https://doi.org/10.48047/AFJBS.6.8.2024.2997-3007

African Journal of Biological Sciences

3D Printed Orodispersible Film Using Semi-Solid Extrusion of Antihistamine Drugs

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Article History

Volume 6, Issue 8, June 2024
Received: 15 May 2024
Accepted: 10 June 2024
Published: 1 July 2024
Doi:10.48047/AFJBS.6.8.2024.2997-3007

Abstract:
Orodispersible films (ODFs) present a promising avenue for personalized drug delivery systems, offering an alternative method to enhance consumer acceptance through features like rapid dissolution and administration without water. This study aimed to establish a platform for creating tailored treatments suitable for the on-the-spot production of ODFs using semi-solid extrusion 3D printing. The polymer of choice for ODFs was Hydroxypropyl Methyl Cellulose (HPMC), with Bilastine and levocetirizine hydrochloride as the model drug. This research endeavors to create orally disintegrating films (ODFs) loaded with drugs using a syringe extrusion 3D printer. Formulation with drug, characterization, Solubility study, identification, and calibration curve of both drugs has been done. The ODFs were formulated by dissolving drugs in a dispersion of polymers and other additives, which were then utilized for fabrication through 3D printing. Then disintegration time and drug Content (%) study was conducted in 0.1 N HCl at 37°C of both drugs and selected one drug which showed good results. Drug excipients compatibility study by IR spectroscopy was performed with and without excipients of the drug. This study underscores the potential application of 3D-printing technology in the fabrication of drug-containing ODFs, showcasing advancements in drug delivery systems.

Keywords: orodispersible film; 3D-printing; hydroxypropyl methylcellulose; Bilastine; Levocetrizine; pressure-assisted micro syringe.

1. Introduction

In recent decades, there has been a growing interest in the medical and pharmaceutical fields to use three-dimensional (3D) printing technologies to create solid dosage forms tailored to the different needs, requirements, and individual characteristics of each patient. One]. 3D printing is a manufacturing process that lays down materials layer by layer to create 3D printed products of any required shape and size using digital design software [2]. These include the three most widely used technologies: ink-jet-based (IJ) printing systems, nozzle-based deposition systems or print-based (solid, -rock) printing technologies, and laser engraving systems. Among these, printing and printing technology is known to be the most widely used technology for the production of oral solid dosage forms due to its excellent ability to print various types of polymers and drugs at room temperature and its ability to absorb large amounts of money Free drugs [1,3]. Many studies have been conducted on the advantages of 3D printing about its adoption in the design of new constructs such as poly-fills, tumor sources, and oral transparent films (ODF) [4]. ODF is a new formulation made with hydrophilic polymers and is designed to break down rapidly within one minute without water. This formulation has several advantages over other oral formulations, including ease of administration in pediatric patients and patients with dysphagia (difficulty swallowing), ease of dosing, and better bio-availability of the drug due to high vascularization and high penetration into the oral cavity. The main advantages of preparing ODFs by 3D printing for standard film casting are the ability to print objects with different fillings (hollow, matrix, or solid) and the ability to control drug dosage by calculating the amount of material collected during dosing. We produce prints in the design category suitable for personal treatment. Also, 3D movies can be produced in less time.

