# Desloratadine-Loaded Flexible Orally Dissolvable Tablets Made of Electrospun Fiber Mats

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# Abstract

Patient compliance and personalized dose adjustments are important factors, especially in pediatric care. Orodispersible tablets (ODTs) are gaining importance as they increase patient compliance compared to other solid oral dosage forms. ODTs are solid dosage forms that disintegrate within seconds upon contact with a small amount of liquid. However, the main drawback of the ODTs is their brittle nature which requires special packaging and careful handling and use. In this study, flexible ODTs were fabricated with the electrospinning method. The formulation composed of Kollidon 90F and ethanol was selected for desloratadine-loaded fiber fabrication due to its ease of production and reduced electrospinning time. The single-dose fiber mat fabrication time was adjusted to 2 and 4 minutes to obtain a pediatric dose of 2.5 mg and a 5 mg adult dose, respectively. A 3D-printed tablet compression tool was successfully used to transform the electrospun fibers into ODTs. Fabricated ODTs were compared with commercial desloratadine ODTs and the results showed that they both have similar disintegration times. However, ODTs fabricated from electrospun mats demonstrated a distinct advantage in terms of flexibility, as they did not fracture under applied pressure by a texture profile analyzer. The manufacturing process, along with the utilization of 3D-printed tools, streamlined the production of flexible ODTs and simplified dose adjustments. These advancements hold the potential to facilitate customized therapies for individual patients, thereby enhancing patient compliance, particularly among pediatric populations.


# Introduction

Patient compliance, especially for pediatric patients, is critical for successful treatment. The development of pediatric formulation has been a challenging task. The pediatric population is distinct from the adult populations due to their specific therapeutic needs throughout growth and development and due to having different pharmacokinetics and pharmacodynamics compared to adults [1]. In addition, excipients commonly regarded as safe for adults may not be suitable for children [2].

The oral administration route is the most preferred drug administration route, however, tablets and capsules are not suitable for children under the age of four [3, 4] or children may refuse to take medicines for many reasons, such as difficulty in swallowing. Liquid pharmaceutical forms are often the preferred choice for children, due to ease of swallowing, flavoring, reduced choking risk, and reduced absorption time in comparison to solid forms. Nevertheless, they have limitations in comparison to other forms of dosage such as accurate measurement and application by the caregiver [5].

A more recent trend in dosage form development involves orally disintegrating tablets (ODTs) [6], which are being explored for their suitability in pediatric medicine [7]. These tablets are designed to disintegrate quickly in the mouth, obviating the need for swallowing and making them particularly suitable for pediatric patients. However, ODTs require special packaging, and more careful handling and use due to their brittle nature. [8].

Electrospinning has gained widespread use in the production of drug-loaded mats, with a particular emphasis on applications in wound healing [9, 10]. Electrospinning can be used to create flexible polymer-based nanofiber matrices that can serve as a component in the formulation to improve drug delivery, disintegration, or taste masking. The fast fabrication, ease of dose adjustments, and lack of need for excipients such as super disintegrants make this technique suitable for pediatric medication.

The World Health Organization (WHO) has recognized flexible, solid oral dosage forms as the most suitable option for pediatric medications [11]. In this context, electrospun fibers can be transformed into flexible ODTs, making them a fitting choice within this category.

ODT fabrication does not require high compression forces, in contrast to conventional tablets. Instead, the compression force should be kept low to preserve a porous structure, facilitating rapid dissolution [12]. Using a comparable method, electrospun fibers could be compressed and converted into flexible ODTs with much simpler tools. This approach would enable enhanced ease of handling and usage compared to both electrospun mats and conventional ODTs.

3D printing technology is gaining increasing significance in many industrial areas due to its remarkable ability to rapidly produce required tools [13]. As this technology continues to advance, it is becoming more straightforward and user-friendly. The use of 3D printing would streamline the production of manual tablet compression tools, thereby eliminating human errors and enabling a patient-tailored fabrication process.

The aim of this study was to simplify the fabrication and improve the mechanical characteristics of ODTs with easy-to-fabricate and use tools. Desloratadine, an antihistamine commonly used for treating pediatric patients with allergic rhinitis, was selected as the model drug for this study. Desloratadine-loaded fiber mats were fabricated through electrospinning and transformed into flexible ODTs using simple 3D-printed tools. The fabrication process was optimized and simplified to offer patient-tailored medications with minimal human errors. The flexible structure of electrospun ODTs not only makes them ideal for pediatric medications, but also eliminates the need for specialized packaging and handling procedures.

