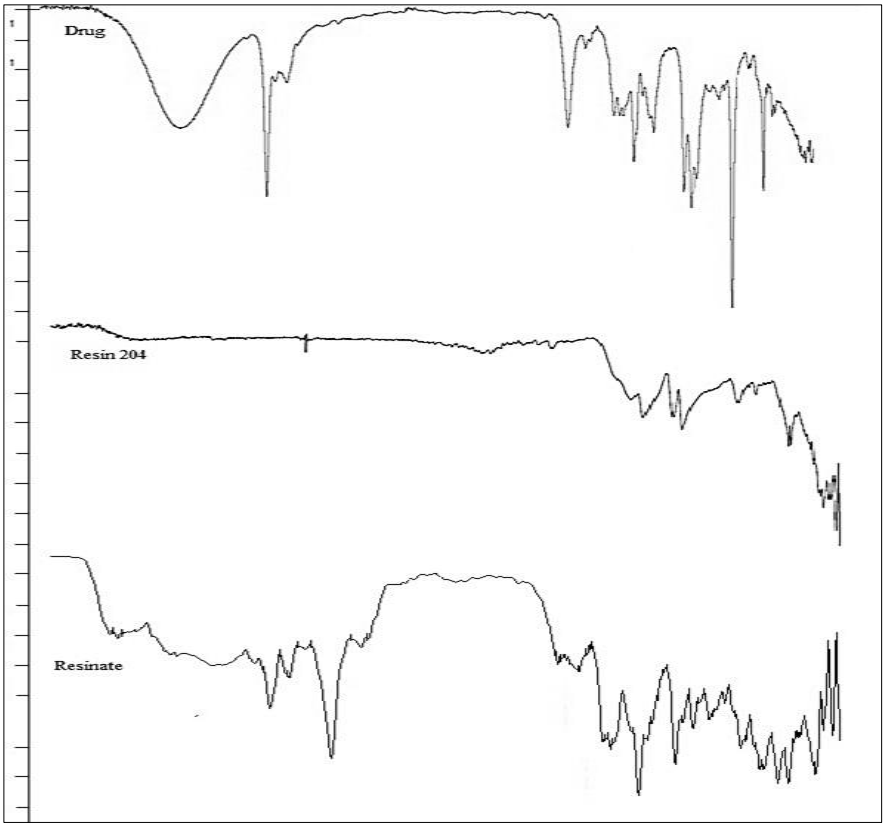

Fig 4: FTIR spectra of drug, resin and Resinat

FTIR spectroscopy was used to investigate how Desloratadine interacted with the excipients included in the formulations. The KBr press was used to produce the pellets for the FTIR analysis. The spectra were collected from 4-400 cm-1, which is a range of wave numbers. Infrared spectra of Desloratadine showed many prominent peaks, including those at 3324.64 (3300-3400) cm-1 (N-H) stretching of 2 -amine, 1704.73 (1665-2000) cm-1 (C=C), 1279 cm-1 (C-N) stretching of tertiary amine, and 727.11 (600-800) cm-1 (C-CL) stretching in the benzene ring. DRC's lack of peaks at 1705 cm1 and 1279 cm1 shows that drug and resin have formed a complex. The absence of the 3297.90 cm-1 peak in DRC corresponding to -OH stretching indicates that the amino group of the medication interacts with the carboxyl group of the resin during DRC synthesis.

Differential Scanning Calorimetry (DSC)

