Nanotechnology Perceptions
ISSN 1660-6795
www.nano-ntp.com

Design Development and Evaluation of Solid Dispersion Fast Dissolving Antihistamine Drug

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ABSTRACT: Enhancing the solubility and dissolution rate of poorly water-soluble antihistamines is critical for ensuring rapid therapeutic action in allergic conditions. This study explores the development of fast-dissolving tablets utilizing solid dispersion techniques, with Spirulina serving as a natural bioenhancer due to its antioxidant and anti-inflammatory properties. Hydrophilic carriers such as PVP K-30 and Microcrystalline cellulose were incorporated to optimize drug dispersion and dissolution. The prepared formulations were systematically analyzed for physicochemical attributes, including dissolution efficiency, stability, and bioavailability. Findings indicate that solid dispersion technology significantly improves drug solubility, enhancing therapeutic effectiveness and patient adherence. Moreover, the inclusion of Spirulina contributes to improved bioavailability and potential synergistic effects, offering a promising approach for allergy management, particularly in pediatric and geriatric populations.

Keywords: Antihistamine, Spirulina, Solid dispersion, Microcrystalline cellulose.

INTRODUCTION: Solid dispersion is a formulation method in which one or more active pharmaceutical ingredients (APIs) are uniformly incorporated into a solid carrier matrix. This technique is primarily employed to enhance the solubility and dissolution rate of drugs that are poorly soluble in water.

Objective: The main goal is to boost the drug's bioavailability and overall therapeutic performance by accelerating its dissolution once administered.

Mechanism of Action:

- **Particle Size Reduction:** By dispersing the API at a molecular or near-molecular level, the technique drastically decreases particle size, which facilitates a faster onset of dissolution.

- **Amorphization:** The process often converts the API from a crystalline structure to an amorphous form. The amorphous state, with its higher energy, typically dissolves more quickly than its crystalline counterpart.

- **Enhanced Wettability:** Incorporating a hydrophilic carrier improves the drug's ability to interact with dissolution media, further promoting a rapid release and absorption.

Common Carriers: Hydrophilic polymers such as polyvinylpyrrolidone (PVP) and hydroxypropyl methylcellulose (HPMC) are frequently used because they effectively enhance solubility and are highly compatible with a range of drugs.

Preparation Methods:

- **Fusion (Melting) Method:** In this approach, the drug is mixed with the carrier and heated until the carrier melts. The molten mixture is then rapidly cooled to form a solid, homogeneous matrix.

- **Solvent Evaporation Method:** Both the drug and the carrier are dissolved in a suitable solvent. The solvent is then evaporated, leaving behind a well-dispersed, solid formulation.

- **Other Techniques:** Additional methods like spray drying, lyophilization, and melt extrusion can also be applied based on the drug's specific properties and processing requirements.

Advantages:

- Enhanced solubility and dissolution rate lead to improved bioavailability.

- Better therapeutic outcomes may be achieved, potentially allowing for dose reductions due to more efficient drug delivery.

Challenges:

- **Stability Concerns:** The amorphous state is inherently less stable, which may lead to recrystallization over time.

- **Scalability and Reproducibility:** Maintaining consistent product quality on a large scale requires careful optimization of the process parameters.

Applications: Solid dispersion is widely used in formulating oral dosage forms, particularly for drugs categorized under BCS Class II, where the issue of poor solubility is a major concern despite high permeability.

MATERIALS AND METHODS:

Selection of Drug and Excipients

This study employs Spirulina as an immunosuppressive agent, primarily used to prevent organ rejection following transplantation. It has also demonstrated potential in managing autoimmune conditions such as rheumatoid arthritis, particularly in cases where methotrexate has proven insufficient. To enhance the solubility and dissolution rate of Spirulina, solid dispersion techniques were applied, utilizing PVP K-30 as a carrier at varying concentrations.

For optimal tablet formulation:

- Microcrystalline cellulose and lactose were selected as diluents to support disintegration.
- Crospovidone and croscarmellose sodium served as superdisintegrants to promote rapid drug release.
- Magnesium stearate and talc functioned as lubricants and glidants, ensuring smooth tablet processing.
- Sodium saccharin was included as a sweetening agent to improve palatability.