## Materials and Methods

# Materials

Desloratadine was kindly gifted by Santa Farma Pharmaceuticals Inc. (Türkiye). PVP 30K was obtained from Sekisui (Japan), Kollidon 90F was obtained from BASF (Germany), and PEO (900k) was purchased from Sigma-Aldrich (Germany). De-ionized water was obtained from the ultrapure water system (Model-Arium 611) of Sartorius (Germany). All the solvents used in this study were HPLC-grade obtained from Merck.

## Preparation of electrospun fibers

Drug-free fibers were prepared by using polyvinyl pyrrolidone (PVP 30k), Kollidon 90F (900-1200k), and polyethylene oxide (900k) dissolved/dispersed in either water, ethanol, or their mixture as shown in Table 1. A vortex mixer with tube holders or a magnetic stirrer was used to prepare the samples. Formulations with shorter preparation times (e.g., under one hour) and homogenous structures were selected for the fabrication of drug-loaded fibers to enable the fabrication of patient-tailored medicine quickly while providing dosage uniformity. After the pre-formulation studies, one of the blank formulations was selected to add 1–5% (w/v) desloratadine to form the drug-loaded fibers.

Table 1
Composition of formulations for the electrospinning process

| | Ethanol (mL) | Water (mL) | Polymers (g) | | |
|---|---|---|---|---|---|
| | | | PVP 30k | Kollidon 90F | PEO 900k |
| F1 | 5 | 5 | 2 | - | - |
| F2 | 5 | 5 | 5 | - | - |
| F3 | 5 | 5 | - | 1 | - |
| F4 | - | 10 | - | 1 | - |
| F5 | 5 | 5 | - | 1 | - |
| F6 | 4 | 6 | - | 1 | - |
| F7 | 10 | - | - | 1 | - |
| F8 | 10 | - | - | 0.5 | 0.5 |
| F9 | 10 | - | - | - | 1 |

Fiber mats were prepared via the electrospinning method using Ne200 NanoSpinner (Inovenso, Turkey) using a single nozzle prepared with a blunt 22G needle [10]. The device is a closed-door system allowing bottom-up spinning and is composed of a syringe pump, connection apparatuses, polyethylene connection tubes, high voltage power supply, flat, and drum collector. The electrospinning process was optimized by changing the voltage (5–25 kV), distance to the collector (5–20 cm), and the flow rate (0.5–5 mL/h). A flat collector was used for single-dose mat fabrication while a drum collector rotating at 100 rpm was used for multiple-dose fiber fabrication. After collecting the fibers on the drum collector, a paper cutter (Mühlen Säge GL-410-M) was used to cut the long fiber mat into equal pieces of 3 $cm^2$ rectangle strips (1.5 x 2 cm). For single-dose fiber mats, the fabrication time was aimed at 1–2 minutes to minimize human error while collecting the fiber mat. Fiber mats were loaded either with 2.5 mg (pediatric dose) or 5 mg (adult dose) desloratadine to compare later with the commercially available ODTs. For this purpose, desloratadine (1–5% w/v) was added to the polymer solution.

# Characterization of desloratadine-loaded electrospun fibers

Fibers were collected on a glass slide for 10 and 60 seconds and imaged by microscopy (Zeiss Primostar, Germany). Images were analyzed by image software (Zeiss, ZEN image software, Germany) by measuring at least 10 fibers per sample. Subsequently, the average fiber diameter was calculated.

UV spectrophotometry at a wavelength of 241.5 nm was used for the quantification of desloratadine. A stock solution of desloratadine was prepared in methanol at 1 mg/mL concentration. Calibration samples with concentrations of 4, 6, 8, 10, 20, and 40 µg/mL were prepared from the stock solution by making dilutions using methanol. The quantification method was validated according to the ICH Q2 R1 guideline.

Fiber mats were weighted after fabrication to check the fabrication uniformity. Static charges can cause unstable balance readings. Therefore, a glass beaker was placed on a scale upside down and used as a spacer to avoid the effect of static charge and improve the accuracy of weighing.

Desloratadine was extracted from fiber mats by dissolving the fiber mat in methanol. The drug amount in the fiber mats was determined using the UV spectroscopy method described above with at least 6 replicates.

The thermal profile of desloratadine, Kollidon 90F, Kollidon 90F blank fiber, and desloratadine-loaded Kollidon 90F fiber were evaluated using differential scanning calorimetry (DSC) (PerkinElmer DSC 6000). Samples were placed separately into standard aluminum pans and sealed non-hermetically. The desloratadine amount was matched with the desloratadine-loaded fiber sample and pure desloratadine for comparison. The samples were scanned between 20 and 200°C with a heating rate of 10°C/min under a 50 mL/min nitrogen atmosphere while an empty aluminum pan was used as a reference.

