# PREPARATION AND EVALUATION OF ORAL FILM OF GELATINIZED SAGO STARCH USING MODEL DRUG

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## Abstract

The objective of the presented work was to evaluate the film forming property of sago starch and formulate a film for the delivery of drug in the oral cavity. In the present research we also evaluated the effect of water soluble drug (levocetirizine dihydrochloride) and water insoluble drug (famotidine) on the properties of sago starch bases oral film. The formulations were prepared using semisolid casting method. The starch dispersion was pregelatinized at 90 0C before casting into films. Films were dried at 50 0C. A full 32factorial design was applied and 9 batches for each drug (L1-L9) for levocetirizine dihydrochloride and F1-F9 for famotidine) were formulated. The two independent variables selected were concentration of sago starch (X1) and heating time of starch dispersion at 90 0C (X2). The formulated films were evaluated for various parameters. Scanning Electron Microscopy study of the films was also performed and it was observed that the film containing water insoluble drug was having rougher surface and there were a large number of micro cracks were present. Thus it can be concluded that sago starch can be used as a film forming agent for the delivery of drug whether soluble/insoluble in the oralcavity.

**Keywords**: oralcavity, levocetirizine dihydrochloride, famotidine, Gelatinized Sago Starch, Oral Film

**DOI Number: 10.14704/nq.2022.20.9.NQ44366** **Neuro Quantology 2022; 20(9):3180-3193**

## INTRODUCTION

For a variety of reasons, including the fact that smooth muscle (which is not particularly mobile and has a lot of blood flow) and Lagerphone's cells are uncommon, it makes sense to investigate intraoral drug administration. Using internal jugular veins, medications can be injected directly into the circulatory system. Bioavailability is increased as a result of this method. Anatomy of the mouth (1-4)

Among the many structures that comprise the mouth are the tongue, the lips, the hard palate (chew), the buccal (buccal), and the soft palate. A total of around 200 cm2 of membranes line the inside of the mouth. Depending on where in the mouth they are, the mucous membranes vary in thickness, blood flow, and structure.(5)

### Oral films

In research and medicine administration, oral films were the most commonly utilised dosage form up until recently, although they are now widely used (API). Because of their oral behaviour and subsequent attachment to the mucosa, it is very impossible to spit them out after application. (5,6) As a method of drug delivery, oral films have many advantages (6,7)

Oral films, like DDS, have a number of advantages.(8-10)

- Disabled and unwilling patients will find it simple to administer.
- When administering the medication, no water is needed.
- Oral films can be used to hide the metallic, bitter, or unpleasant taste of certain medications.
- There are many ways to provide a pleasing mouthfeel. "
- These films make it possible to load drugs efficiently.
- There is no risk of choking with oral films, unlike with oraltablets.
- Patients who have difficulty swallowing can benefit from the use of these oral films.

- Oral films are an excellent method of administering medications to children and the elderly.
- More patients will take their medication as directed when it is administered via oral film.
- Oral films are a cost-effective and safe method of administering medication.
- Restriction
- Bioavailability is lower for drugs that cannot pass through the oral mucosa.
- It is not possible to administer drugs that have an unpleasant taste or odour without the use of taste and odour masking.
- In order to prevent disintegration, the oral films must be stored in a dry environment.
- A drug cannot be delivered if its pH is unstable in the salivary glands

**Physical Characterization(11)**

Levocetirizine dihydrochloride and famotidine were physically characterized as color, odor and taste. All the physical parameters were recorded and compared with literature.

**Melting point (12)**

The measurement of the melting point is very much important in preformulation studies. Reason to detect the melting point during preformulation is the crystalline solubility.

The melting points of both the drugs were determined by the capillary melting technique.

**CalibrationCurves(13)**

**Preparation of Calibration Curves of Levocetirizinedihydrochloride**

Accurately 10mg of drug weighed & dissolved in phosphate buffer(100 ml) solution (pH 6.2) In a 100 ml volumetric flask. Dilutions of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10µg/ml were prepared.After that the absorbance was measured using UV-visible spectrophoto meter at 230.5 nm.

**Table 1. Calibration curve of levocetirizine dihydrochloride**

| S. No. | Concentration (µg/ml) | absorbance | |
|---|---|---|---|
| 1 | 0 | 0±0 | **λmax=** 230.5nm Phosphate buffer (pH 6.2) **Equation:**y=0.05x+0.004 $R^2$= 0.999 |
| 2 | 1 | 0.057±0.004 | |
| 3 | 2 | 0.107±0.003 | |
| 4 | 3 | 0.158±0.005 | |
| 5 | 4 | 0.210±0.001 | |
| 6 | 5 | 0.261±0.003 | |
| 7 | 6 | 0.311±0.002 | |
| 8 | 7 | 0.361±0.002 | |
| 9 | 8 | 0.410±0.004 | |
| 10 | 9 | 0.460±0.005 | |
| 11 | 10 | 0.512±0.003 | |