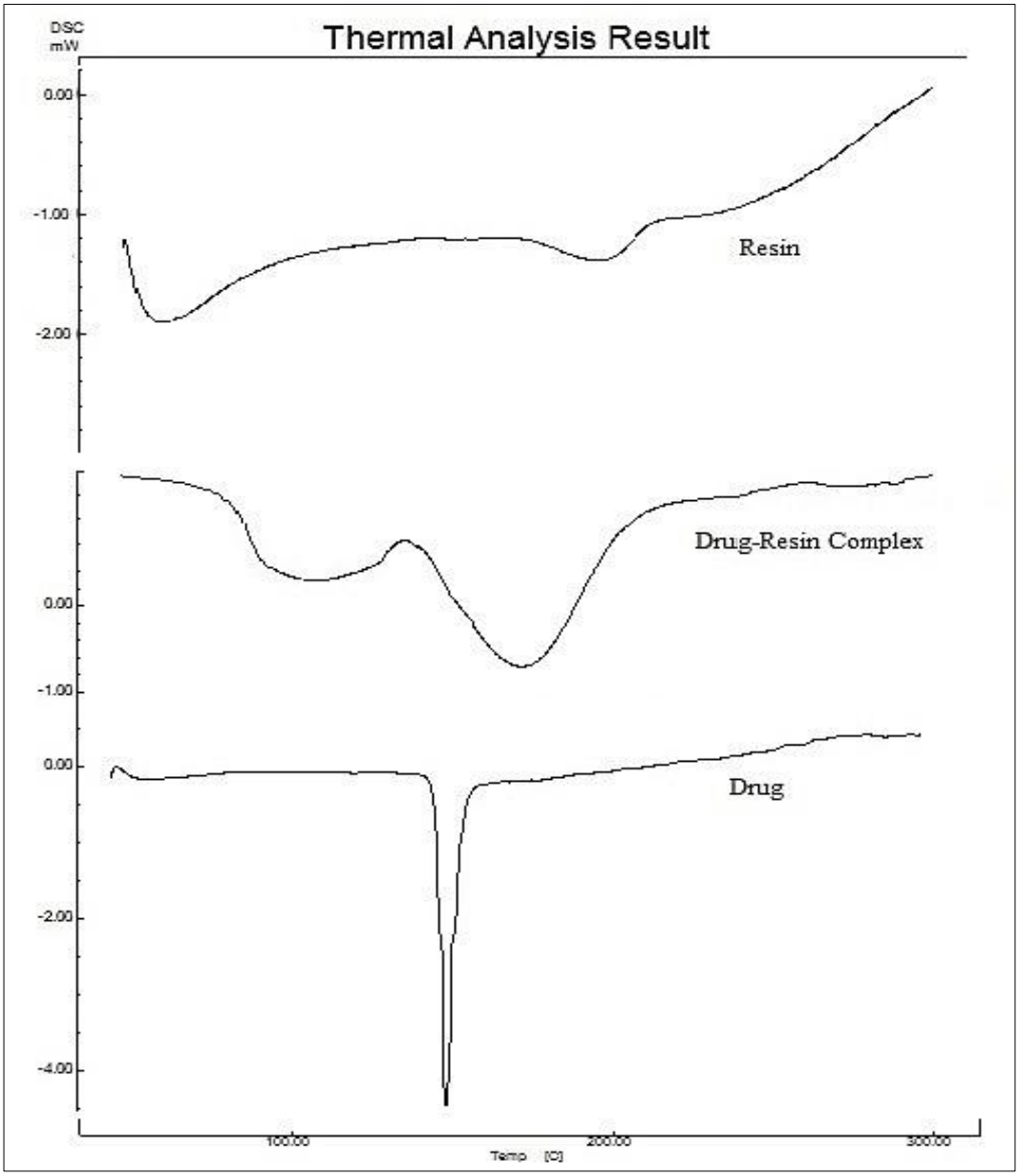

Fig 5: DSC thermo gram of Drug, Resin and Resinate

DSC analysis was performed on the samples by the Japanese company Shimadzu. The samples were stored in an aluminum container that had been cut open. Research was conducted at a heating rate of 10 degrees Celsius per minute in a static air environment with temperatures ranging from 50°C to 250°C. After comparing to a standard, the maximum temperatures were calculated. Desloratadine's melting point, as shown on a DSC thermogram, corresponds to an endothermic peak at 151°C. An interaction between the medication and the resin was indicated by an endothermic peak in the melting temperature of the resin at 162 °C with the peak intensity decreasing as the melting temperature increased.