Preformulation Study of Drug

Melting Point Determination

The melting point of pure Spirulina was determined using the open capillary method. A capillary tube, sealed at one end, was filled with Spirulina and placed in Thiele's melting

point apparatus. The temperature at which the drug melted was recorded, and an average of three readings was compared with literature values for accuracy.

Determination of λ max of Spirulina in Phosphate Buffer (pH 6.8)

- 100 mg of pure Spirulina was dissolved in 100 mL of phosphate buffer (pH 6.8) in a volumetric flask.
- A 10 mL sample was withdrawn and diluted to 100 mL, producing a 100 mcg/mL stock solution.
- From this stock solution, 1 mL was diluted to 100 mL, creating a 10 µg/mL final solution.
- The UV-visible spectrophotometer scanned between 200-400 nm, recording the maximum absorption wavelength (λ max).

Calibration Curve of Spirulina in Phosphate Buffer (pH 6.8)

- 100 mg of pure Spirulina was dissolved in 100 mL of phosphate buffer (pH 6.8).
- A 10 mL sample was withdrawn and diluted to 100 mL, forming a 100 mcg/mL stock solution.
- From this stock, solutions with concentrations ranging from 5 µg/mL to 50 µg/mL were prepared.
- Absorbance at λ max 319 nm was recorded using a UV-visible spectrophotometer, and a graph was plotted to illustrate the concentration-absorbance relationship.

Differential Scanning Calorimetry (DSC)

To analyze thermal properties, DSC was performed on pure Spirulina using a thermal analyzer. The sample was subjected to heating from 25°C to 500°C at a rate of 10°C/min under a nitrogen atmosphere, generating a thermogram to assess thermal transitions.

Fourier Transform Infrared (FTIR) Spectroscopy

FTIR analysis was conducted to characterize functional groups in Spirulina. A small sample was directly placed on the FTIR spectrometer, and spectra were recorded over the 4000-400 cm^{-1} wavelength region at a resolution of 4 cm^{-1}, ensuring precise identification of key molecular interactions.

Evaluation of Solid Dispersion

Physical Appearance

Each batch of Spirulina solid dispersion was carefully assessed for color and overall appearance to ensure consistency in formulation characteristics.

Drug Content Uniformity

- A quantity of solid dispersion equivalent to 100 mg of Spirulina was dissolved in a minimal amount of ethanol and diluted to 100 mL using phosphate buffer (pH 6.8).
- The solution was filtered and further diluted to ensure absorbance measurements aligned with the standard curve.

Percentage Practical Yield

- Practical yield (%) was calculated to evaluate the efficiency of the formulation method, guiding the selection of the optimal production process.

Solubility Study

- An excess amount of Spirulina was added to distilled water and solid dispersions containing carrier in 20 mL of phosphate buffer (pH 6.8) within a conical flask.
- Flasks were sealed with stoppers and covered with cellophane membranes to prevent solvent loss.

- Samples were subjected to continuous agitation on a mechanical shaker for 72 hours at room temperature, followed by filtration through 0.45 µm membranes.
- The filtrate was suitably diluted and analyzed spectroscopically. All solubility measurements were conducted in triplicate for accuracy.

In-vitro Dissolution Studies

- Dissolution testing was carried out in 900 mL phosphate buffer (pH 6.8) at 37 ± 0.5 °C using a USP Type II dissolution apparatus with a paddle speed of 50 rpm.
- 25 mg of Spirulina (equivalent solid dispersion) was enclosed in muslin cloth and attached to the rotating paddle.
- At predetermined time intervals, 5 mL samples were withdrawn, with an equal volume of fresh dissolution medium replenished.
- Samples were filtered through 0.45 µm membrane filters and analyzed for drug content at 319 nm using a UV-visible spectrophotometer.

Differential Scanning Calorimetry (DSC)

- DSC analysis was performed to investigate the thermal properties and phase transitions of Spirulina and its carrier system.
- Samples were heated from 25°C to 500°C at a controlled rate of 10°C/min in an inert nitrogen atmosphere to obtain a thermal profile.

