

Physical Characteristics of Selected Over-the-Counter Medications

Antoine Al-Achi, PhD Shawnte Shipp

Water

The physical characteristics of over-the-counter medications may be useful to the compounding pharmacist in preparing dosage forms by serving as physical limits for the basis of choice of vehicles and supporting ingredients for formulations. In this study, three bottles of 16 different products were tested for their specific gravity, pH, surface tension and rheological properties. All products tested were heavier than water, with the exception of the lotions. The pH value varied greatly among the products, and the lotions were neutral to slightly acidic; the other preparations were acidic with the exception of Dulcolax and Maalox, which showed a basic pH. Aqueous solutions had a surface tension very close in value to water; all other products that were tested exhibited lower surface tension than water. The viscosity of the products varied greatly; lotions and suspensions demonstrated shear-thinning properties of either plastic or pseudoplastic type; and all solutions had low viscosity similar to that of water, except for Children's Dimetapp and Vicks Nyquil, which showed a somewhat higher viscosity than water.

Introduction

Over-the-counter (OTC), or nonprescription, medications make up a large class of products in the United States; they account for half of drug costs¹ and play a big role in keeping down the health-care cost of medications.² Although these products can be purchased by patients without healthcare advice, many pharmacists find themselves providing information on their use and therapeutic effectiveness. Many practicing physicians in various disciplines recommend the use of OTC products to their patients.³ Nutritional supplements (vitamins, minerals, etc.), analgesics and laxatives are the most commonly used products; the use of laxatives increases with a person's age, while the use of analgesics decreases.^{4,5} In the United States, about 40% of OTC medications are taken by elderly patients,⁶ with an average of 1.8 OTC drug products per elderly person per day.^{5,7} Although more young than elderly patients purchase OTC products, elderly patients are more likely to thoroughly read the labels on OTC products and are more likely to request help from the pharmacist in purchasing OTC preparations.⁸ Labels on OTC packages can be difficult to read, because of factors such as the use of a small font or all-uppercase font or the lack of bold-face. Elderly patients were also less likely than young adults to

Antoine Al-Achi, PhD

Shawnte Shipp

*Campbell University School of Pharmacy
Buies Creek, North Carolina*

coadminister OTC products with prescription drugs, a potential problem for drug/drug interaction.⁹ A pharmacist's intervention via a consultation may reduce the potential of drug/drug interactions between OTC and prescription medications.¹⁰ In general, women use more OTC products than men, and educated patients use OTC products more often than less educated individuals.⁴⁻⁵ In terms of geographic area and ethnicity, the highest use of OTC medications was found in the Midwest United States. Whites had the highest use, followed by African-Americans and Hispanics, in decreasing order.⁵ A survey done in Great Britain showed that when pharmacists recommended OTC preparations, the most common factors for their recommendations were the product's efficacy, active ingredients, patient friendliness and the patient's specific medical conditions.¹¹

Pharmacists and physicians are the only two professions that can legally compound medications. Although they vary from one state to another, regulations governing OTC compounding by the pharmacist must meet basic common rules:

- Drugs compounded must be selected from a list of OTC approved medications, ie, if the drug is approved only as a prescription medication by the US Food and Drug Administration, then the pharmacist should not compound it as an OTC formulation.
- The compounded OTC preparations must be sold in the same store where the compounding is performed.
- The pharmacist must adhere to state-of-the-art compounding practices.¹²

By compounding OTC preparations, the pharmacist provides patients with preparations that better fit their needs, eg, the pharmacist can compound a mouthwash with a particular taste that may not be available commercially. Compounded OTC preparations for instore sale, however, should not exactly duplicate commercially available formulations. Commercial formulations may be used to guide the compounding pharmacist in selecting the appropriate ingredients to be included in the preparation. In this article, we present some physical characteristics of a selected sample of commercially available OTC products.