Optimization of Drug Loading for Indion-204

- The preparation of drug-resinate was perfected by adjusting the pH and temperature during the sorption process and the percentage of drug-resin used. Experiments were conducted using the cation exchange resins Indion-234 and Indion-204 for batch loading.
- In under three hours, using Indion 204, a 96.83% drug-resin combination was produced at a 1:3 ratio.
- After using the optimal ratio at pH levels between 4.2 and 8, including 5, 6, 7, and 8. The highest percentage of complex formation was found at a pH of 7.7 compared to the other pH values considered. Evidence suggests no drug-resin compound was formed in an acidic environment.
- After using the ideal ratio and pH at temperatures of 30, 40, 50, and 60 degrees the highest percentage of complex production occurs at a temperature of 40 degrees Celsius, when 98.56 percent of complexes are created.

Table 4: Amount of complexed drug of different drug to resin (Indion 204) ratio

Drug: Resin Ratio	Time (hrs.)	Free Drug (%)	Complexation Efficiency (%)
1:1	3	34.00	64.00
1:2	3	01.00	94.55
1:3	3	00.75	96.83
1:4	3	01.25	94.71

Table 5: Amount of complexed drug of different drug to resin (Indion 234) ratio

Drug: Resin Ratio	Time (hrs.)	Free Drug (%)	Complexation Efficiency (%)
1:1	3	46.00	51.00
1:2	3	09.00	86.00
1:3	3	03.00	92.31
1:4	3	04.00	93.27

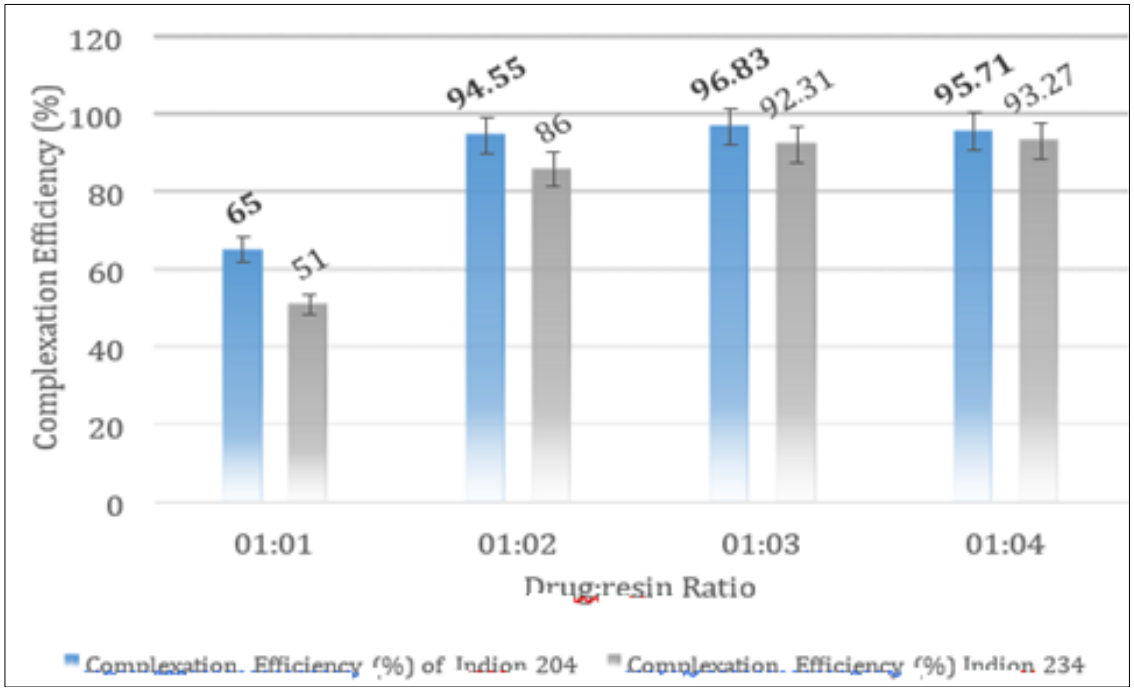

Fig 6: Chart for amount of complexed drug of different drug to resin (Indion 234 &Indion 234) ratio