A assortment of hydrophilic polymers such as polyvinyl liquor (PVA), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), hydroxypropyl cellulose (HPC) and hydroxypropyl methylcellulose (HPMC) are utilized as film-forming polymers for the arrangement of ODFs, and most of them can too be utilized as printing materials for extrusion-based 3D printers.[7,8]. Hydroxypropyl methylcellulose (HPMC), moreover known as hypromellose, is broadly executed in pharmaceutical manufacturing as a binder, thickening agent, hydrophilic network material, and film-forming material. It is classified into a few grades based on consistency, degree of hydroxypropyl substitution, and degree of methoxy substitution. The diverse viscosity HPMC grades are frequently utilized for ODF preparation and are appropriate for extrusion-based 3D printing of oral dose forms. [8–10]. In addition, the utilization of HPMC, which could be a hydrophilic polymer, can be beneficial in terms of upgrading the solubility and dissolution of ineffectively water-soluble drugs within the manufacture of strong scattering. In any case, there are still constrained ponders accessible on the planning of 3D-printed ODFs while utilizing low-viscosity HPMC as a film-forming polymer. In a past ponder, levocetirizine dihydrochloride ODFs consisting of HPMC E15 and pregelatinized starch were prepared using a semi-solid extrusion (SSE) 3D printer. The 3D-printed ODFs showed great flexibility and rapid drug release in vitro by dissolving totally in two minutes [11]. In expansion, previous work on the extrusion-based 3D printing of HPMC within the pharmaceutical field can be found [12]. The extrusion-based (fused-deposition modeling) 3D printer was utilized to fabricate 3D-printed tablets by utilizing their created HPMC filament. Different approaches were utilized to overcome the solvency issue of distinctive drugs. Solid dispersion of the drug in a hydrophilic polymer is additionally one of the promising procedures for improving its solubility. There are numerous accessible dosage forms of drugs on the market, such as oral suspension, chewable tablets, capsules, and intravenous injections. The improvement of ODF has various points of interest over conventional dosage forms such as comfort for patient administration, precise drug dosing, quick onset of activity with expanded bio-availability due to bypassing hepatic first-pass impact and noninvasiveness. In addition, ODF can be utilized for patients and can be taken without water due to its ability to disintegrate within a few minutes to release medication within the mouth.

2. Materials and Methods

2.1. Materials

Table 1 List of materials

Sr. No.	Material	Function	Manufacturer
1.	HPMC K 15 M	Polymer	Colorcon, India.
2.	HPMC K100 M	Polymer	Colorcon, India.
3.	PEG 400	Plasticizer	Molychem, India
4.	Glycerol	Plasticizer	Molychem, India
5.	Sucralose	Sweetener	Firmeniech, Mumbai.
6.	Citric Acid	Saliva Stimulating Agent	Sudeep Pharma, Mumbai.
7.	Isopropyl alcohol	Solvent	Molychem

2.2. List of Equipments

Table 2 List of Equipments

Sr. No.	Equipments	Manufacturers
1	Digital weighing balance	Reptech weighing balance ltd., Ahmedabad.
2	Sonicater	Lava lab, India.
3	Dissolution apparatus	Electro lab ltd, Mumbai.
6	Magnetic stirrer	Janki Impex Pvt. Ltd, Ahmedabad.
7	pH Meter	Janki Impex Pvt. Ltd, Ahmedabad.
8	Vernier Calliper	Mitutoyo, Japan.
9	3D Printer	3 Fce Tech, Himmatnagar.

2.3. Fabrication of 3D-Printed OrodispersibleFilm

Feasibility Trials were initiated to identify suitable film-forming polymers for film preparation. Different water-soluble polymers were used in this and finally, HPMC K15 M 180 mg and HPMC K100 M 260 mg were used. The combination of polymers showed good results after that at a fixed ratio taken and selection of solvent in singular and in combination batches were taken and selected in the ratio of Water: IPA (3:7). Evaporation rate is competitively good for Water: IPA combination so, that is fixed for formula. Afterward, the finalization of the polymer HPMC ratio was dispersed in specific proportions in the solvents and stirred in a magnetic stirrer for 2 minutes then put in a sonicator for 10 minutes at room temperature (25 ± 2 ◦C) after that both drugs were added in individual formulations. Subsequently, the two different plasticizers (glycerin and propylene glycol 400) were added into the dispersions of 0.1 ml. The dispersions were sonicated for around 10 minutes at room temperature (25 ± 2 ◦C) gently until all of the air bubbles disappeared. The scattering was loaded into a 10 mL disposable syringe joined with 21 G needle tips and after that printed with the 3d printer's parameters. The entire printing time was around 2 min for each film. After printing, the printed ODFs were put at room temperature for 15–30 min to total the drying process.

