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Pharma Sci-Determining Sucrose Concentration in Syrups by Pharmaceutical Methods- Al-Achi A-Campbell Univesity

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Introduction

Syrups are viscous oral liquids that may contain one or more active ingredients in solution. Sucrose is the primary component in syrups. Other substances may be added to syrups for taste enhancement or retarding the crystallization of sucrose. In non-sugar-based syrups, the formulation is primarily made of cellulose type agents with added artificial sweeteners for taste enrichment. For compounding purposes, and as a quality control test for syrups, it is essential to document the amount of sucrose (or lack of) in the final preparation. The addition of sucrose to an aqueous solution renders that solution more viscous. Thus syrups are known to be viscous liquids. The viscosity of a liquid formulation may serve as an indicator for reproducibility among different batches of the product. Added ingredients in syrups may potentially modify the formulation viscosity, and thus influence its mechanical and physical characteristics important for formulation handling. Viscosity is the term used to describe the internal friction in a fluid In general, liquids that follow Newton's law of flow are measured by instruments such as capillary viscometers. On the other hand, non-Newtonian systems require more advanced instrumentation to detect the changes in viscosity with increasing the shear rate. For syrup formulations, it is expected that their viscosity to follow a Newtonian flow. Current methods available for the determination of sucrose are cumbersome and require complex procedures and instrumentation. This study proposes the use of simple rheological measurements for the quick determination of sucrose in aqueous solutions. More specifically, we aim to develop a rheological method by which the concentration of sucrose in an aqueous liquid can be estimated from knowledge of its Newtonian viscosity. Furthermore, this method will also be used to correlate the concentration of sucrose in syrup to the time needed for the syrup to descend through a bed of granulation.

Materials and Methods

Materials

Chemicals used for the preparation of granules were dextrose (D-Glucose, anhydrous, granular, Macron Fine Chemicals™), gelatin solution (Knox®), starch (Spectrum®), water-soluble dye (blue), and magnesium stearate (octadecanoic acid magnesium salt, Spectrum®). Chemicals used for the preparation of different concentrations of syrups were sucrose (granulated sugar, Spectrum®) and distilled water. Instruments and techniques used for measurement of viscosity were Ostwald viscometer (capillary viscometer) and granule columns (large pipette tips). Specific gravity was determined by using a pycnometer (**Figure 1**).

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Figure 1: Pycnometers.

Figure 2: Air dried granules.

Figure 1: Pycnometers.

Methods

This study dealt with the determination of three parameters: The concentration of sucrose, the density/specific gravity of the syrup, the time needed for a liquid to descend through a bed of granulation, and the viscosity of the formulation.

Preparation of granules: The granulation contained dextrose (50 g), 10% gelatin solution (7.5 mL-10 mL), starch (3.75 g), water-soluble dye (FD&C) (a desired quantity), and magnesium stearate (0.5 g). The granules (**Figure 2**) were prepared by mixing the powdered ingredients (except for magnesium stearate) by a geometric dilution method using a glass mortar and pestle. Two to three drops of a water-soluble dye were added to the blend, and then a 10 mL volume of gelatin solution was added in portions, and the content of mortar was thoroughly mixed after each addition. The final mixture was passed through sieve number 8 and then it was air-dried over a week. The dry granules were passed through sieve number 12. Magnesium stearate (0.5 g) was added and mixed with the granules on paper using a spatula. Four batches of granules were prepared to obtain a total of 350 g of granules.

Figure 2: Air dried granules.

Syrup preparation: Syrups with different concentration of sucrose were required for this experiment. The concentrations (% w/v) used were 0% (distilled water), 5%, 10%, 25%, 50%, 65%, and 85%. Even at the highest concentration of 85%, the syrup solution was not considered to be saturated because the solubility of sucrose in water at room temperature is relatively high (1 g of sucrose in 0.5 mL of water) (Parrott, 1970). Sucrose was completely dissolved in distilled boiling water. The final product was then made to the desired volume with distilled water.

Determination of time taken for the syrup to pass through the granule bed: The column (8.5 cm long pipette tips with a capacity of 10 mL of the brand Thermo Fischer Scientific, Model number-9401300) was blocked by a cotton ball at the lower tip and filled with granules (14.6 g). 5 mL of distilled water or syrups were passed through the pipette. The time needed for complete elution of the solution from the column was recorded in seconds. Fresh granule bed was used for every run.

Determination of specific gravity: Pycnometers were used for the determination of specific gravity.

Determination of viscosity by Ostwald's viscometer: The time needed for the test syrup to pass through the viscometer between the two

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marked lines seen on the instrument was recorded in seconds. The viscosity of the solution is calculated from equation 1.

$$\eta_1/\eta_2 = (\rho_1/\rho_2)(t_1/t_2) \qquad (1)$$

In the above equation, η_1 and η_2 are the viscosity of water (1 centipoise) and viscosity of syrup solutions, respectively; $\rho_1$and ρ_2 are densities of water and syrup solutions, respectively; t1, and t2 are time of water and syrup solutions through the viscometer, respectively.