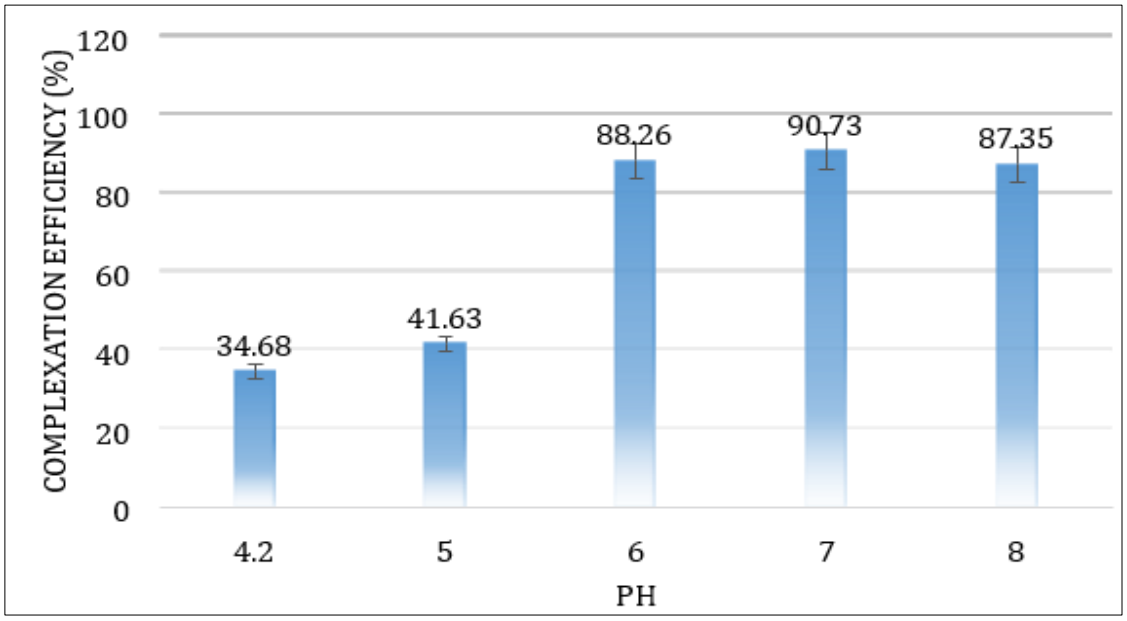

Fig 7: Graph showing the effect of pH on Complexation efficiency

Table 6: Amount of complexes drug for different times of mixing using Indion 204

Drug: Resin Ratio	Time (hrs.)	Free Drug (%)	Complexation Efficiency (%)
1:3	3	00.79	96.55
1:3	4	00.77	96.61
1:3	5	00.75	96.79
1:3	6	00.75	96.95
1:3	7	00.64	97.35
1:3	8	00.60	97.35

Table 7: Amount of complexed drug for different pH using Indion 204

pH	Drug: Resin Ratio	Time (hrs.)	Free Drug (%)	Complexation Efficiency (%)
4.2	1:3	3	64.75	34.68
5	1:3	3	58.37	41.63
6	1:3	3	11.73	88.26
7	1:3	3	09.26	90.73
8	1:3	3	10.65	87.35

Table 8: Amount of complexed drug for different temperature using Indion 204

Temperature	Drug: Resin Ratio	Time (hrs.)	Free Drug (%)	Complexation Efficiency (%)
30° C	1:3	3	02.54	97.46
40° C	1:3	3	01.43	98.56
50° C	1:3	3	07.05	91.95
60° C	1:3	3	14.76	83.21

Complexation efficiency (%)