2.4. 3DPrinter, Design and Printing Parameters

In this study, the syringe extrusion 3D printer developed by the 3 Fce Tech was used to fabricate the 3D-printed ODFs. This was a pre-customized syringe extrusion 3D printer based on a core-XY 3D printer in which an extrusion nozzle can move in an X and Y center and a separated building plate on a Z-axis while printing layer-by-layer for making a 3D structure to avoid vibration on the test. A custom syringe-based extruder was arranged and built in-house for the exact deposition. In Figure, the syringe-based extruder utilized a stepper engine to move a plunger of a 10 mL syringe through a coordinate lead screw drive. The syringe extrusion 3D printer was controlled by a computer and a client interface on the printer. Sometime recently 3D printing, a question was outlined utilizing an

open-source program and was isolated into various two-dimensional (2D) layers with a characterized thickness, infill, and speed of printing. These 2D layers can be piled up by specifically including the required materials in a profoundly reproductive layer-by-layer way beneath the instruction of computer-aided plan (CAD) models.

The 3D printing handle was performed employing a syringe extrusion 3D printer. At first, as appeared in Figure, the 3D designs and models of the printed ODF with the dimension of 20 mm width × 20 mm length × 0.2 mm stature were obtained utilizing the Tinkercad® computer program (2020, Autodesk Inc., San Rafael, CA, USA). The 3D models were built by a streamlined valuable strong geometry strategy and exported as a 3D printer lucid stereolithography (.stl) file format to the Repetier-Host software. At that point, the .stl file was sliced and converted to a 3D printable code (G-code) by the open-source Slic3r computer program. From there on, the tests were transferred into a 10 mL disposable syringe (14.5 mm breadth), and the 3D models were printed with a syringe extrusion 3D printer prepared with a single head printing extruder nozzle with a diameter of 0.51 mm (21 G). The printing handle was conducted at 25 ◦C, 10 mm/s printing speed, and 120 mm/s nozzle traveling speed, and the printing parameters were preset as the taking after the layer height was 0. 2 mm, the fill point was 45◦, the borders were 2, and the infill was characterized as rectilinear with 100% ratio (For the estimation of the diameter of printed filaments, the infill was set as 0% of the volume, and the perimeter was 1).

3. RESULTS & DISCUSSION

3.1. Characterization of Bilastine

Observations of organoleptic characteristics, flow properties and melting point of Bilastine are shown in below table.

Table 3 Characterization of Bilastine

Sr. No.	Characteristic Properties		Observation/Result
1	**Organoleptic Characteristics**	*Colour*	White color powder
		Odor	Odorless
2	**Description**		Bilastine is a white colourcrystalline powder
3	**Flow Properties**	*Bulk density (g/ml)*	0.28 ± 0.02
		Tapped density (g/ml)	0.39 ± 0.03
		Carr's index (%)	28.21 ± 0.05
		Hausner's ratio	1.39 ± 0.04
		Angle of repose (θ°)	31 ± 1 °
4	**Melting Point**		203°C

Based on the above API characterization data, it was found that the API has a good flow. The Melting point observed during the Pre-formulation study was matched with the reference melting point of API. The API was white color crystalline powder.

3.2. Solubility study of Bilastine

Bilastine solubility was checked in different solvents and buffers. The results were recorded in the below table. The comparative is graph also shown in the below figure. The highest solubility was found in methanol.

Table 4 Solubility of Bilastine

Solvent	Solubility (mg/ml
Water	0.002
0.1 N HCl	0.03
6.8 Phosphate buffe	0.003
Methanol	0.02