Fourier Transform Infrared (FTIR) Spectroscopy

- FTIR analysis was conducted to verify the compatibility between Spirulina and excipients.
- The infrared spectrum of Spirulina solid dispersion was recorded using an FTIR spectrophotometer, with baseline correction applied using dried potassium bromide.
- Spectra were scanned over 4000-400 cm^{-1} at a resolution of 4 cm^{-1} for functional group identification.

Preparation of Fast-Dissolving Tablets

In this study, direct compression was employed using superdisintegrants to formulate fast-dissolving tablets containing Spirulina solid dispersions.

- Selected solid dispersion formulations were incorporated into tablet formulations using appropriate superdisintegrants.
- A 25 mg dose of Spirulina was chosen for optimization.
- The formulation design was tailored based on the type and concentration of superdisintegrants, ensuring tablets with favorable disintegration and dissolution properties.
- Two different superdisintegrants were tested at varying concentrations to achieve optimal physical properties

Table No.1: Formulation of conventional tablets of Spirulina by direct compression method

Ingredients (mg)	Qty
Spirulina	25
Microcrystelline cellulose	80
Sodium saccharine	3
Magnesium stearate	3
Talc	3
Lactose	q.s.

Evaluation of Fast-Dissolving Tablets

Pre-Compression Parameters

Angle of Repose

- Evaluates the flowability of powder blends used in tablet manufacturing.

- Measured using the fixed funnel method, where the angle formed by the accumulated powder is analyzed.
- A lower angle suggests better flow properties, while a higher angle indicates potential flow issues.

Bulk Density

- Represents the mass of powder per unit volume before it undergoes tapping or compression.

Tapped Density

- Measures the volume reduction of powder upon tapping, providing insights into its ability to pack efficiently.

Hausner's Ratio

- Indicates powder cohesiveness and its flow properties.
- A ratio greater than 1.25 suggests poor flow characteristics, potentially requiring adjustments to formulation techniques.

Compressibility Index (Carr's Index)

- Measures the compressibility of powder blends, assessing their suitability for tablet formation.
- Lower values (<15%) indicate good flowability and compressibility, while higher values suggest formulation challenges that may require optimization.

Evaluation of Post-Compression Parameters for Fast-Dissolving Tablets

Following compression, the tablets underwent assessment to ensure optimal physical, mechanical, and dissolution characteristics. The key parameters examined include:

Hardness

- Evaluates the structural integrity and resistance of tablets against breakage during handling, transport, and packaging.
- Measured using Monsanto hardness tester or tablet hardness tester, with values typically expressed in kg/cm².

Friability

- Determines the tablet's ability to withstand abrasion and mechanical stress.
- Conducted using a friabilator, where tablets undergo rotational impact testing.
- A weight loss below 1% indicates acceptable friability.

Weight Variation

- Ensures uniformity in tablet weight, which is essential for maintaining dose accuracy.
- Evaluated by weighing multiple tablets individually and calculating variations against the average.
- Compliance with USP and IP standards ensures consistency.

Uniformity of Thickness

- Confirms the consistency of tablet thickness, which influences packaging and dissolution rates.
- Measured using a micrometer screw gauge or digital caliper, ensuring uniformity across batches.

Drug Content Uniformity

- Determines whether the active pharmaceutical ingredient (API) is evenly distributed in each tablet.
- Tablets are dissolved in phosphate buffer (pH 6.8) and analyzed via UV-visible spectrophotometry at 319 nm to quantify drug concentration.

Wetting Time

- Measures the speed at which a tablet absorbs water, crucial for fast-dissolving formulations.

- Assessed by placing the tablet on moistened tissue paper and recording the time taken for complete wetting.

In-Vitro Disintegration Time

- Evaluates how quickly the tablet disintegrates in a simulated gastrointestinal environment.
- Conducted in a disintegration apparatus with phosphate buffer (pH 6.8) at 37°C.
- For fast-dissolving tablets, the ideal disintegration time is under 60 seconds.