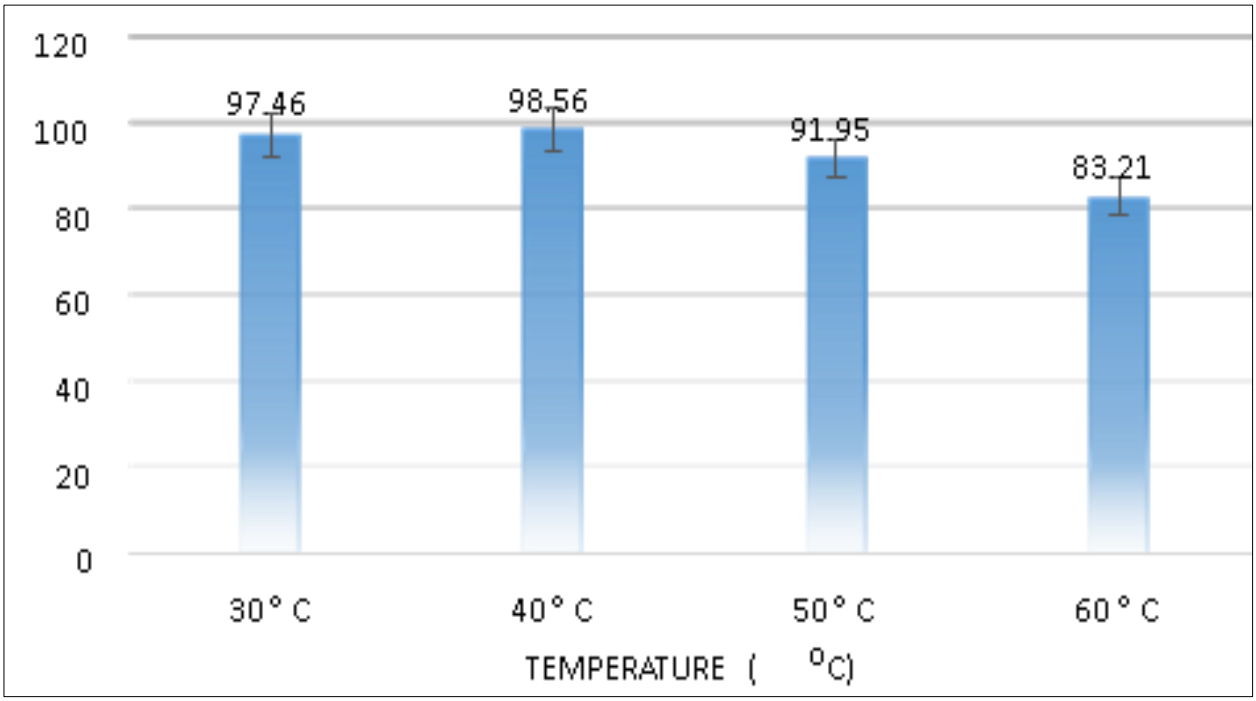

Fig 8: Graph showing the effect of temperature on Complexation efficiency

Evaluation of drug-polymer complex

Table 9: Evaluation parameter of drug-polymer complex for indion-204

Sr. No.	Parameter	Result (n3)
1	%Yield	83.00%
2	Angle of repose	29.88±0.16°
3	Carr's index	11.41±0.022
4	Hausner's Ratio	1.20±0.015

% Yield

These metrics are crucial for understanding how effective the complexation procedure is. It's useful for deciding which manufacturing technique to use. Complexation was found to have a yield of around 83%.

Flow Property

Angle of Repose

It is a tool for approximating the powder's flow characteristics. The

angle of rest was calculated to be 29.88±0.16° Therefore, the results suggested powder due to its high flow characteristic.

Compressibility Index

Powders and granules may have their compressibility estimated with the use of a metric called carr's index. The compressibility index is the easiest way to quantify the ease with which a powder flows. Here, the number was 11.41, which is less than 15, and hence indicative of a powder that often gives rise to outstanding flow characteristics.

Hausner's Ratio (H)

Powder flowability may be measured indirectly by this. As in the previous case, the lower the Hausner's ratio (1.25), the better the flow qualities.