Table 1. Over-the-Counter Medications Selected for Testing.			
Product	Manufacturer	City & State of Manufacturer	Lot No.
Caladryl Clear Lotion	Pfizer Ltd.	Morris Plains, New Jersey	06823B
Children's Dimetapp Grape Flavor	Wyeth	Madison, New Jersey	A24638; A50397
Children's Motrin	McNeil Consumer & Specialty Pharmaceuticals	Fort Washington, Pennsylvania	HMM09; HPM061
Children's Tylenol	McNeil Consumer & Specialty Pharmaceuticals	Fort Washington, Pennsylvania	HMM254
Cocoa Butter Daily Moisturizer with Shea Butter	Suave (Unilever)	Greenwich, Connecticut	12223J00
Dulcolax Milk of Magnesia Original Flavor	Boehringer Ingelheim Pharmaceuticals, Inc.	Ridgefield, Connecticut	3JB0101
Eucerin Original Moisturizing Lotion	Beiersdorf Inc.	Wilton, Connecticut	32323
Hydrogen Peroxide Topical Solution USP	GoodSense (Distributed by Cumberland Swan)	Smyrna, Tennessee	4BF0155
Listerine Antiseptic Mouthwash	Pfizer Ltd. (Distributed by Warner-Lambert Consumer Healthcare)	Morris Plains, New Jersey	02983L
Lubriderm Skin Therapy Moisturizing Lotion	Warner-Lambert Consumer Healthcare	Morris Plains, New Jersey	20312L; 30622L
Maalox Regular Strength Smooth Cherry	Novartis Pharmaceuticals	Parsippany, New Jersey	319605; 319610; 320935
Magnesium Citrate Oral Solution Saline Laxative	Goodsense (Distributed by Cumberland Swan)	Smyrna, Tennessee	4BG0067
Saline Solution for Soft (Hydrophilic) Contact Lenses	KC Pharmaceuticals, Inc.	Pomona, California	3P223
Scope Mouthwash Original Mint	Proctor & Gamble	Cincinnati, Ohio	41708A
Vicks Nyquil Cold/Flu	Proctor & Gamble	Cincinnati, Ohio	3349SG41; 3357SG42
Vitamin E Enriched Lotion with Lanolin	Suave (Unilever)	Chicago, Illinois	12183J00

Materials

Sixteen different OTC products were selected for testing (Table 1). All products tested were purchased and selected from a local pharmacy and a supermarket in North Carolina. Three different containers were obtained for each product tested.

Methods

When applicable, several tests were performed on the products listed in Table 1. Collectively, these tests aimed to characterize the physical properties of the products.

Specific Gravity Measurement

Specific gravity is defined as the ratio of the weight of the product to the weight of an equal volume of water at room temperature. This was determined either by simply weighing 1 mL of the product and dividing it by the weight of 1 mL of water or by using a grease pycnometer (Catalog No. 3-247, Fisher Scientific, Pittsburgh, Pennsylvania). The pycnometer was weighed empty, the sample was introduced into the pycnometer, and the pycnometer was reweighed. The sample weight was obtained from the difference between the loaded pycnometer and the empty one. The procedure was repeated using water (boiled and then cooled) as a reference standard.

Table 2. Specific Gravity of Products.

Product Name	Specific Gravity Mean (Standard Deviation) ^a			Mean
	Bottle 1	Bottle 2	Bottle 3	
Caladryl Clear	1.0212 (0.0063)	1.0231 (0.0072)	1.0361 (0.0025)	1.0268 (0.0081)
Children's Dimetapp ^b	1.2504 (0.0059)	1.1312 (0.0054)	1.1297 (0.0056)	1.1304 (0.0011) ^c
Children's Motrin	1.1657 (0.0008)	1.1620 (0.0006)	1.1632 (0.0134)	1.1636 (0.0019)
Children's Tylenol	1.3061 (0.0027)	1.3123 (0.0007)	1.2998 (0.0155)	1.3061 (0.0062)
Cocoa Butter Lotion	0.9974 (0.0060)	1.0010 (0.0082)	0.9999 (0.0031)	0.9994 (0.0018)
Dulcolax	1.0094 (0.0085)	1.0027 (0.0033)	0.9954 (0.0088)	1.0025 (0.007)
Eucerin Lotion	0.9680 (0.0021)	0.9617 (0.0025)	0.9606 (0.0049)	0.9634 (0.004)
Hydrogen Peroxide Solution	1.0048 (0.0216)	1.0143 (0.0023)	1.0210 (0.0185)	1.0134 (0.0081)
Listerine	1.0399 (0.0083)	1.0389 (0.0062)	1.0459 (0.0062)	1.0416 (0.0038)
Lubriderm Lotion	0.9755 (0.0102)	0.9711 (0.0060)	0.9647 (0.0112)	0.9704 (0.0054)
Maalox	1.0197 (0.0198)	1.0441 (0.0183)	1.0627 (0.0151)	1.0422 (0.0216)
Magnesium Citrate Oral Solution	1.0598 (0.0052)	1.0605 (0.0050)	1.0333 (0.0093)	1.0512 (0.0155)
Saline Solution for Soft Contact Lenses	1.0141 (0.0027)	1.0130 (0.0010)	1.0128 (0.0028)	1.0133 (0.0007)
Scope	0.9997 (0.0067)	1.0129 (0.0082)	1.0136 (0.0135)	1.0087 (0.0078)
Vicks Nyquil Cold/Flu	1.1847 (0.0018)	1.1877 (0.0069)	1.1822 (0.0023)	1.1848 (0.0028)
Vitamin E Lotion	0.9949 (0.0037)	1.0050 (0.0038)	0.9986 (0.0082)	0.9995 (0.0051)

^a Values are the mean of three to six independent measurements.