# Tablet formation from electrospun fiber mats

A custom-made tablet compression tool (Fig. 1a) was designed and fabricated with a 3D printer (Ultimaker 2, Netherlands) for the formation of ODTs from electrospun fiber mats. The electrospun fibers were collected from the aluminum foil and placed into the tablet compression tool. The fiber was compressed between the lower and upper punches. The height of the flexible tablet was adjusted by the gap between the punches. Another longer punch was used to eject the flexible tablet (Fig. 1c). The ODTs were used for mechanical strength and disintegration testing and compared with the commercially available product for their flexibility and disintegration time.

# Mechanical properties

ODTs made of electrospun fiber mats were analyzed for their flexibility by using a texture profile analyzer and compared with the commercially available desloratadine ODTs. For this purpose, a Texture Analyzer (TA.XT. PlusTexture Analyzer, Stable Micro Systems, UK) was used. ODTs were placed on a fixed surface. The Texture Analyzer was set in compression mode and the force was applied to the center of the samples with a blunt end probe.

# Disintegration test

Initial disintegration tests were carried out with electrospun fiber mats. The fiber mats were placed in a well plate and artificial saliva was added dropwise. The disintegration was observed continuously with a microscope.

ODTs made of electrospun fiber mats were tested and compared with the commercially available desloratadine ODTs for disintegration time. For this purpose, an artificial saliva solution was prepared as previously described [14]. 50 mL centrifuge tubes were filled with 20 mL artificial saliva solution. Both ODTs were dropped into the tubes and observed for tablet disintegration time.

## Results and Discussion

The specific advantages of ODTs may vary depending on the formulation and medication, but their ease of use and suitability for a wide range of patients makes them a valuable option in the pharmaceutical industry. However, the fabrication process for ODTs may limit the application of their use. Here we aimed to fabricate ODTs from electrospun fibers to enhance their properties and remove some of the disadvantages that naturally come from the fabrication method.

The preparation of blank polymer and polymer-drug solutions is a critical parameter in fabricating electrospun fiber mats [15]. We aimed to keep the solution preparation time short while obtaining a suitable solution for the electrospinning process. The compositions of the pre-formulations can be found in Table 1. Since desloratadine is poorly soluble in water [16], PVP and PEO were selected as polymers to enhance the solubility of the drug in the final formulation [17]. PVP with two different molecular weights and PEO, along with their mixtures, were dissolved in either ethanol, water, or their mixtures. 10–50% polymer in solvent was prepared to achieve the desired viscosity for the electrospinning process. Formulations prepared with low molecular weight PVP resulted in a homogenous polymer solution (F1 and F2). Due to the solubility of the polymers, a suspension was formed with the lowest polymer concentrations for Kollidon F90 and PEO in water and ethanol (F4 and F9), respectively. Formulations prepared with the ethanol:water mixture and Kollidon F90 resulted in a homogenous solution (F3 and F5) by using a minimum 40% (v/v) ethanol in the mixture. The Kollidon 90 and PEO mixture also resulted in a homogenous solution. All these formulations had the potential for an electrospinning process, but the preparation time was long in all these conditions. A minimum 1-hour preparation time resulted in a homogenous polymer solution with F7 formulation where Kollidon 90F formulation was dissolved in ethanol only. This formulation was selected to move forward with drug-loaded studies and further optimize the electrospinning process.

The electrospinning process parameters were determined by observing the Taylor cone formation. It is critical to have a stable Taylor cone formation during the desired fabrication time for an uninterrupted fiber mat fabrication [10]. The electrospinning parameters were optimized for the most stable flow and mat formation. A stable electrospinning process was achieved with 1 mL/h flow rate and 6 kV voltage

from a 10 cm distance. We then tried to increase the flow rate to reduce the fabrication time. The flow rate was increased from 1 mL/h to 3 mL/h, keeping the distance at 10 cm but increasing the voltage to 15 kV. While these parameters were suitable for initial electrospinning, the fibers started to scatter and were not collected on the collection plate due to the high voltage. Up to 3 hours of uninterrupted fabrication was achieved by lowering the voltage to 12 kV, keeping the flow rate and the distance 3 mL/h and 10 cm, respectively. After the optimization of the electrospinning parameters, the fabrication time was arranged for desired drug loading by either collecting the fiber mats on a flat or drum collector for single and multiple-dose fabrications. Incorporation of the drug at a 5% ratio resulted in a fabrication time of less than 1 minute for single-dose fiber mat production. To minimize the error while collecting the fiber mat from the aluminum foil, the studies continued with the 2.5% drug-added solutions. Fibers were collected on a flat collector for 2 and 4 minutes to obtain a pediatric dose of 2.5 mg and a 5 mg adult dose of desloratadine, respectively.