Taste Evaluation

***In vitro* Taste Sensing System: INSENT TS- 5000 Z**

Table 10: Electrical response of sensor to Desloratadine

Desloratadine concentration (ppm)	Electrical Response of Sensors		
	CO0	AN0	AE1
Characteristics	Acidic groups	Basic Groups	Astringent
2.88	0	0	0
12	0.3±0.37	1±0.36	0.7±0.15
60	0.5±0.45	4±0.15	0.4±0.87
120	0.7±0.36	7±0.84	0.7±0.40
180	0.8±1.25	8±0.32	0.8±0.64
240	0.8±0.72	8±0.17	0.8±1.21

Table 11: Desloratadine Solutions for Taste Analysis

Batches	Concentration (ppm)	Original CPA (CO0)(mV)	Estimated CPA(CO0)(mV)
DF1 (Placebo batch)	36.24	0.37±0.15	0.26±0.43
DF2 (Desloratadine)	36.24	0.62±0.39	0.59±0.52
DF3 (Desloratadine with Indion 204)	36.24	0.67±0.55	0.36±0.16

Table 12: Comparison of Bitterness Score and Sensor Response for Quinine Hydrochloride

Concentration of Quinine hydrochloride (ppm)	Bitterness Score	CPA (CO0)(mV)	Calculated Bitterness Score
1.56	1	0.30	1.26
8.30	2	0.49	2.12
10.82	3	0.57	2.94
16.23	4	0.64	3.38
24.35	5	0.72	4.05

Table 13: Samples for human sensory testing

Combination solutions for human sensory panel	Quinine concentration (mM)	Indion 204 concentration (% w/v)
Bitterness score 4 + low concentration of Indion 204	16.23	0.0003
Bitterness score 5 + low concentration of Indion 204	24.35	0.0003
Bitterness score 6 + low concentration of Indion 204	32.44	0.0003
Bitterness score 4 + Moderate concentration of Indion 204	16.23	0.003
Bitterness score 5 + Moderate concentration of Indion 204	24.35	0.003
Bitterness score 6 + Moderate concentration of Indion 204	32.44	0.003
Bitterness score 4 + High concentration of Indion 204	16.23	0.001
Bitterness score 5 + high concentration of Indion 204	24.35	0.001
Bitterness score 6 + High concentration of Indion 204	32.44	0.001

As measured by a reduction in the bitterness intensity as Change in Membrane Potential (CPA values) perceived as "After Taste" from 0.67mv to 0.36mv, Indion 204 was shown to be an improved taste masking agent for Desloratadine. Sample score is good & found bitter less after treatment of Desloratadine API with Indion 204 resin at the 1:3 ratios (Desloratadine: Indion 204, 1:3 ratio).