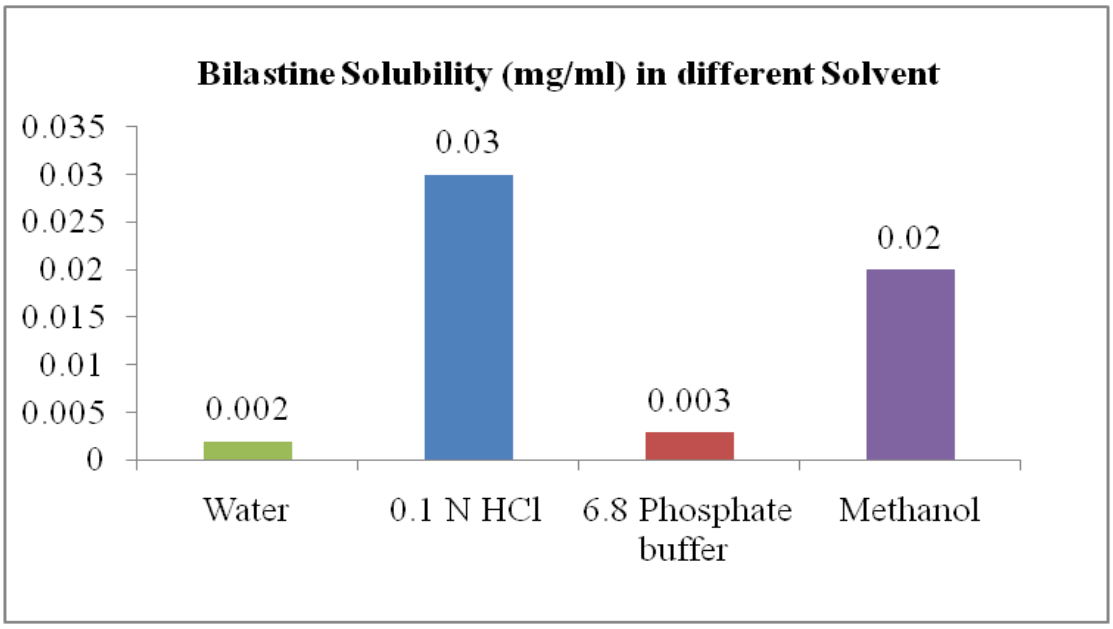

Figure 1 Solubility of Bilastine

The solubility study of API helps to identify the solvent for making the final dosage form. Further, the selection of buffer media for calibration curve preparation can be identified. The calibration curve was prepared in 0.1 N HCl (pH 1.2) and 6.8 phosphate buffer.

3.2.1. Preparation of Calibration curve in 0.1 N HCl (pH 1.2)

The standard Calibration curve of Bilastine was prepared in 0.1 N HCl and λ_{max} was found 206 nm.

Table 5 Calibration curve of Bilastine in 0.1 N HCl at 206 nm

Concentration (µg/ml	Mean Absorbance (nm	Standard Deviation(nm
2	0.221	0.002
4	0.463	0.003
6	0.661	0.002
8	0.872	0.005
10	1.099	0.004