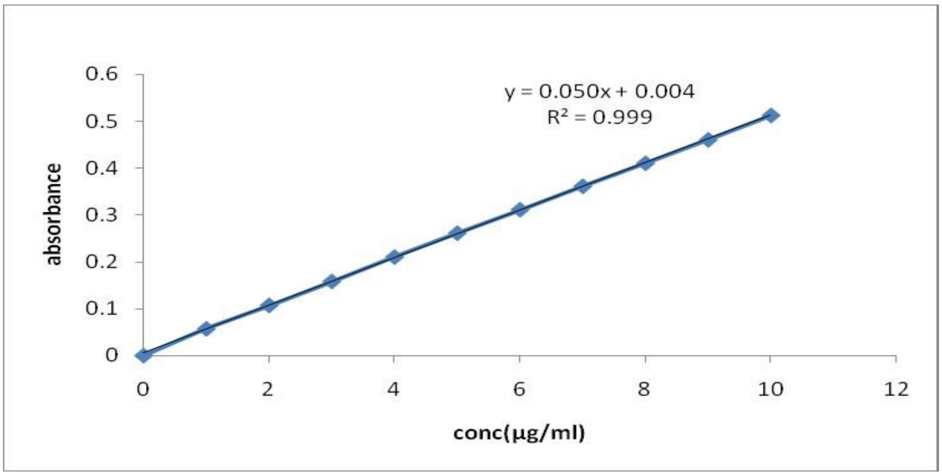


**Figure 1. Calibration curve of levocetirizine dihydrochloride**

**Preparation Of Calibration Curves Of Famotidine**

Volumetric flasks were filled with phosphate buffer solution (pH 6.2) and aliquotes of standard stock solution (0.5 mg/ml) were taken to get concentrations of 5, 10, 15, 20, 25, 30, 35, 40, 45, and 50 g/ml. At a wavelength of 268.5 nm, the absorbance of several solutions was determined. Standard curve was plotted same as above.

Table 2.: Calibration curve of famotidine

| **S.No.** | Concentration (µg/ml) | Absorbance | |
|---|---|---|---|
| **1** | 0 | 0±0 | **λmax**= 268.5nm<br>Phosphate buffer (pH=6.2)<br>**Equation:**y=0.034x+0.005<br>**R**$^2$= 0.998 |
| **2** | 5 | 0.17±0.002 | |
| **3** | 10 | 0.336±0.003 | |
| **4** | 15 | 0.542±0 | |
| **5** | 20 | 0.653±0.004 | |
| **6** | 25 | 0.859±0.003 | |
| **7** | 30 | 1.071±0.006 | |
| **8** | 35 | 1.202±0.005 | |
| **9** | 40 | 1.354±0.007 | |
| **10** | 45 | 1.561±0.002 | |
| **11** | 50 | 1.67±0.005 | |

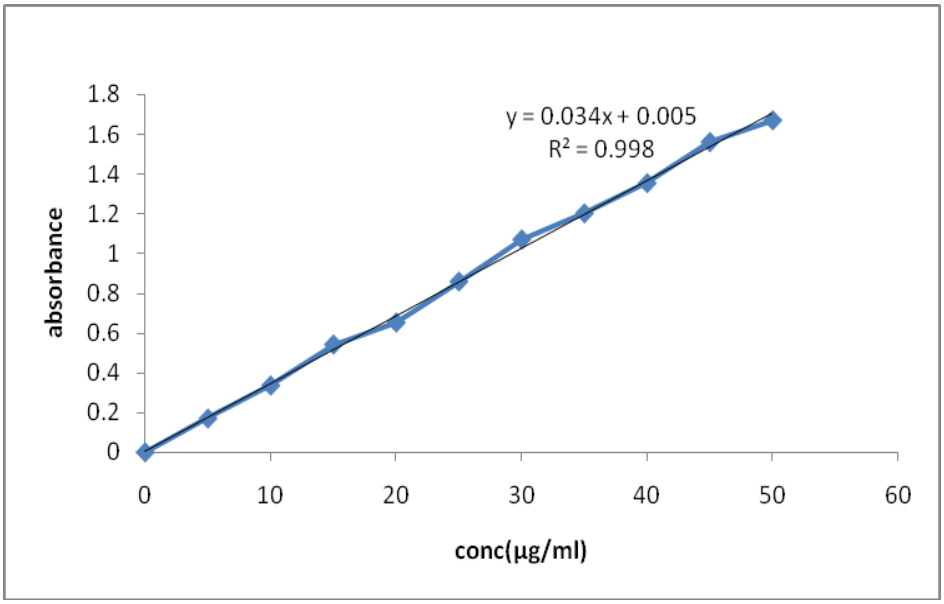


Figure 2. Calibration curve of famotidine

**Solubility of Drugs in Different Solvents(14)**

Drugs were tested for solubility in different solvents. For the determination of the solubility profile the drugs were kept in 5 ml of different solvents in 5 ml volumetric flasks. Solutions were shaken using shaker..5nm for levocetirizine dihydrochloride and 268.5nm for famotidine.