In-Vitro Dissolution Study

- Determines the rate and extent of drug release in a dissolution medium.
- Conducted using USP Type II dissolution apparatus with 900 mL phosphate buffer (pH 6.8) at 37 ± 0.5°C, rotating at 50 rpm.
- Withdrawn samples are filtered and analyzed spectrophotometrically at 319 nm.

Differential Scanning Calorimetry (DSC)

- Examines thermal behavior and stability of drug-excipient interactions.
- Samples are heated from 25°C to 500°C at a rate of 10°C/min in a nitrogen atmosphere, generating a thermal profile.

. Fourier Transform Infrared (FTIR) Spectroscopy

- Investigates compatibility between drug and excipients to detect potential interactions.
- Infrared spectra of the tablets are recorded over a 4000-400 cm^{-1} wavelength range using FTIR spectrophotometry.

RESULTS AND DISCUSSION

Preformulation Study of Drug:

Melting Point-

The melting point of Spirulina was found to be 1610c which complies with range that given in the literature i.e. 158-1620c.

Determination of λ max of the Spirulina-

The standard solution of Spirulina shows maximum absorbance at 228 nm wavelength in spectroscopy.

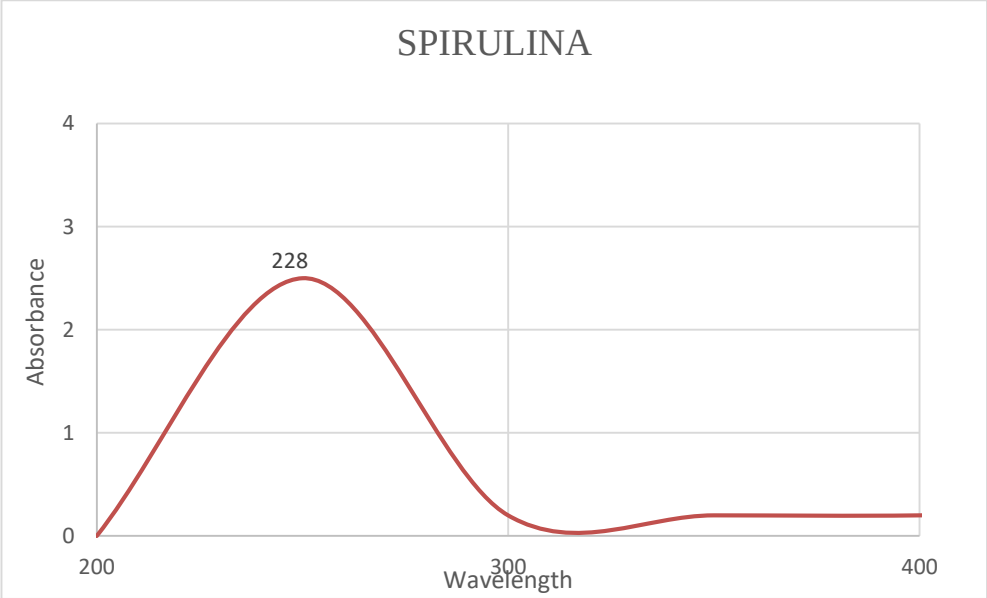

Fig. No.1: UV spectrum of Spirulina

Preparation of standard calibration curve of Spirulina

Standard calibration curve of Spirulina in phosphate buffer pH 6.8 at 319 nm was plotted using various concentrations ranging from 2-50 g/ml.