# Characterization of desloratadine-loaded electrospun fibers

The fiber formation was confirmed by using microscopy. Fibers were collected on a glass slide for 10 and 60 seconds can be seen in Fig. 2. More fabrication time resulted in more fiber formation when images were compared between 10 and 60 seconds. The average fiber diameter was calculated as 0.96 ± 0.1 µm.

Fiber mats were weighted after fabrication to check the fabrication uniformity. Single-dose fiber mats were used for this study and collected on aluminum foil on a flat collector for 2 minutes. The average weight was found 13.4 ± 1.1 mg (Relative standard deviation, RSD: 4.54). Desloratadine was extracted from the fiber mats by dissolving the fiber mat in methanol, and the drug amount in the single dose fiber mats was found to be 2.48 ± 0.11 mg for the pediatric dose fabrication. For the 4-minute adult dose fabrication, the average weight was 24.95 mg ± 0.40 mg (RSD: 1.61) and the drug loading was 0.49 ± 0.02 mg. It is noted that with the increase in the fabrication time, a more standardized and uniform fiber mat fabrication with a lower RSD was achieved.

The DSC thermograms of desloratadine, Kollidon 90F, Kollidon 90F fiber, and desloratadine-loaded Kollidon 90F fiber can be found in Fig. 3. No changes were observed between Kollidon 90F and Kollidon 90F blank fiber. When scanned as a pure drug, the endothermic melting peak of desloratadine was seen at 157°C [18]. This characteristic melting peak of desloratadine is not seen in the desloratadine-loaded Kollidon 90F fiber DSC thermogram even though the drug amount was kept the same as the pure drug for comparison between the two samples. The drug compound embedded within electrospun nanofibers can display an amorphous nature owing to the rapid evaporation of the solvent during the electrospinning procedure [19]. This indicates that desloratadine could be in an amorphous state in the fiber mats which may increase the solubility of the drug compared to the crystalline form.

# Tablet formation from electrospun fiber mats

One of the challenges, specifically for the pediatric doses of ODTs is the scale-up process. Even with the pre-compressed excipients, the compactibility of the final formulation after the addition of the drug must be shown in addition to uniformity and dosage homogeneity [20]. To test the mechanical properties and disintegration time, the single-dose fiber mats were transformed into a tablet shape using a custom-made tablet compression tool as described above. For this purpose, single-dose fiber mats were prepared by either collecting on a drum collector or flat collector to test the ODT formation. Multiple doses of fiber mats were prepared using the drum collector and later cut into a single dose (Fig. 4a). Fiber mats collected on a flat collector were directly used after removing from the aluminum foil without further modification (Fig. 4b). ODTs were successfully prepared from the fiber mats without any addition of any tablet excipients. The resulting tablet showing the compactibility of the fiber mats is shown in Fig. 4c.

# Mechanical properties

The formulations of ODTs should balance between sufficiently high mechanical strength and short disintegration times [21]. To achieve rapid disintegration, compromises are made on mechanical properties, leading to the implementation of specialized packaging and handling procedures.

The compression tests showed that commercial ODTs were broken apart while creating dust. However, when the same procedure was performed with electrospun ODTs, it was observed that the tablet could be completely squeezed, yet it did not break apart. Even when the probe came into contact with the analysis surface, causing a 100% strain, it was noted that the tablet maintained its single-piece structure (Fig. 5).

# Disintegration test

Microscopy images revealed that upon contact with water, desloratadine-loaded Kollidon 90F fiber mats were disintegrated immediately (Fig. 6).

This was followed by testing with ODTs. We conducted assessments on electrospun ODTs and made comparisons with commercially available ODTs. Both European Pharmacopeia and The United States Food and Drug Administration define ODTs as solid dosage forms that disintegrate quickly in the mouth before swallowing [21, 22] Both commercial and electrospun ODTs were disintegrated in under 10 seconds and found to meet the criteria.

## Conclusion

In this study alternative ODT formulations made of electrospun fiber mats were prepared and compared for their performance with the commercially available ODT product. Electrospun fibers loaded with desloratadine were fabricated using Kollidon F90 as the polymer both with drum and flat collectors for multiple-dose and single-dose fabrication.

Using a drum collector, we achieved up to 3 hours of electrospinning without interruption for the fabrication of multiple-dose large fiber mats. A patient-tailored dose arrangement was achieved by

adjusting the fabrication time. Two different doses, 2.5 mg for the pediatric dose and 5 mg for the adult dose of desloratadine fiber mats were prepared with the optimized electrospinning process parameters by collecting fibers for 2 and 4 minutes on a flat collector, respectively. The fiber formation was confirmed with microscopy images.