**Table 3. Solubility of drugs in different solvents**

| S.No. | Solvents | Solubility(mg/ml) | |
|---|---|---|---|
| | | Levocetirizine dihydrochloride | Famotidine |
| 1 | Chloroform | Soluble | Insoluble |
| 2 | Water | Soluble | Insoluble |
| 3 | Acetic acid | Soluble | Soluble |
| 4 | Ethanol | Soluble | Slightly soluble |
| 5 | Methanol | Soluble | Slightly soluble |
| 6 | Acetone | Insoluble | Slightly soluble |
| 7 | Ethyl acetate | Soluble | Insoluble |
| 8 | Isopropanol | Soluble | Insoluble |
| 9 | Hexane | Insoluble | Insoluble |
| 10 | Formic acid | Soluble | Soluble |
| 11 | n-propanol | Soluble | Soluble |
| 12 | Benzene | Soluble | Insoluble |
| 13 | Acetonitrile | Soluble | Insoluble |

**Partition Coefficient(15,16)**

The amount of levocetirizine dihydrochloride and famotidine solubilized in each phase was measured using an absorbance spectrophotometer at a wavelength of 230.5 nm and 268.5 nm, respectively. The partition coefficient was derived from the ratio of drug concentrations in organic and aqueous phases.

Levocetirizine dihydrochloride had a partition coefficient of 1.12, while famotidine had a partition coefficient of 1.31.

Shimadzu FTIR 8400S was used to record the infrared (IR) spectroscopy IR spectrum.

Between 10000 and 15000 PSI, the KBR press could withstand

**Formulation of Films(17)**

**Method of preparation**

To create the films, a semi-solid casting method was employed. Before the addition of plasticizers, starch dispersions were weighed and dispersed in distilled water. In order to dry the film following starch gelation, the dispersion was heated and put onto a plastic laminated glass plate. A dessicator was then used to keep these films after they had been peeled off. Efforts to fine-tune the formulation.

Table 4. Effect of heating time and temperature on sago starch film.

| S.No. | Heating temperature ($^0$C) | Heating time (min) | Observation |
|---|---|---|---|
| 1 | 70 | 5 | Separation of water from dispersion due to incomplete gelation |
| | | 10 | Separation of water from dispersion due to incomplete gelation |
| 2 | 80 | 5 | Separation of water from dispersion due to incomplete gelation |
| | | 10 | Separation of water from dispersion due to incomplete gelation |
| 3 | 90 | 5 | Separation of water from dispersion due to incomplete gelation |
| | | 10 | Complete gelation & good quality film |

**Effect of drying temperature**

The temperature at which the film is dried also affects the properties of the film formulated. The drying of film should neither be too rapid or it should be too slow. Very rapid drying (i.e. at higher temperature) can form air bubbles due to very rapid evaporation of solvent. if the drying is very slow (i.e. at lower temperature) the shrinking of films was observed. So to formulate the good quality film the drying temperature was optimized and results are given in **table below.**

**Table 5. Effect of drying temperature on sago starch film**

| S.No. | Drying temperature ($^0$C) | Observation |
|---|---|---|
| 1 | Room Temp | Shrinking of films |
| 2 | 50 | Proper film and drying |
| 3 | 60 | Formation of air bubbles |
| 4 | 70 | Formation of air bubbles |

**Formulation of levocetirizine dihydrochloride containing starchfilm**

The films containing levocetirizine dihydrochloride (water soluble drug) were prepared by following method **(Table 12)**:

Weighed the ingredients accurately Dissolved the drug in the 50ml of water

⇩

Added sago starch and glycerol in drug solution Heated the above dispersion at 90$^0$c till the required time

⇩

Casted the gelatinized solution on plastic laminated glass molds (9x9 cm$^2$) Dried overnight in the oven at 50$^0$c

⇩

Remove the film after drying and store in dessicator till further use

**Table 6. Composition of sago starch based oral films for levocetirizine dihydrochloride**

| Ingredients | $L_1$ | $L_2$ | $L_3$ | $L_4$ | $L_5$ | $L_6$ | $L_7$ | $L_8$ | $L_9$ |
|---|---|---|---|---|---|---|---|---|---|
| Sago starch(gm) | 2.5 | 2.5 | 2.5 | 3.75 | 3.75 | 3.75 | 5 | 5 | 5 |
| Levocetirizine dihydrochloride(gm) | 0.405 | 0.405 | 0.405 | 0.405 | 0.405 | 0.405 | 0.405 | 0.405 | 0.405 |
| Glycerine(gm) | 0.625 | 0.625 | 0.625 | 0.937 | 0.937 | 0.937 | 1.25 | 1.25 | 1.25 |
| Saccharine sodium(gm) | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Methyl paraben(gm) | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Propyl paraben(gm) | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 | 0.001 |
| Distilled water (ml) | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |

**RESULT & DISCUSSION**

**Thickness**

Five measurements were made to ensure that the thickness of the sago-based oral films was the same across the board. Table 5.1 displays results for levocetirizine dihydrochloride, while Table 5.2 shows results for levocetirizine dihydrochloride-based films. As the starch concentration increased, the films became thicker.