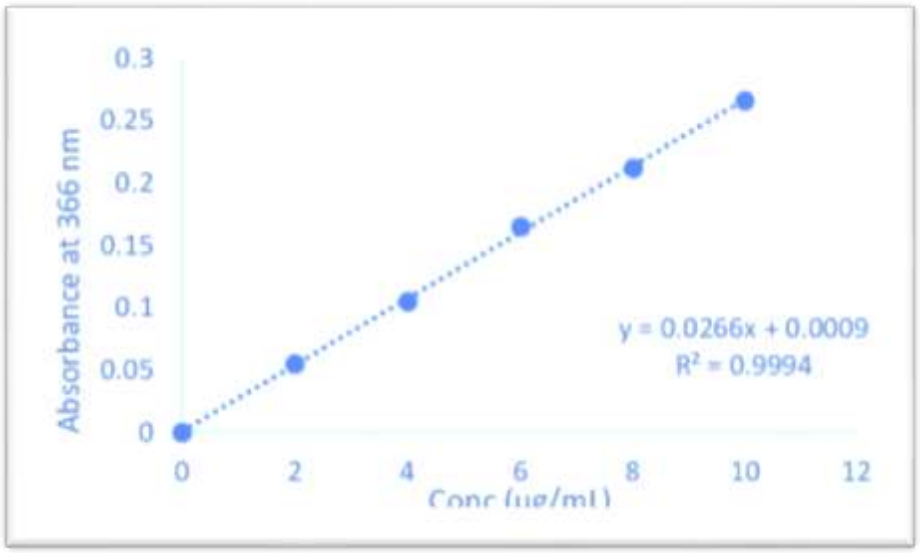

Fig. No.2: Standard calibration curve of Spirulina in pH 6.8 phosphate Buffer at 319nm

Table. No.2: Observations for standard calibration curve of Spirulina in pH 6.8 phosphate buffer at 319 nm66

Sr. no	Concentration	Absorbance
1	0	0
2	5	0.0084
3	10	0.1859
4	15	0.2637
5	20	0.3545
6	25	0.4573
7	30	0.5574
8	35	0.6325
9	40	0.7184
10	45	0.8147
11	50	0.9158

Differential scanning colorimetry (DSC):

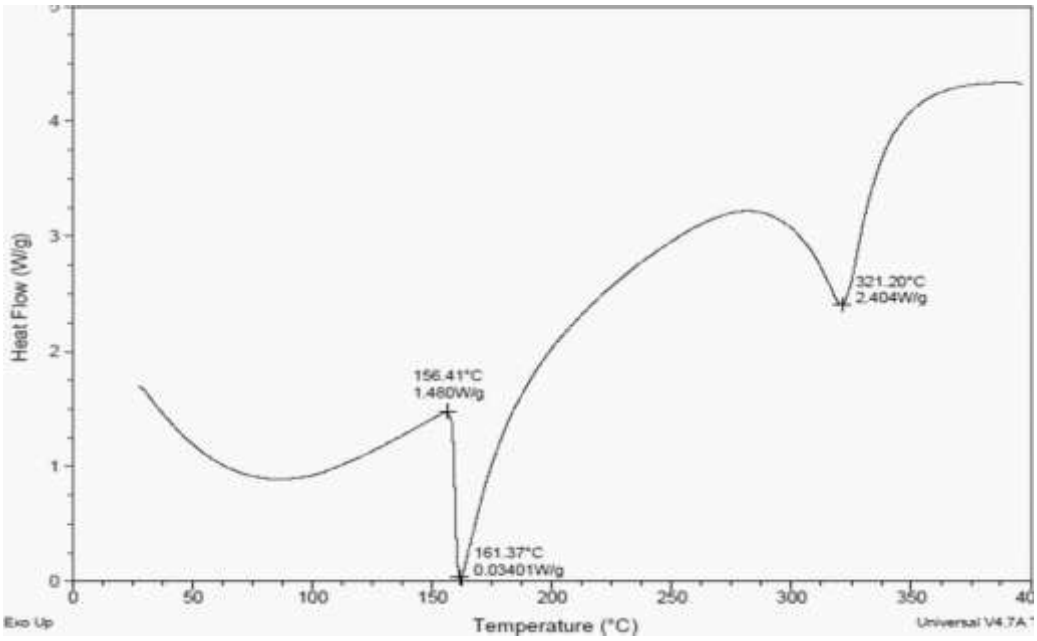

Fig. No.3: DSC of Pure Spirulina

The DSC thermogram of Spirulina reveals a prominent endothermic peak at 161.37°C, confirming its crystalline structure and purity.

Fourier Transform Infra-Red (FTIR) Spectroscopy:
An IR spectrum of Spirulina is presented in figure no 4. Observed peaks are shown in table no.16 these peaks are similar to reported peaks of Spirulina.