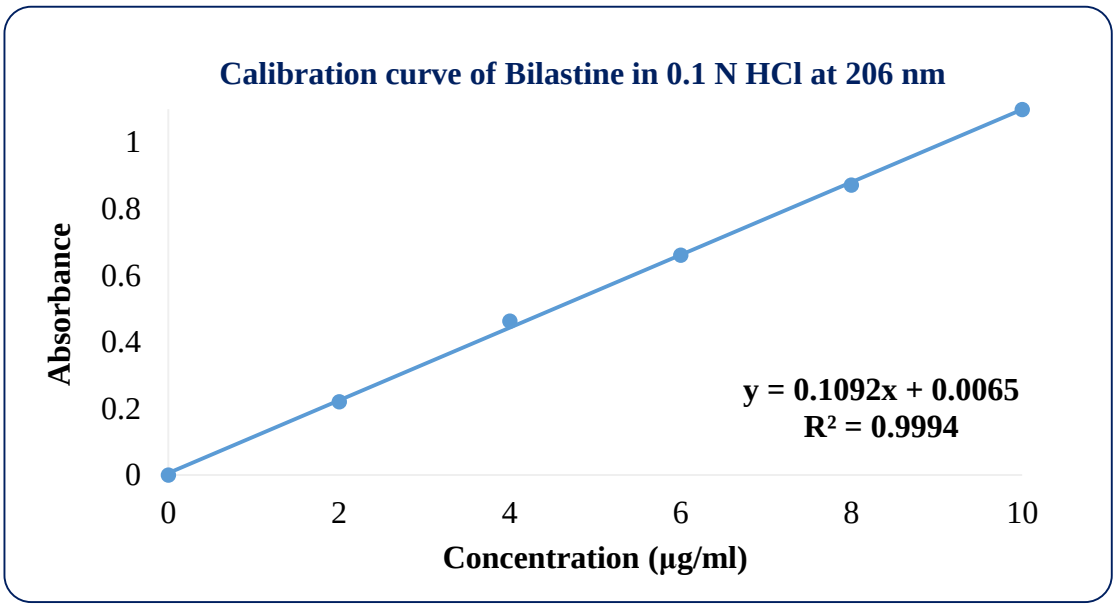

Figure 2 Calibration curve of Bilastine in 0.1 N HCl at 206 nm

3.2.2. Preparation of Calibration curve in 6.8 Phosphate Buffer

The standard Calibration curve of Bilastine was prepared in 6.8 phosphate buffer and λ_{max} was found 206 nm.

Table 3 Calibration curve of Bilastine in 6.8 phosphate buffer at 210 nm

Concentration (µg/ml	Mean Absorbance (nm	Standard Deviation(nm
4	0.231	0.003
8	0.421	0.003
12	0.627	0.003
16	0.856	0.006
20	1.058	0.008

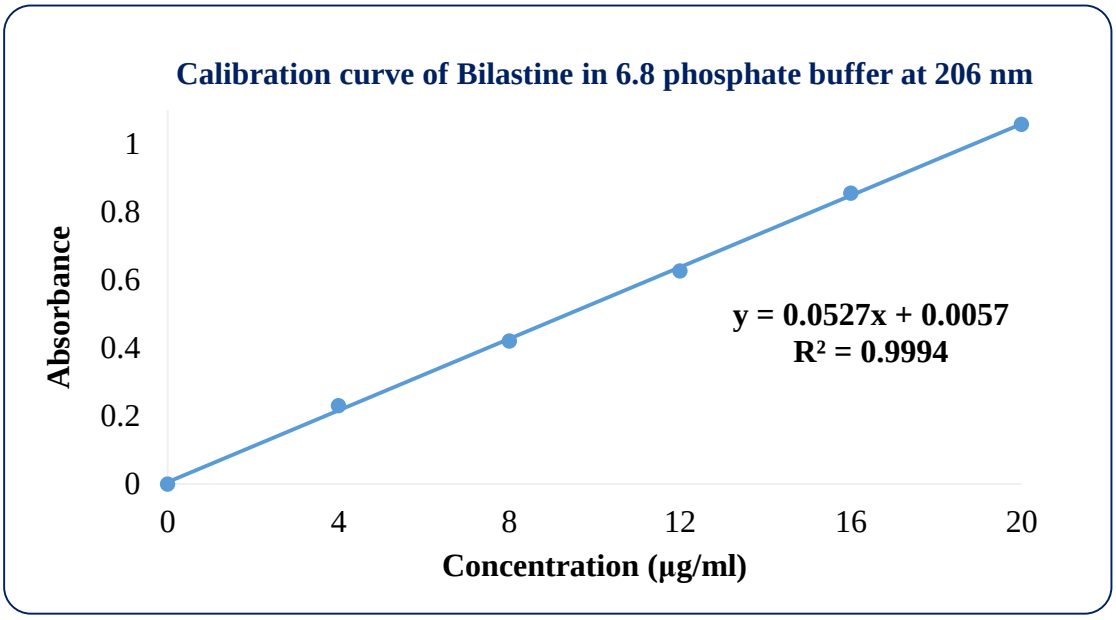

Figure 3 Calibration curve of Bilastine in 6.8 phosphate buffer at 206 nm

3.3. *Characterization of Levocetirizine Dihydrochloride*

Observations of organoleptic characteristics, flow properties, and melting point of the drug are shown in the below table.