**Weight uniformity**

Five 1x1cm2 sections of each film were weighed to evaluate the weight homogeneity of all 18 batches (L1-L2 & F1-F7). The data demonstrates that the weights of all the batches were consistent. At least one of the following is true: INTERMEDIATE DRYING TIME

Researchers studied the film's moisture loss % after three days of storage at a low humidity level. Figure 5.1 shows the results. Batch L6 of levocetirizine dihydrochloride had the highest PML (37.51.03%) while batch F3 of famotidine had the highest PML (42.860.65%). Table 5.1

and Table 5.2) Heating duration increased PML, but polymer concentration decreased it. Compared to levocetirizine dihydrochloride, famotidine had a higher PML value

**Percentage Moisture absorption**

The formulations' PMA (percentage moisture absorption) was also measured by exposing them to extreme humidity for three days. Table 5.1 shows the results for levocetirizine dihydrochloride, while Table 5.2 shows the results for famotidine. PMA levels in starch films containing famotidine and levocetirizine dihydrochloride are shown side by side in Figure 5.2 (left). Batch L3 (66.670.92 percent) and Batch F3 (85.712.55 percent) had the highest PMA values. Values were higher for drugs that were not water soluble than for those that were



**Table 7: Evaluation of sago starch films containing levocetirizine dihydrochloride**

| S.No. | Batch | Thickness* (mm) | Weight* (mg) | PMA# | PML# | WVP# (mg-mm/cm²) |
|---|---|---|---|---|---|---|
| 1 | $L_1$ | 0.378±0.0098 | 64±5.48 | 33.33±1.93 | 16.67±0.36 | 19.26±1.67 |
| 2 | $L_2$ | 0.371±0.0056 | 68±4.47 | 50±1.70 | 33.33±0.75 | 22.68±0.84 |
| 3 | $L_3$ | 0.3738±0.0088 | 66±5.48 | 66.67±0.92 | 33.33±0.94 | 26.67±2.94 |
| 4 | $L_4$ | 0.4216±0.0067 | 80±0 | 25±1.14 | 12.5±1.3 | 16.11±1.04 |
| 5 | $L_5$ | 0.4402±0.0044 | 82±8.37 | 37.5±1.78 | 25±0.14 | 18.51±0.73 |
| 6 | $L_6$ | 0.431±0.0068 | 82±8.37 | 50±2.42 | 37.5±1.03 | 24.71±0.63 |
| 7 | $L_7$ | 0.5404±0.0042 | 106±5.48 | 20±0.34 | 10±0.37 | 15.15±0.87 |
| 8 | $L_8$ | 0.5414±0.0043 | 104±5.48 | 30±0.73 | 20±0.26 | 16.55±0.62 |
| 9 | $L_9$ | 0.5428±0.0032 | 104±5.48 | 40±1.87 | 30±0.36 | 22.13±0.73 |

*** = readings are mean ± standard deviation (n=5) # = readings are mean ± standard deviation (n=3)**

**Table 8. Evaluation of sago starch films containing famotidine**

| S.No. | Batch | Thickness*(mm) | Weight*(mg) | PMA# | PML# | WVP# (mg-mm/cm²) |
|---|---|---|---|---|---|---|
| 1 | $F_1$ | 0.374±0.0043 | 66±5.48 | 42.86±1.03 | 14.29±1.05 | 23.35±0.74 |
| 2 | $F_2$ | 0.3736±0.007 | 64±5.48 | 57.14±1.77 | 28.57±0.76 | 26.65±0.82 |
| 3 | $F_3$ | 0.3758±0.0071 | 66±5.48 | 85.71±2.55 | 42.86±0.65 | 31.60±1.98 |
| 4 | $F_4$ | 0.4204±0.0084 | 82±8.94 | 22.22±1.43 | 22.22±0.44 | 21.42±1.73 |
| 5 | $F_5$ | 0.4196±0.0071 | 80±7.07 | 33.33±0.45 | 33.33±0.34 | 24.59±1.53 |
| 6 | $F_6$ | 0.4202±0.0073 | 82±8.37 | 44.44±2.19 | 44.44±1.22 | 28.37±1.01 |
| 7 | $F_7$ | 0.5396±0.0110 | 110±7.07 | 9.09±0.32 | 18.18±0.45 | 17.74±0.52 |
| 8 | $F_8$ | 0.5396±0.0094 | 106±5.48 | 18.18±0.29 | 27.27±0.84 | 21.99±0.65 |
| 9 | $F_9$ | 0.5392±0.0075 | 104±5.48 | 27.27±0.67 | 36.36±0.44 | 25.42±0.88 |

*** = readings are mean ± standard deviation (n=5) # = readings are mean ± standard deviation (n=3)**

**Swelling properties**

Results of starch film water vapour permeability tests are shown in Table 5.1 and Table 5.2, respectively. Famotidine starch films are more water vapour permeable than levocetirizine dihydrochloride starch films. Permeability to water vapour was highest in batches L3, F3, and L7, while it was lowest in batches L7, L6, and F6, respectively, at 15.150.87 mg-mm/cm2 and 17.740.52 mg-mm/cm2. graph of oral films made of starch derived from Sago shows how water vapour permeability changes over time.