Fiber mats were successfully transformed into ODTs using a simple 3D-printed tablet compression tool. Mechanical analyses showed that ODTs made of electrospun fibers were flexible with improved physical appearance compared to the commercially available product. Disintegration tests showed that the ODTs made of electrospun fiber mats achieved comparable disintegration time with the commercially available product meeting the criteria indicated by both FDA and European Pharmacopoeia.

In conclusion, a flexible ODT was prepared using desloratadine-loaded Kollidon F90 fiber mats which can be used for the pediatric population as well as adult population. The proposed formulation eliminates the handling issue while keeping the desired mechanical strength compared to the currently commercially available product. This method could be scaled up and can be used for both pediatric and adult dose ODT fabrication in the pharmaceutical industry.

# Declarations

Acknowledgments

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Ethical Statement and Declarations

Ethics approval and consent to participate:

Not applicable

Consent for publication:

Not applicable

Availability of data and materials:

Data are available by contacting the authors

Competing interests:

Not applicable

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Authors' contributions

Gülçin Arslan Azizoğlu: Conceptualization, methodology, validation, investigation, formal analysis, data curation, writing - original draft, visualization.

Buse Dönder: Formal analysis, writing - review & editing.

Nergis İnal: Formal analysis, writing - review & editing.

Erkan Azizoğlu: Conceptualization, formal analysis, writing - review & editing, supervision, funding acquisition, project administration.

All authors read and approved the final manuscript.

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Data Availability Statement

Data are available by contacting the authors

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# Figures

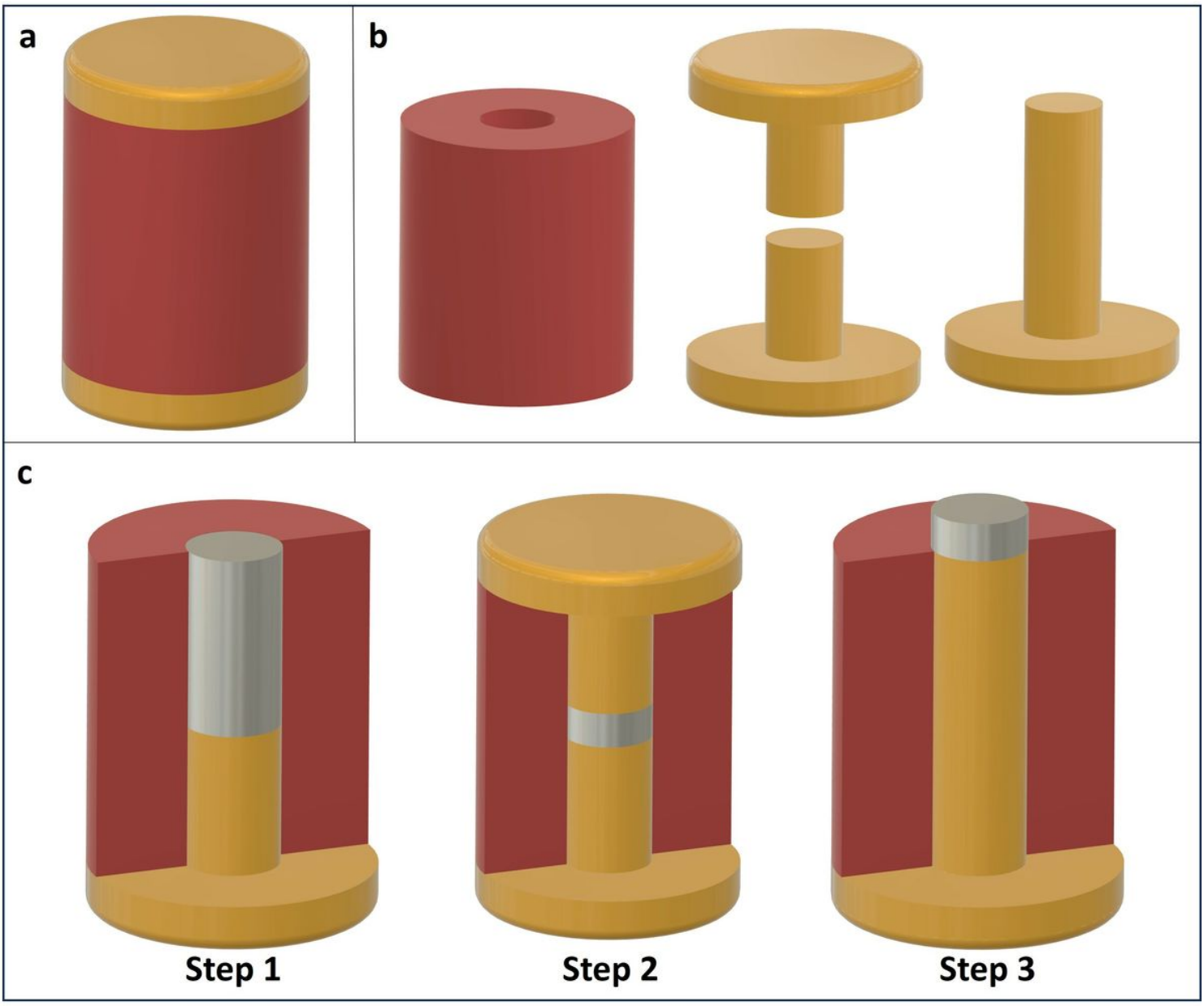
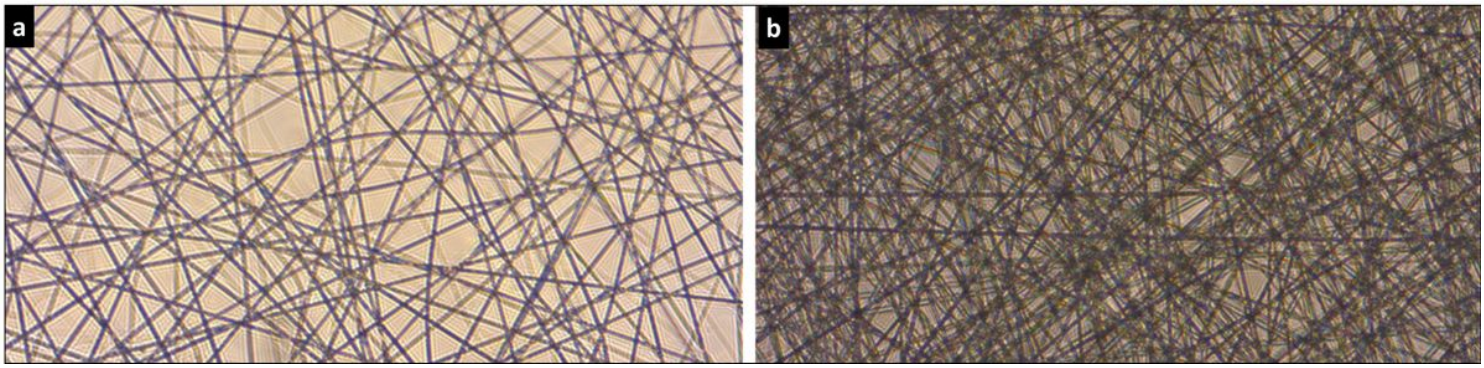