Table 7 Characterization of Levocetirizine Dihydrochloride

Sr. No.	Characteristic Properties		Observation/Result
1	**Organoleptic Characteristics**	*Colour*	White color powder
		Odor	Odorless
2	**Description**		Levocetirizine Dihydrochloride is a white colourcrystalline powder
3	**Flow Properties**	*Bulk density (g/ml)*	0.31 ± 0.01
		Tapped density (g/ml)	0.43 ± 0.02
		Carr's index (%)	27.90 ± 0.01
		Hausner's ratio	1.39 ± 0.03
		Angle of repose	36 ± 2 °

		(θ°)	
4	**Melting Point**		205°C

Based on the above API characterization data, it was found that the API has a good flow. The Melting point observed during the Pre-formulation study was matched with the reference melting point of API. The API was white color crystalline powder.

3.4. Solubility study of Levocetirizine Dihydrochloride

Levocetirizine Dihydrochloride solubility was checked in different solvents and buffers. The results were recorded in the below table.

Table 1 Solubility of Levocetirizine Dihydrochloride

Solvent	Solubility (mg/ml
Water	26.0
0.1 N HCl	5.9
6.8 Phosphate buffe	17.8

3.5. Identification and Calibration curve of Levocetirizine Dihydrochloride

3.5.1. Preparation of Calibration curve in 0.1 N HCl (pH 1.2)

The standard Calibration curve of Levocetirizine Dihydrochloride was prepared in 0.1 N HCl and λ_{max} was found at 211 nm.

Table 2 Calibration curve of Levocetirizine Dihydrochloride in 0.1 N HCl at 211 nm.

Concentration (µg/ml	Mean Absorbance (nm	Standard Deviation(nm
5	0.162	0.001
10	0.318	0.001
15	0.491	0.003
20	0.654	0.002
25	0.805	0.001

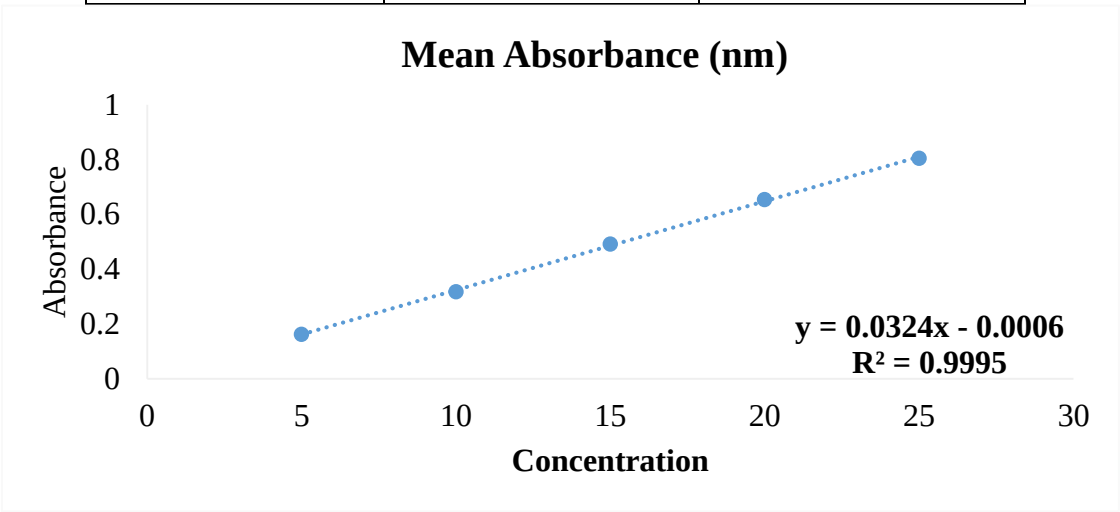

Figure 4 Calibration curve of Levocetirizine Dihydrochloridein 0.1 N HCl at 211 nm