**Table 5.3: Swelling of starch films containing levocetirizine dihydrochloride**.

| Time (h) | Swelling (%) (mean±sd) (n=3) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | L1 | L2 | L3 | L4 | L5 | L6 | L7 | L8 | L9 |
| 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 | 0± 0 |
| 0 . 5 | 33.33 ±3.42 | 50 ±2.48 | 66.67 ±3.46 | 25 ±2.49 | 37.5 ±1.63 | 50 ±1.35 | 30 ±2.49 | 40 ±2.49 | 54.55 ±4.72 |
| 1 | 50 ±2.40 | 83.33 ±3.54 | 116.67 ±2.34 | 50 ±2.44 | 75 ±2.88 | 100 ±4.56 | 30 ±3.29 | 60 ±2.45 | 63.64 ±3.28 |
| 1.5 | 100 ±3.50 | 116.67 ±4.56 | 166.67 ±2.56 | 75 ±1.44 | 100 ±2.94 | 137.5 ±4.66 | 50 ±0.43 | 70 ±2.99 | 81.82 ±5.37 |
| 2 | 116.67 ±4.35 | 150 ±5.68 | 200 ±3.45 | 87.5 ±4.57 | 100 ±3.29 | 162.5 ±0.24 | 60 ±2.43 | 80 ±3.55 | 100 ±6.90 |
| 2.5 | 150 ±3.56 | 200 ±6.34 | 250 ±4.36 | 112.5 ±6.44 | 137.5 ±0.42 | 187.5 ±1.29 | 90 ±4.32 | 110 ±5.93 | 118.18 ±3.89 |
| 3 | 150 ±2.43 | 216.67 ±4.56 | 283.33 ±2.67 | 137.5 ±0.57 | 175 ±5.20 | 200 ±4.39 | 100 ±5.95 | 130 ±4.30 | 127.27 ±2.48 |
| 3.5 | 183.33 ±1.84 | 216.67 ±5.34 | 283.33 ±2.90 | 150 ±5.23 | 200 ±2.49 | 237.5 ±4.55 | 120 ±4.56 | 160 ±3.29 | 154.55 ±1.46 |
| 4 | 200 ±2.43 | 266.67 ±4.56 | 300 ±3.65 | 150 ±3.54 | 212.5 ±0.94 | 250 ±5.30 | 130 ±5.39 | 180 ±1.93 | 172.73 ±2.35 |
| 4.5 | 200 ±5.32 | 283.33 ±4.68 | 316.67 ±1.89 | 175 ±3.29 | 225 ±2.39 | 275 ±2.94 | 140 ±4.29 | 190 ±0.58 | 190.91 ±3.39 |
| 5 | 216.67 ±3.56 | 283.33 ±4.59 | 333.33 ±2.95 | 187.5 ±0.84 | 250 ±3.29 | 275 ±6.49 | 160 ±3.64 | 200 ±2.58 | 190.91 ±3.54 |
| 5.5 | 216.67 ±3.45 | 300 ±2.34 | 316.67 ±2.98 | 175 ±1.84 | 250 ±1.38 | 262.5 ±4.2 | 170 ±4.02 | 210 ±6.83 | 200 ±2.89 |
| 6 | 216.67 ±4.65 | 266.67 ±4.32 | 333.33 ±4.35 | 187.5 ±0.84 | 225 ±2.48 | 275 ±3.29 | 170 ±3.59 | 210 ±8.63 | 200 ±1.49 |
| 6.5 | 200 ±3.43 | 266.67 ±5.21 | 333.33 ±3.57 | 200 ±2.48 | 237.5 ±3.44 | 287.5 ±4.92 | 180 ±2.58 | 210 ±3.59 | 190.91 ±3.55 |
| 7 | 183.33 ±1.43 | 250 ±3.09 | 316.6 ±2.81 | 187.5 ±4.33 | 237.5 ±5.09 | 275 ±2.48 | 180 ±5.30 | 200 ±2.85 | 190.91 ±4.59 |
| 7.5 | 183.33 ±4.98 | 250 ±1.23 | 300 ±3.56 | 187.5 ±2.44 | 225 ±4.88 | 250 ±0.93 | 170 ±1.30 | 200 ±3.58 | 190.91 ±5.20 |
| 8 | 166.67 ±3.59 | 233.33 ±4.39 | 300 ±2.50 | 175 ±3.49 | 225 ±5.29 | 237.5 ±1.35 | 170 ±4.39 | 200 ±2.49 | 190.91 ±4.93 |