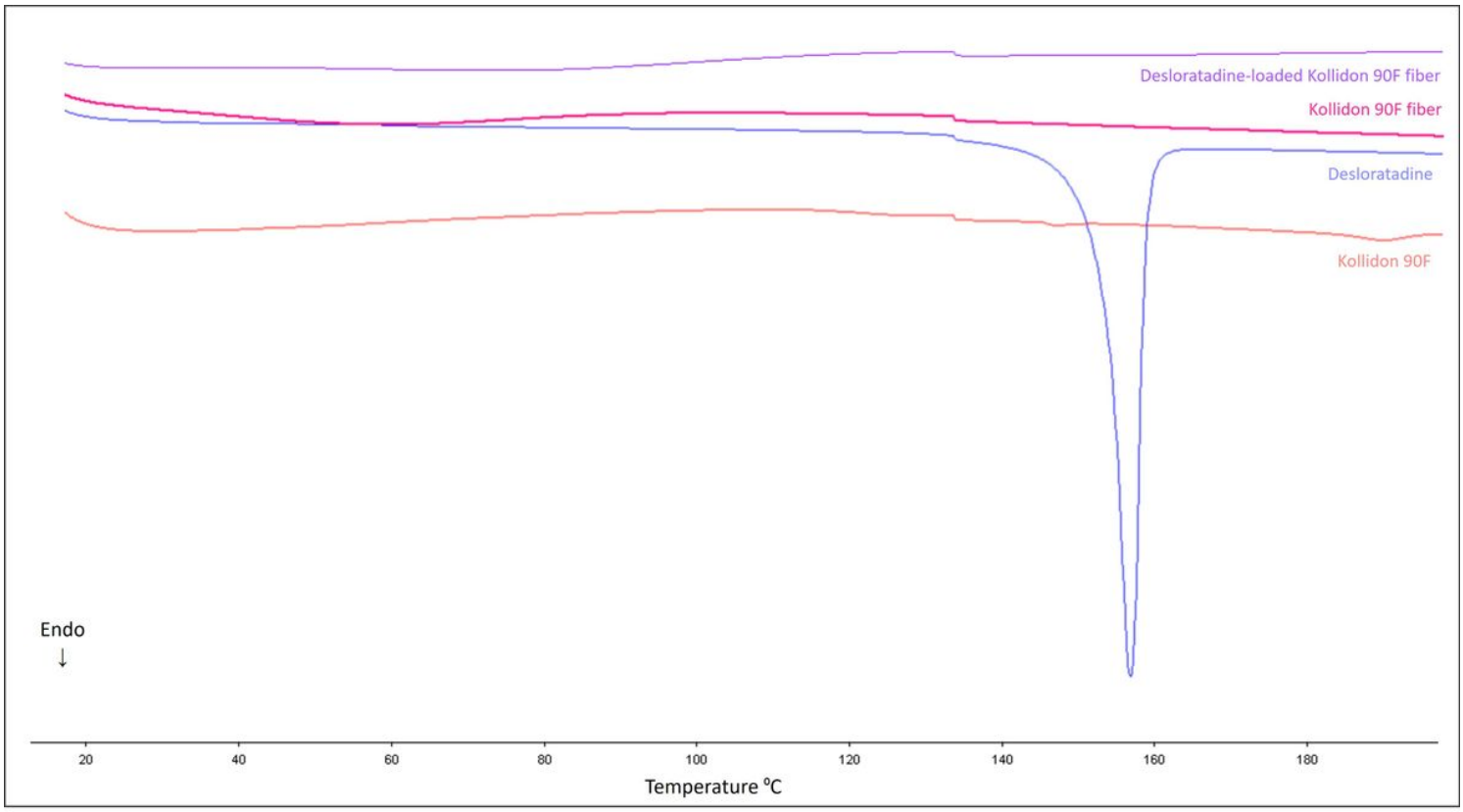

**Figure 1**

a) A schematic illustration of a custom-made 3D-printed tablet compression tool, b) parts of the tablet press apparatus; compression die, upper and lower punches for the tablet formation, and a longer punch to eject the tablet, c) steps of ODT formation from fiber mat; fiber mat is placed in the cylinder on top of the lower punch in step one and pressed with the upper punch in step 2. Finally, the ODT is ejected using the longer punch.




## Figure 2

Representative microscopy images of fibers collected on glass slides for a) 10 and b) 60 seconds.




## Figure 3

DSC thermograms of desloratadine, Kollidon 90F, Kollidon 90F blank fiber, and desloratadine-loaded Kollidon 90F