3.5. Results of Drug loaded 3D printed Final Formulation

Table 3 Results of Drug loaded 3D printed Final Formulation

Evaluation Parameters	B1	L1
Surface	Smooth	Smooth
Transparency	Transparent	Transparent
Stickiness	Non-Sticky	Non-Sticky
Weight variation (mg)	469.2 ± 1.5	454.2 ± 1.53
Thickness (mm`)	0.064 ± 0.002	0.060 ± 0.001
Surface pH	6.5 ± 0.3	7.1 ± 0.1
Drug Content (%)	99.7 ± 1.3	99.3 ± 1.7
Folding Endurance	26 ± 5	21± 2
Disintegrating time(sec)	40 ± 2	38 ± 5
Tensile Strength (kg/cm^2)	0.440 ± 0.02	0.338 ± 0.03
% Elongation	18.22 ± 0.02	18.25 ± 0.01
% Drug Release at 10 min	99.5 ± 1.5	99.2 ± 1.9

3.6. *Drug excipients compatibility study by IR spectroscopy*

Pure Drug Bilastine was first identified by IR. The pure IR spectrum of Bilastine was taken and it was matched with the reference spectra. All the characteristic peaks of API are shown in Figure 5. Further, the pure API IR spectra were compared with the mixture of API with HPMC polymer. It is shown in the below figure. Based on IR spectra, it was concluded that the API was compatible with the selected excipients.