Table 9. Swelling of starch films containing famotidine

| Time (h) | Swelling (%) (mean ± sd) (n = 3) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
| **0** | 0±0 | 0±0 | 0±0 | 0±0 | 0±0 | 0±0 | 0±0 | 0 ± 0 | 0 ±0 |
| **0 . 5** | 42.86 ±1.24 | 57.14 ±4.72 | 83.33 ±2.89 | 33.33 ±3.44 | 44.44 ±2.45 | 55.56 ±3.78 | 45.45 ±1.09 | 70 ±1.16 | 72.73 ±0.96 |
| **1** | 85.72 ±2.34 | 85.71 ±2.34 | 133.33 ±2.34 | 66.67 ±2.45 | 88.89 ±5.43 | 88.89 ±0.99 | 54.55 ±3.20 | 100 ±2.41 | 118.18 ±2.3 |
| **1.5** | 114.29 ±2.94 | 128.57 ±3.43 | 183.33 ±3.43 | 100 ±1.58 | 122.22 ±0.44 | 111.11 ±1.49 | 63.64 ±4.35 | 120 ±3.90 | 136.36 ±3.43 |
| **2** | 128.57 ±1.84 | 157.14 ±0.26 | 216.67 ±0.98 | 122.22 ±2.48 | 155.56 ±6.04 | 133.33 ±2.48 | 81.82 ±5.35 | 140 ±3.94 | 172.73 ±4.32 |
| **2.5** | 157.14 ±3.28 | 171.43 ±2.34 | 266.67 ±0.95 | 133.33 ±1.90 | 177.78 ±4.30 | 155.56 ±5.49 | 90.91 ±3.50 | 160 ±4.93 | 181.82 ±2.43 |
| **3** | 171.42 ±0.39 | 185.71 ±3.55 | 300 ±1.48 | 133.33 ±2.46 | 222.22 ±1.64 | 188.89 ±4.59 | 90.91 ±4.37 | 170 ±5.38 | 200 ±3.43 |
| **3.5** | 200 ±1.38 | 228.57 ±1.45 | 333.33 ±2.48 | 144.44 ±2.98 | 255.56 ±2.55 | 211.11 ±3.58 | 118.18 ±3.48 | 190 ±2.95 | 218.18 ±3.58 |
| **4** | 214.28 ±3.892 | 242.86 ±1.98 | 366.67 ±5.38 | 166.67 ±4.69 | 255.56 ±3.52 | 233.33 ±5.38 | 136.36 ±3.45 | 210 ±5.28 | 227.27 ±4.28 |
| **4.5** | 228.57 ±0.49 | 242.86 ±2.38 | 400 ±4.58 | 188.89 ±3.54 | 266.67 ±3.98 | 255.56 ±2.48 | 154.55 ±3.40 | 240 ±4.92 | 245.46 ±5.39 |
| **5** | 257.14 ±2.98 | 271.43 ±1.34 | 366.67 ±5.49 | 222.22 ±4.23 | 277.78 ±4.39 | 277.78 ±4.57 | 172.73 ±4.43 | 260 ±6.3 | 254.55 ±4.39 |
| **5.5** | 285.71 ±3.56 | 285.72 ±2.48 | 366.67 ±3.57 | 244.44 ±2.68 | 288.89 ±0.879 | 288.89 ±2.57 | 172.73 ±3.56 | 260 ±2.4 | 263.64 ±5.38 |
| **6** | 214.29 ±4.57 | 314.29 ±3.45 | 383.33 ±0.589 | 255.56 ±3.56 | 288.89 ±6.25 | 322.22 ±4.39 | 190.91 ±5.57 | 260 ±4.20 | 254.55 ±3.49 |
| **6.5** | 200 ±3.49 | 242.86 ±5.35 | 366.67 ±0.397 | 255.56 ±2.66 | 288.89 ±3.65 | 322.22 ±4.38 | 209.09 ±4.65 | 250 ±4.84 | 254.55 ±5.38 |
| **7** | 185.71 ±6.54 | 214.29 ±3.55 | 366.6 ±3.58 | 244.44 ±3.65 | 288.89 ±2.59 | 322.22 ±2.58 | 209.09 ±0.99 | 260 ±2.49 | 245.46 ±5.49 |
| **7.5** | 171.43 ±0.34 | 214.29 ±4.55 | 350 ±1.38 | 233.33 ±3.99 | 277.78 ±1.50 | 322.22 ±3.58 | 200 ±2.45 | 260 ±3.29 | 245.46 ±4.93 |
| **8** | 171.43 | 228.57 | 350 | 233.33 | 277.78 | 311.11 | 200 | 250 | 245.46 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | ±2.43 | ±0.99 | ±0.61 | ±2.57 | ±2.49 | ±3.59 | ±1.48 | ±1.08 | ±0.87 |