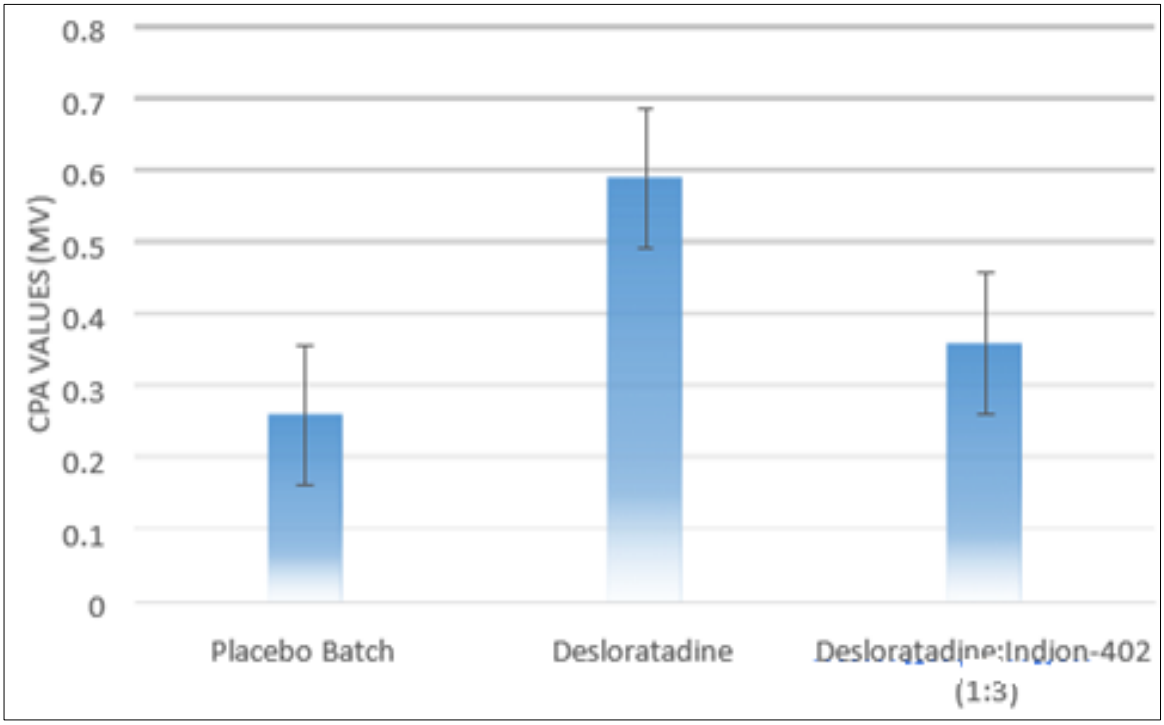

Fig 9: Graph showing bitterness value of Desloratadine and Desloratadine: Indion-402 (1:3) Compl

Formulation of mouth dissolving film

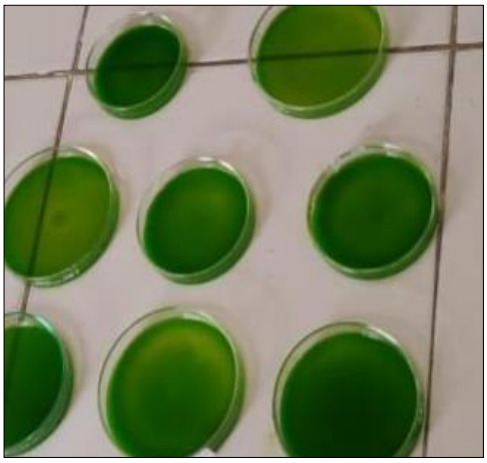

Fig 11: Desloratadine mouth dissolving film in petridish

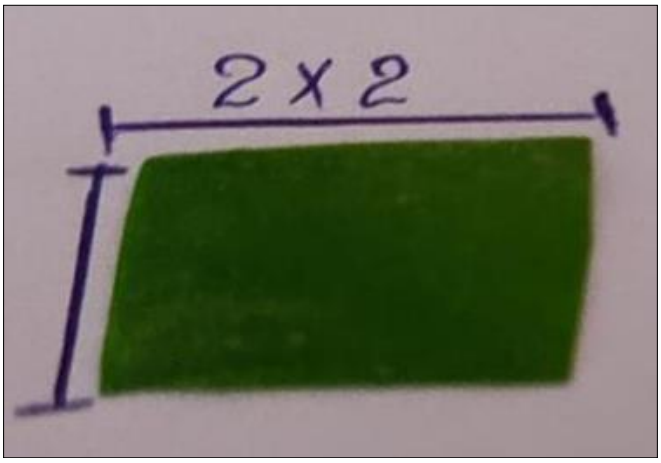

Fig 12: Desloratadine Mouth dissolving film in cutted 2x2 cm^2

Table 14: Evaluation data of mouth dissolving film of Desloratadine

Formulation	Weight variation (mg) Mean±SD	Thickness (mm) Mean±SD	Folding endurance (Times) Mean±SD	Drug Content (%) Mean±SD	Disintegration Time (sec) Mean±SD
F1	10.03±0.17	0.052±0.005	410.00±.29	99.56±0.57	7.61±0.48
F2	12.18±0.12	0.057±0.016	420.33±2.45	98.51±.79	10.66±0.47
F3	12.76±0.25	0.060±0.008	434.00±.28	98.19±.74	12.22±0.58
F4	12.46±0.11	0.058±0.019	424.00±4.23	98.42±.11	10.93±0.13