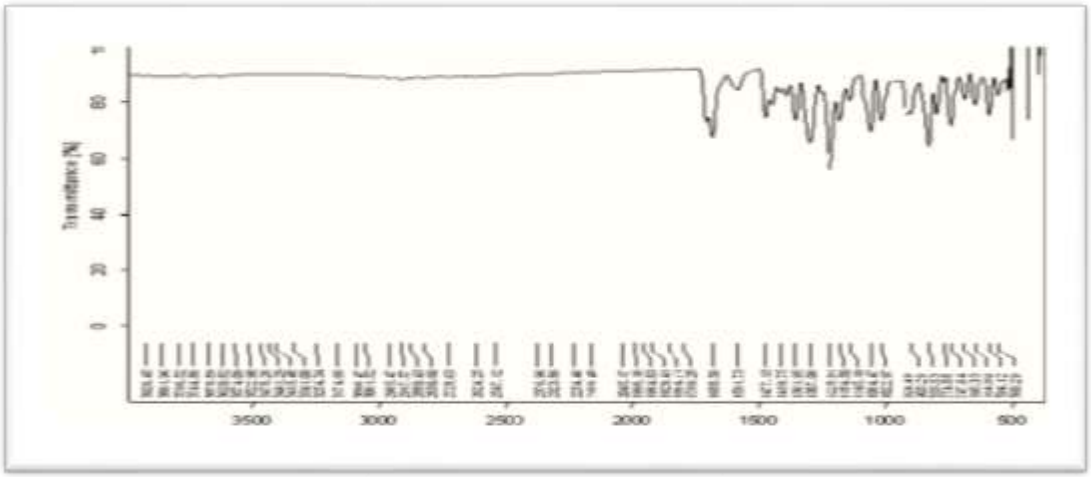

Fig. No.4: FTIR Spectrum of Pure Spirulina

Evaluation of Solid Dispersion Incorporated Spirulina Fast-Dissolving and Conventional Tablets

Results of Pre-Compression Parameters

Pre-compression parameters are crucial in optimizing the flow properties of pharmaceutical powders, particularly for tablet formulations. These assessments include angle of repose, bulk density, tapped density, Hausner's ratio, and Carr's index, which help determine the suitability of powder blends for compression.

Two groups of Spirulina fast-dissolving tablets were formulated:

- TP1 to TP5: Prepared using PM3 solid dispersion
- TS1 to TS5: Developed using SE3 solid dispersion

The optimized batches (PM3 and SE3) were combined with various excipients, including superdisintegrants, diluents, sweeteners, glidants, and lubricants. These powder blends underwent pre-compression evaluations to ensure uniformity in tablet weight and overall processing quality.

Pre-Compression Results

- Angle of Repose: Found within the range of 16.18° to 22.45°, indicating favorable flow characteristics.
- Bulk Density: Recorded between 0.418 g/cc and 0.814 g/cc, reflecting compactness of powder blends before tapping.
- Tapped Density: Measured between 0.444 g/cc and 0.665 g/cc, helping assess powder compressibility.
- Carr's Index: Determined to be in the range of 8.18% to 16.51%, indicating good powder flow and compressibility.
- Hausner's Ratio: Values ranged between 1.08 and 1.15, signifying satisfactory flowability of powder blends.

These results confirmed that all formulation batches exhibited suitable flow properties, making them well-suited for direct compression in tablet manufacturing.

Table No.3: Results of Pre-Compression Parameters:

Formulation code	Angle of repose (degrees)	Bulk Density g/cc	Tapped Density g/cc	Hausner's Ratio	Carr's Index %
CT	22.45 0.11	0.421 0.15	0.478 0.23	1.09 0.01	12.35 1.35
TP1	16.18 0.66	0.450+0.13	0.492 0.15	1.09 0.02	8.36 2.13
TP2	20.00 0.90	0.418+0.19	0.502 0.15	1.10 0.005	9.53 0.45
TP3	22.90 0.24	0.466+0.10	0.455 0.08	1.15 0.08	9.68 1.99
TP4	20.47 0.90	0.547+0.14	0.503 0.05	1.14 0.02	12.99 2.17
TP5	21.56 0.91	0.739+0.29	0.665 0.14	1.09 0.02	8.48 2.32
TS1	17.98 0.69	0.466+0.24	0.444 0.11	1.19 0.02	9.73 2.38
TS2	19.02 0.30	0.478+0.34	0.545 0.12	1.09 0.02	8.91 1.69
TS3	21.29 0.57	0.581+0.21	0.637 0.13	1.12 0.01	10.83 1.4
TS4	20.67 0.35	0.814+0.49	0.532 0.11	1.12 0.03	11.33 2.5
TS5	21.80 0.39	0.525+0.30	0.502 0.13	1.08 0.03	8.18 2.61