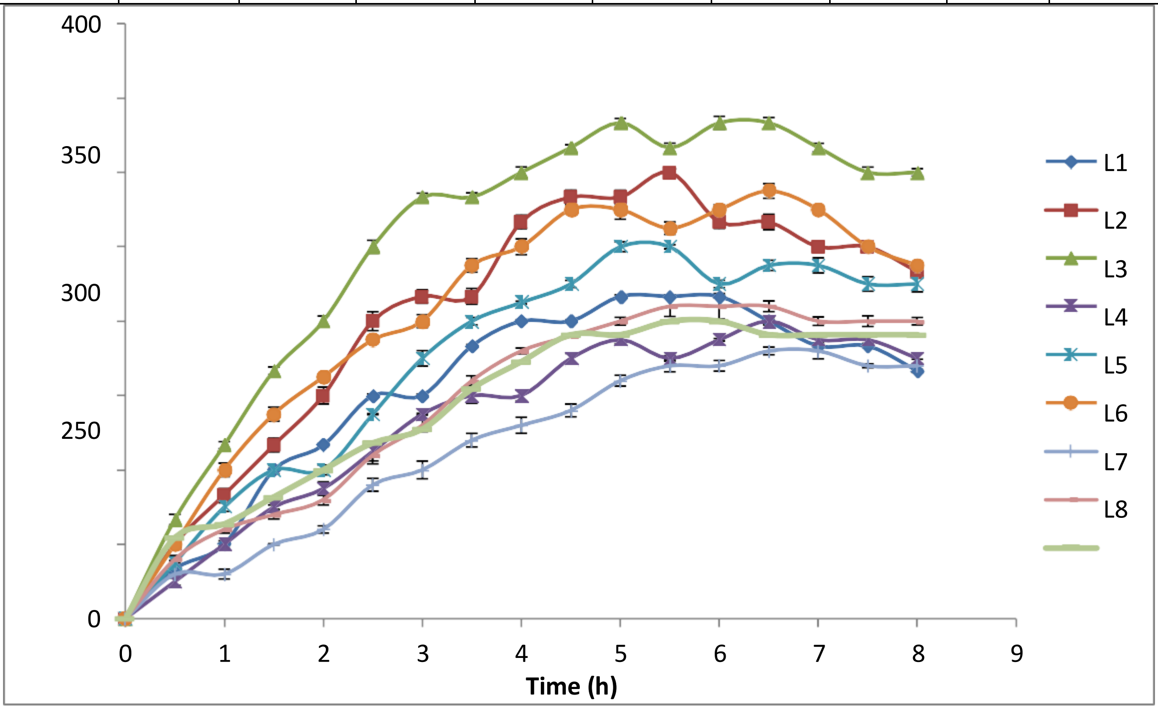


Figure 3. Swelling of starch films containing levocetirizine dihydrochloride

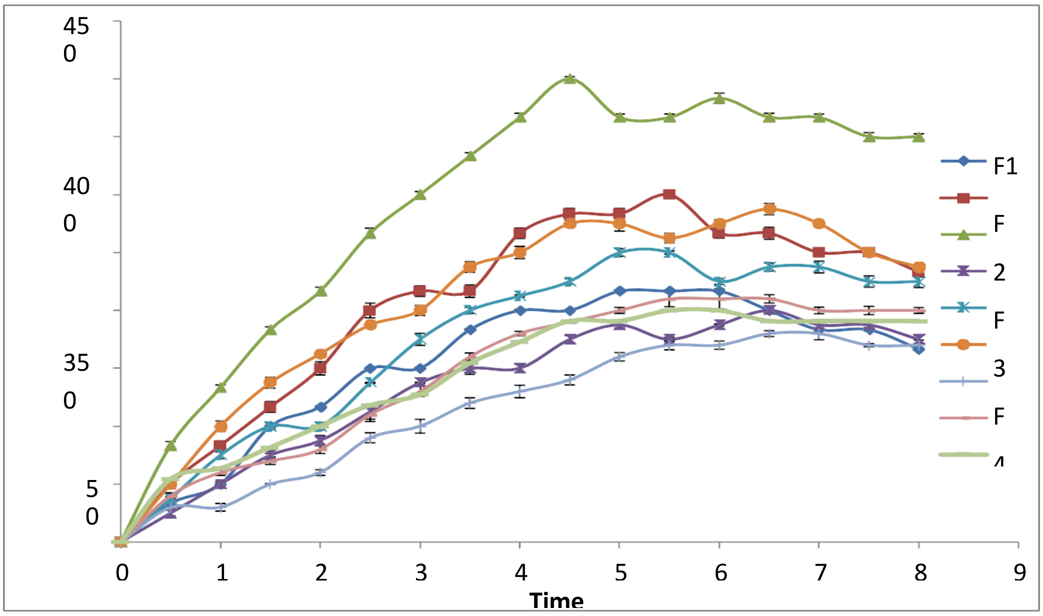


Figure 4. Swelling of starch films containing famotidine

**STABILITYSTUDIES**

The physicalappearanceanddrugcontentwasdeterminedafter30daysinterval.After 90 days, there was no big change in the way the films looked or how many drugs they had. Results are shown in for sago starch films containing levocetirizine dihydrochloride and famotidine respectively.

**Table 10. Stability tests on sago starch films with levocetirizine dihydrochloride were done.**

| Batch | Drug content | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 25± 2 ° C/ 60± 5%RH | | | | 30± 2 °C/ 65± 5%RH | | | | 40± 2 °C/ 75± 5 %RH | | | |
| Days | 00 | 30 | 60 | 90 | 00 | 30 | 60 | 90 | 00 | 30 | 60 | 90 |
| $L_1$ | 5.02 | 5 | 4.98 | 4.95 | 5.02 | 4.95 | 4.9 | 4.85 | 5.02 | 4.91 | 4.85 | 4.79 |
| $L_2$ | 4.97 | 4.97 | 4.96 | 4.95 | 4.97 | 4.9 | 4.86 | 4.8 | 4.97 | 4.86 | 4.81 | 4.75 |
| $L_3$ | 4.99 | 4.98 | 4.96 | 4.93 | 4.99 | 4.9 | 4.84 | 4.77 | 4.99 | 4.84 | 4.79 | 4.73 |
| $L_4$ | 4.96 | 4.94 | 4.94 | 4.9 | 4.96 | 4.88 | 4.83 | 4.78 | 4.96 | 4.9 | 4.85 | 4.75 |
| $L_5$ | 4.97 | 4.97 | 4.96 | 4.94 | 4.97 | 4.89 | 4.85 | 4.79 | 4.97 | 4.9 | 4.84 | 4.75 |
| $L_6$ | 5.02 | 5.02 | 5.01 | 4.99 | 5.02 | 4.88 | 4.82 | 4.75 | 5.02 | 4.92 | 4.86 | 4.77 |
| $L_7$ | 4.99 | 4.98 | 4.96 | 4.93 | 4.99 | 4.92 | 4.86 | 4.81 | 4.99 | 4.92 | 4.85 | 4.78 |
| $L_8$ | 5.01 | 4.99 | 4.99 | 4.95 | 5.01 | 4.92 | 4.88 | 4.82 | 5.01 | 4.89 | 4.84 | 4.73 |
| $L_9$ | 4.96 | 4.92 | 4.91 | 4.87 | 4.96 | 4.85 | 4.8 | 4.73 | 4.96 | 4.88 | 4.82 | 4.76 |