***In vitro* dissolution study of mouth dissolving film of Desloratadine**

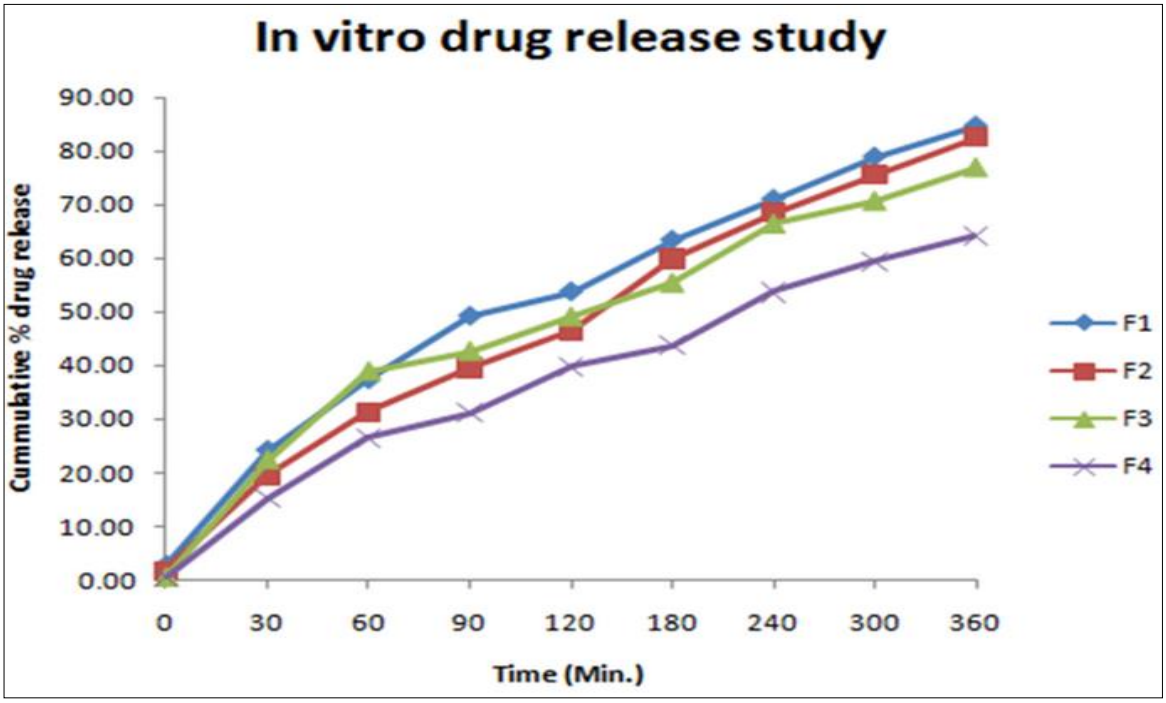

Fig 13: *In vitro* drug Release study

Stability study

The result of stability study indicated that the drug product falls well within the proposed stability specification. The data showed that there is no significant physical or chemical change indicating that the formulation would maintain its efficacy and quality throughout its proposed shelf life

Conclusion

The formulation and evaluation of mouth dissolving films (MDFs) of Desloratadine have gained significant attention due to their potential benefits such as improved patient compliance, rapid onset of action, and ease of administration. Use of cation exchange resins offers good method for preparing bitterless Desloratadine formulation using drug-resin complex the drug is dispersed in purified water under stirring at 100rpm in room temperature. The pH of the drug dispersion is adjusted to pH 6.5±0.5 with 2% citric acid solution. The resin is then added to the ph adjusted drug dispersion and stirred for 3 hours. Use of cation exchange resins offers good method for preparing bitterless Desloratadine formulation using drug-resin complex

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