All value is expressed as mean ± SD,

Result of Post -Compression Parameters:

Table No.4: Results of post-compression parameters for the tablets like hardness, friability, weight variation, and uniformity of thickness:

Formulation code	**Hardness Kg/cm$_2$**	**Friability %**	**Weight Variation mg**	**Uniformity of thickness**
CT	3.2 0.2	0.51	396 0.62	3.2 0.15

TP1	3.2 0.2	0.64	397 0.48	3.3 0.20
TP2	3.2 0.2	0.47	397 0.90	3.2 0.11
TP3	3.2 0.31	0.66	31396 0.90	3.1 0.17
TP4	3.1 0.11	0.40	395 0.55	3.2 0.1
TP5	2.9 0.23	0.52	396 0.7	3.2 0.15
TS1	3.1 0.05	0.68	397 1.06	3.2 0.11
TS2	3.1 0.11	0.54	397 1.22	3.4 0.41
TS3	3 0.2	0.32	396 0.85	3.1 0.15
TS4	3.0 0.23	0.41	396 0.80	3.2 0.11
TS5	3.0 0.30	0.32	395 0.99	3.2 0.15

All value are expressed as mean ± SD, n=3

Table No.5: Results of post-compression parameters for the tablets

Formulation code	Drug content Uniformity %	Wetting Time sec	In -vitro Disintegrationn time sec
CT	99.09 0.04	186 2	263 2.08
TP1	90.67 0.01	49 2.64	57 1.73
TP2	98.56 0.39	44 2	56 2
TP3	93.51 3.06	41 1	54 2
TP4	94.25 0.11	41 1	54 1
TP5	99.51 0.23	46 2	56 2.64
TS1	93.83 0.05	26 1.73	45 1.73
TS2	98.07 0.11	30 3.60	35 2.64
TS3	95.86 0.2	32 2	51 1.73
TS4	99.34 0.23	20 1	33 1.73
TS5	98.99 0.30	17 1	28 1

All value is expressed as mean ± SD, n=3

CONCLUSION:

The development and evaluation of solid dispersion-based fast-dissolving Spirulina tablets successfully enhanced the solubility, dissolution rate, and bioavailability of the antihistamine drug. Utilizing solid dispersion techniques, the formulation improved drug release, facilitating a rapid onset of action, making it particularly effective for allergic conditions requiring immediate relief.

The optimized formulations demonstrated desirable pre-compression and post-compression properties, including uniform drug distribution, rapid disintegration, and efficient dissolution profiles. The addition of superdisintegrants, hydrophilic carriers, and excipients contributed to the tablet's fast-dissolving functionality, ensuring suitability for pediatric, geriatric, and dysphagic patients. Additionally, DSC and FTIR analyses verified the stability and compatibility of Spirulina with formulation excipients, ensuring long-term integrity and effectiveness. These findings highlight the potential of solid dispersion technology in enhancing antihistamine drug delivery, promoting patient compliance, and achieving optimal therapeutic outcomes.

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ACKNOWLEDGEMENT: The authors are thankful to the Principal, Smt. Sharadchandrika Suresh Patil College of Pharmacy, Chopda, Maharashtra, India. necessary facilities for research work.

CONFLICTS OF INTEREST: Authors have no conflicts of interest to declare.

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25. K Chauhan, R Solanki, S Sharma - Int J App Pharm,(2018)- innovareacademics.org In the present scientific scenario, the drug delivery technology has become extremely competitive and quickly evolving with ever-increasing demand. Fast dissolving tablet (FDT) is one such style of an innovative and distinctive drug delivery system.