Table 11. Stability studies of sago starch films containing famotidine

| Batch | Drug content | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 25± 2 °C/ 60 ±5 %R H | | | | 30± 2 °C/ 65 ±5 %RH | | | | 40± 2 °C/ 75± 5 %R H | | | |
| Days | 00 | 30 | 60 | 90 | 00 | 30 | 60 | 90 | 00 | 30 | 60 | 90 |
| $F_1$ | 5.02 | 5 | 4.98 | 4.95 | 5.02 | 4.95 | 4.9 | 4.85 | 5.02 | 4.91 | 4.85 | 4.79 |
| $F_2$ | 4.95 | 4.93 | 4.93 | 4.91 | 4.95 | 4.9 | 4.86 | 4.81 | 4.95 | 4.86 | 4.81 | 4.75 |
| $F_3$ | 4.99 | 4.98 | 4.96 | 4.93 | 4.99 | 4.94 | 4.9 | 4.85 | 4.99 | 4.93 | 4.88 | 4.83 |
| $F_4$ | 4.99 | 4.99 | 4.96 | 4.94 | 4.99 | 4.95 | 4.88 | 4.84 | 4.99 | 4.9 | 4.85 | 4.78 |
| $F_5$ | 4.94 | 4.92 | 4.9 | 4.9 | 4.94 | 4.89 | 4.85 | 4.8 | 4.94 | 4.88 | 4.82 | 4.75 |
| $F_6$ | 5 | 4.98 | 4.97 | 4.94 | 5 | 4.94 | 4.9 | 4.85 | 5 | 4.92 | 4.86 | 4.77 |
| $F_7$ | 4.96 | 4.95 | 4.93 | 4.9 | 4.96 | 4.92 | 4.86 | 4.81 | 4.96 | 4.9 | 4.85 | 4.77 |
| $F_8$ | 5.03 | 5.01 | 4.99 | 4.95 | 5.03 | 4.98 | 4.92 | 4.88 | 5.03 | 4.95 | 4.89 | 4.82 |
| $F_9$ | 5 | 4.97 | 4.96 | 4.94 | 5 | 4.95 | 4.92 | 4.85 | 5 | 4.93 | 4.88 | 4.83 |

## Conclusion

It is possible to increase the bioavailability of the medications by administering them as oral films. More time for medication absorption and the absence of gastrointestinal degradation may have contributed to an increase in bioavailability. The excipient starch is used in many different ways these days in medications. In terms of cost and safety, this is the best and most affordable pharmaceutical excipient. Glycrol is employed as a plasticizer in the recipe. Because levocetirizine dihydrochloride is water-soluble, it was dissolved in water before being ingested. It was mixed with water-insoluble medications. Both sago starch content (X1) and the time required to heat it to 90°C (X2) were examined using a full 32-factor design. Films containing famotidine swelled more than those containing levocetirizine dihydrochloride, according to a study of the film's swelling. A Franz diffusion cell and a modified magnetic stirrer were used in the in-vitro release research. Neither method differed significantly in the manner in which medicines were released from both. Water-insoluble medicines leached out of the films the fastest, however there was a lot of drug released un the first 4-6 hours. This is because the sago starch films containing water-insoluble medicines had more micro fractures in them. To examine films, scientists utilise a technique known as scanning electron microscopy. When several pharmacokinetic models were applied to the release data, this is what happened. First-order release kinetics were observed in all samples except batch L7 and batch F7. Zero order release is the best solution for long-term pharmaceutical delivery. As a result, we devised the L7 and F7 formulas. Tensile strength increases as starch content increases. Sago starch dispersion-based films were shown to be less durable as the heating duration was extended.

All of the dependent variables were affected by both of the independent factors, albeit to various degrees. As demonstrated in the aforementioned study, sago starch is a superb vehicle for the oral administration of medications. You may control the amount of medication released from sago starch by varying the cooking time and quantity. In addition to potentially affecting the film's drug release and other properties, chemically altering or mixing starch with other polymers is an option.



## Acknowledgement
The conception and writing of this article were greatly assisted by all of the above authors.

## Conflict of interest

The Authors declare no conflict of interest.

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