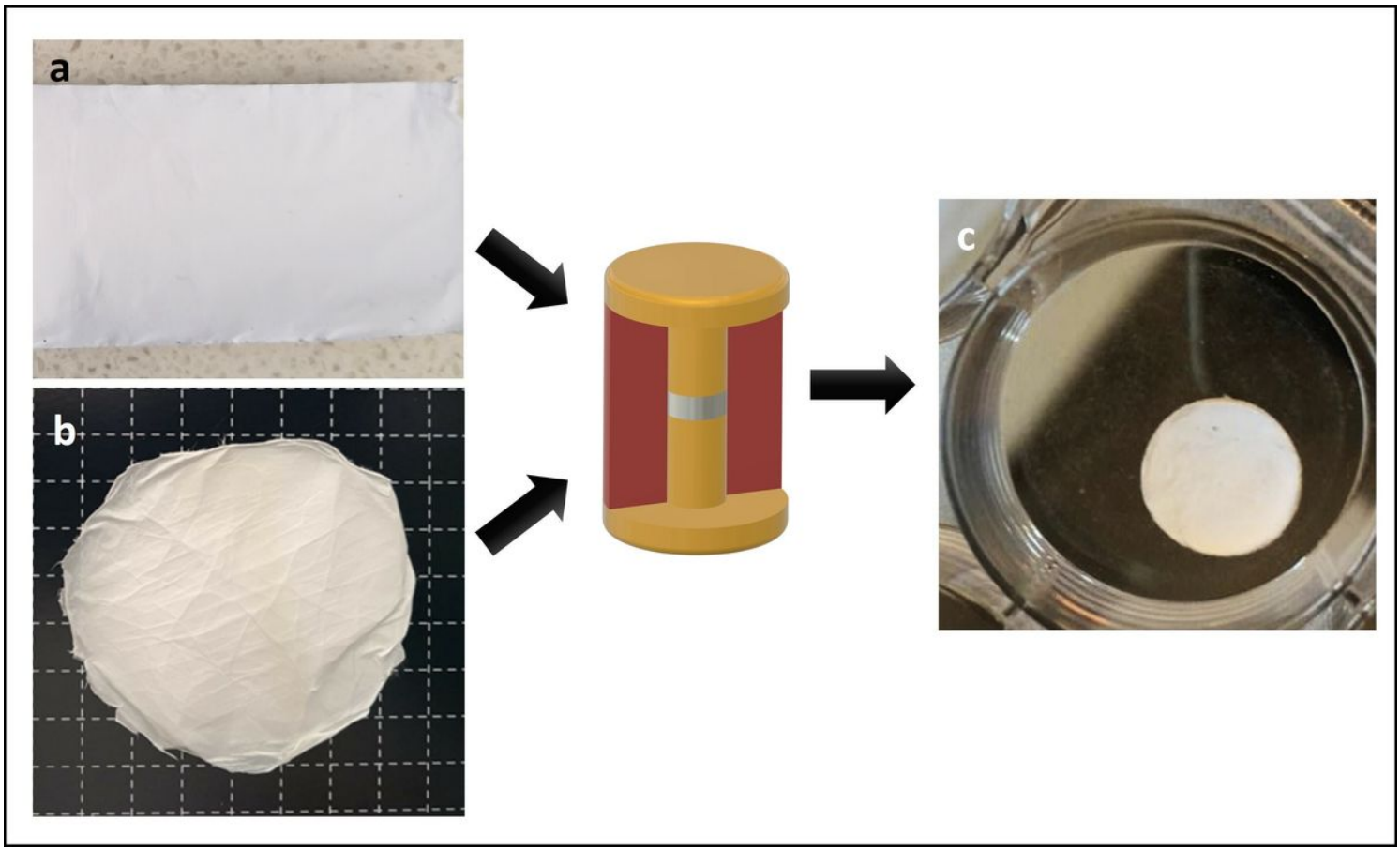



**Figure 4**

ODTs are prepared from single dose desloratadine-loaded Kollidon 90F fiber mats with a custom-made tablet press tool a) single dose cut from multiple dose mat collected on drum collector b) single dose fiber mat collected on flat collector c) a representative ODT shown after using tablet press tool.

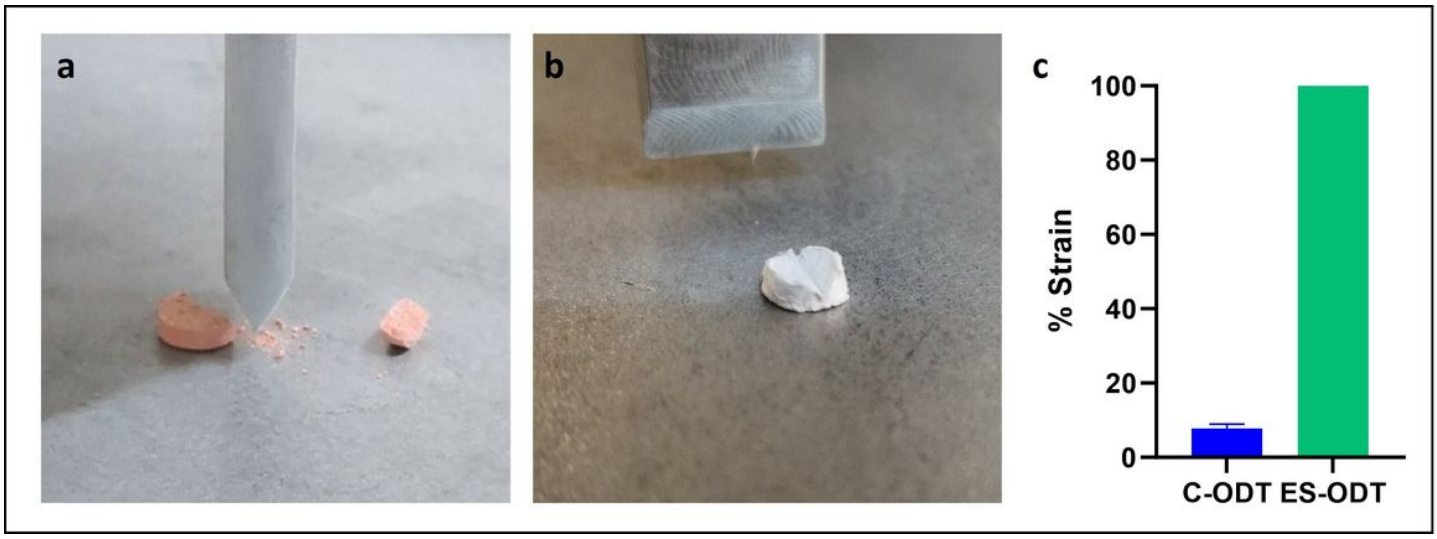



**Figure 5**

Images of samples after mechanical characterization analysis of a) commercial desloratadine ODT (C-ODT) and b) ODT made of electrospun fiber mat (ES-ODT), and c) % strain graph.

**Figure 6**

Disintegration images of desloratadine-loaded Kollidon 90F fiber mats upon exposure to water. Timestamps are shown on the top left corner of each image.

# Supplementary Files

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- GraphicalAbstract.jpg