Results

Determination of time taken for the syrup to pass through the granule bed: The time needed for test solutions to travel through the granule bed is shown in **Table 1**.

Concentration of syrups (% w/v)	Time f
0%	148
5%	165
10%	370.66
25%	407
50%	420.33
65%	489.33
85%	513.33

Table 1: Time (seconds) for syrup preparations to pass through granule bed.

Determination of specific gravity: Table 2 shows the specific gravity values of all the tested solutions.

Sucrose concentration (% w/v)
Distilled water
5%
10%
25%
50%
65%
85%

Table 2: The specific gravity of test solutions at room temperature.

Determination of viscosity by Ostwald viscometer: The time needed for syrup preparation to pass between the two marks on the viscometer was recorded in seconds. **Table 3** shows the time observed and **Table 4** represents the calculated values for viscosity.

Concentration of syrups (% w/v)
0%
5%
10%
25%
50%
65%
85%
Unknown sample

Table 3: Time (seconds) for the test solutions to pass between the two marks present on the viscometer.

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Sucrose concentration (% w/v)	
Distilled water	
5%	
10%	
25%	
50%	
65%	
85%	

Table 4: The viscosity of test solutions at room temperature.

Calculations: The times (seconds) for the tests solutions to pass through the granule bed was fitted against the concentration of the sucrose in syrup solutions (% w/v). The data showed a polynomial fit with the equation (R2=0.9467; p=0.0028):

Concentration of sucrose (% w/v)= -88.30+0.28

*Time for complete elution from the column (seconds)+0.0011

*(Time for complete elution from the column (seconds)-359.09)^2 (2)

Furthermore, when the viscosity of the syrup is plotted against the time of elution of the syrup (seconds), the resulting polynomial equation was found (R_2=0.9196; p=0.0065):

Viscosity (cPs)= -2.76+0.010*Time (seconds)+0.000054*(Time (seconds)-359.09)^2 (3)

Another empirical polynomial equation was found between the viscosity the concentration of sucrose in the syrups (R_2=0.9883; p<0.0001):

Concentration of sucrose (% w/v)= -30.07+41.66*Viscosity (cPs)-11.03 (Viscosity (cPs)-1.84)^2 (4)

Discussion

The results showed that the time for the syrup solution to pass through the granule bed increased as the concentration of the sucrose increased in the syrup (**Table 1**). As expected, the viscosity of the syrup also increased with increasing concentration of sucrose in solution (**Table 4**). An empirical relationship (equation 2) was found between the time for the syrup to pass through the granules and the concentration of sucrose in solution (R2=0.9467; p=0.0028). Likewise, the sucrose concentration in syrups can be estimated from equation (4), relating sucrose concentration (% w/v) to the viscosity of the syrup expressed in centipoises (R2=0.9883; p<0.0001). Also, another empirical relationship (equation 3) was found between the viscosity of the syrup and the time for the test solution to travel through the granule bed (R2=0.9196; p=0.0065). From the experimental findings, it is possible for an unknown solution of sucrose to be determined by either measuring the viscosity of that solution or by determining the time needed for it to pass through a column filled with granules. In either case, the predicted value of the concentration of sucrose in solution would be determined with high accuracy due to the high correlation associated with both empirical equations. The study proposed enzymatic methods/HPLC while other study used a spectrophotometric method for the determination of sucrose in samples. Older methods for sucrose determination rely on refractometry or density measurements. The implications of this study are that compounding pharmacists or formulators in general will be able to check the concentration of sucrose in the final product by using a quick and simple capillary viscometer measurement. This is a more practical way for sucrose determination as the other methods require more complex procedures and instrumentation. As for its limitations, although this method may become attractive due to its simplicity, its sensitivity and specificity may not be as high as the other analytical methods.

In this study, a rheological method was developed by which the concentration of sucrose in syrups can be determined with reasonable accuracy if the viscosity of the test solution was known or if the time for the liquid to pass through a granule bed was measured. More research is needed to check for the reproducibility and effectiveness of this pharmaceutical technique.

Results: A non-linear relationship (second-degree polynomial) was observed between the time needed for complete elution of the syrup from the granule bed and the concentration of sucrose in syrup. Likewise, a seconddegree polynomial relationship was shown to exist between the viscosity of the syrup and its content of sucrose.

Conclusion: This method can determine with reasonable accuracy the concentration of sucrose in syrups if the viscosity of the test solution was known or if the time for the liquid to pass through a granule bed was measured. This method may also be used for identifying non-sugar-based syrups that mimic in their properties the sugar-based formulations.

Biography

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