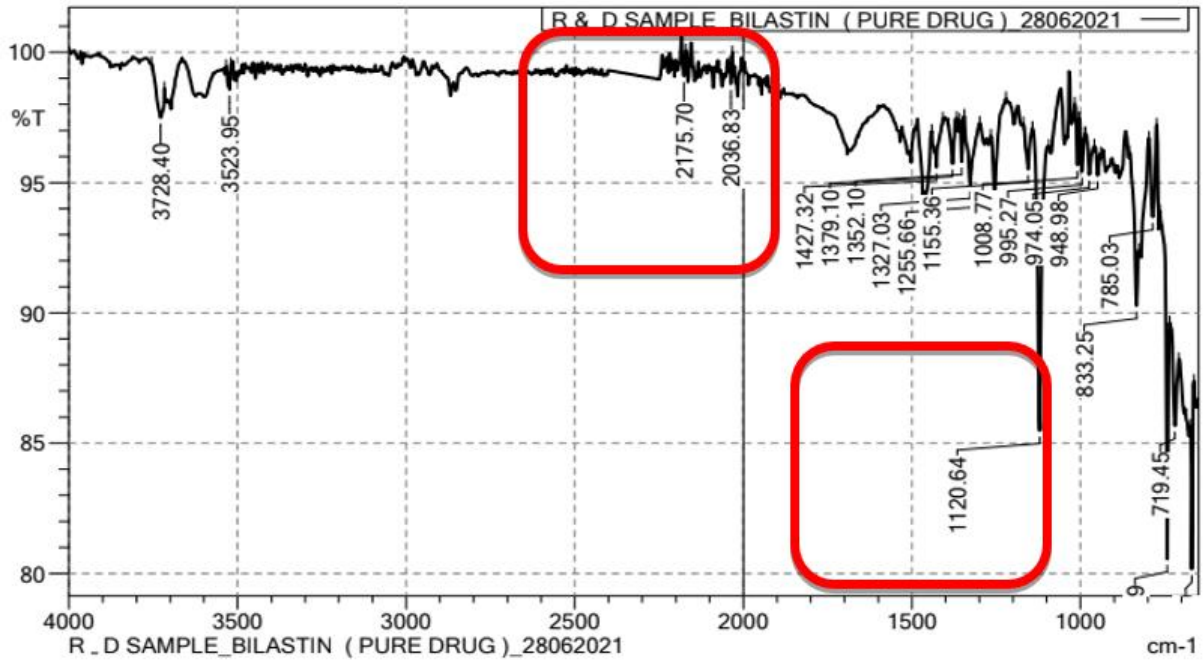

Figure 5 IR spectrum of pure drug Bilastine

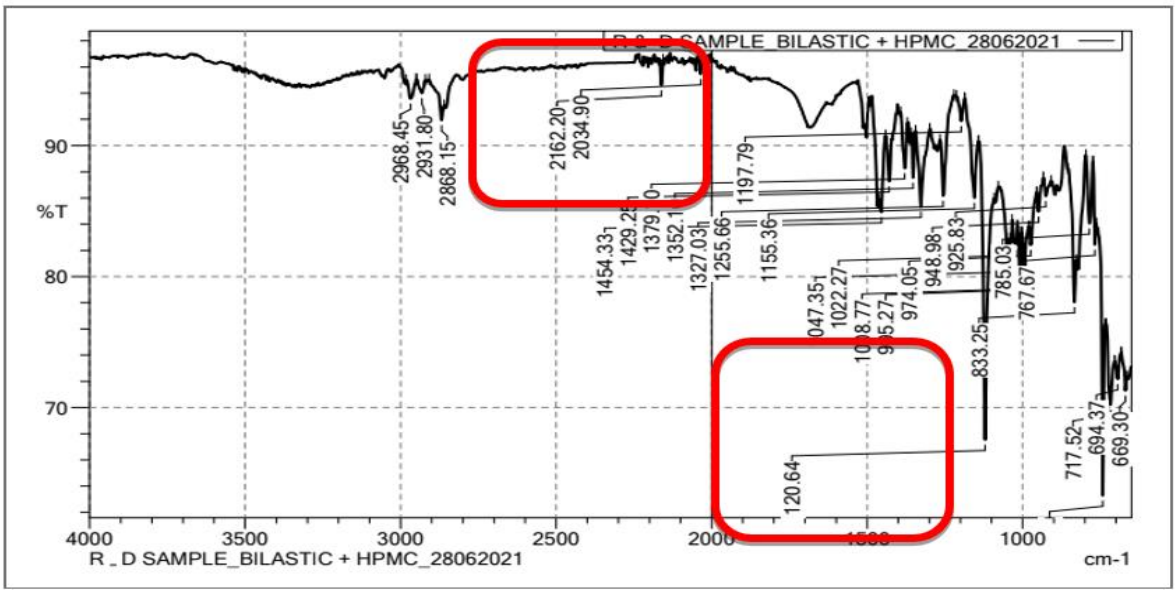

Figure 6 IR spectrum of pure drug Bilastine+HPMC (blend of excipients)

Functional group	Observed frequency in pure Drug (cm^{-1})	Observed frequency in pure Drug+ HPMC(cm^{-1})
C=N stretching	2036.83	2034.90
C-Cstretching	1120.64	1120.64

4. SUMMARY & CONCLUSION

- In the present investigation, Bilastine mouth dissolving film was prepared using a suitable polymer and plasticizer. UV- Visible spectrophotometer analytically developed method was used at Standard Calibration curve of Bilastine was prepared in 0.1 N HCl and λmax was found at 206 nm and Calibration curve of Levocetirizine Dihydrochloride in 0.1 N HCl at 211 nm.
- Pre-formulation study for drug-polymer compatibility study was performed by FTIR which gave confirmation about their purity and showed no interaction between drug and polymers.
- Mouth dissolving film was prepared successfully by 3D printing by pressure-assisted micro syringe method using HPMC K15 M and HPMC K100 M as polymer, Sucralose as sweetener, Citric Acid as saliva stimulating agent, PEG 400 and Glycerine as a plasticizer, IPA and Water as solvent.
- Prepared formulations were evaluated by different physicochemical parameters like thickness, weight variation, folding endurance, tensile strength, % elongation, surface pH, in vitro disintegration time, and in vitro drug release.
- The in vitro drug release of Bilastine was carried out in 0.1 N HCl the % drug release from the formulation B1 (HPMC K15 M 180 mg and HPMC K100 M 260 mg) was 99.5 ± 1.5 % at 10 min.
- All physical parameters evaluated were found to be satisfactory from which formulation B1 was selected as the best formulation. Optimized formulation batches were further subjected to a stability study which showed no significant changes in mechanical properties drug content, or disintegration time after storage at accelerated conditions.
- Initial characterization of the Drug was done. Physical as well as chemical identification was performed and found satisfactory. The calibration curve was prepared by the UV method. IR identification was done for the drug and found satisfactory.
- So it can be concluded that mouth dissolving film of Bilastine is a good dosage form by 3D printer by using a pressure-assisted micro syringe.

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