^b Bottles 2 and 3 contained a new formulation for the product different from that found in bottle 1.

^c Average standard deviation of bottles 1 and 2 only for Children's Dimetapp.

Measurement of pH

For semisolid preparations, a pH paper [Catalog No. 2614991, Whatman pH Indicator Paper (pH = 4.5 to 10.0), Whatman International Ltd., Maidstone, England] or [Color pH Indicator Strips (pH = 0.0 to 6.0), FM Science, Gibbstown, New Jersey] was used. The pH paper was placed into the lotion being tested and kept there for 10 seconds. The color change on the paper was compared to a chart of colors and to pH values that were supplied by the manufacturer. For liquid products, a pH meter (Accumet Basic AB 15 pH Meter, Fisher Scientific) was used.

Surface Tension Measurement

The surface tension of liquid products was determined using a capillary method. A glass capillary tube was immersed in 60 mL of the test product. The capillary tube was positioned in the liquid near the edge of the beaker. The rise in the level of the liquid inside the capillary tube was recorded using a ruler. Water was used as a standard solution ($\gamma = 72.8$ dynes/cm at room temperature). Surface tension of the products was estimated from the following equation:

$$\gamma_1 = (\gamma_2 d_1 h_1) / (d_2 h_2)$$

where γ is the surface tension, d is density and h is the rise of the level of the liquid inside the capillary tube (1 is for the test fluid, and 2 is for water).

Table 3. pH Values of Products.

Product Name	pH Values			Mean
	Bottle 1	Bottle 2	Bottle 3	
Caladryl Clear	4.0	4.0	4.0	4.0 (0.0)
Children's Dimetapp ^a	2.7	3.1	3.1	3.1 (0.0) ^b
Children's Motrin	3.3	3.2	3.2	3.2 (0.1)
Children's Tylenol	4.0	3.9	3.9	3.9 (0.1)
Cocoa Butter Lotion ^c	6.5	7.0	7.0	6.8 (0.3)
Dulcolax	10.2	10.2	10.2	10.2 (0.0)
Eucerin Lotion ^c	5.5	5.0	5.5	5.3 (0.3)
Hydrogen Peroxide Solution	4.1	4.1	3.9	4.0 (0.1)
Listerine	4.2	4.2	4.2	4.2 (0.0)
Lubriderm Lotion ^c	6.5	7.0	6.5	6.7 (0.3)
Maalox	8.2	8.1	8.1	8.1 (0.1)
Magnesium Citrate Oral Solution	3.8	3.8	3.8	3.8 (0.0)
Saline Solution for Soft Contact Lenses	7.4	7.4	7.4	7.4 (0.0)
Scope	5.8	5.8	5.7	5.8 (0.1)
Vicks Nyquil Cold/Flu	5.4	5.3	5.3	5.3 (0.1)
Vitamin E Lotion ^c	7.0	7.0	7.0	7.0 (0.0)

^a Bottles 2 and 3 contained a new formulation for the product different from that found in bottle 1.

^b Average (standard deviation) of bottles 1 and 2 only for Children's Dimetapp.

^c Values were based on a pH paper measurement.

Table 4. Surface Tension of Products.

Product Name	Surface Tension (dynes/cm) Mean (Standard Deviation) ^a			
	Bottle 1	Bottle 2	Bottle 3	Mean
Children's Dimetapp ^b	52.02 (0.00)	52.94 (0.00)	52.87 (0.00)	52.91 (0.05) ^c
Hydrogen Peroxide Solution	72.21 (3.89)	71.46 (3.96)	73.37 (2.41)	72.35 (0.96)
Listerine	44.38 (0.86)	44.80 (0.45)	45.32 (0.00)	44.83 (0.47)
Magnesium Citrate Oral Solution	70.27 (0.92)	69.85 (0.00)	69.05 (1.25)	69.72 (0.62)
Saline Solution for Soft Contact Lenses	74.31 (5.16)	74.70 (1.82)	71.85 (3.25)	73.62 (1.54)
Scope	38.12 (0.00)	36.65 (1.11)	37.77 (0.00)	37.51 (0.77)
Vicks Nyquil Cold/Flu	50.05 (0.99)	51.47 (0.00)	50.72 (0.59)	50.75 (0.71)

^a Values are the means of four independent measurements.

^b Bottles 2 and 3 contained a new formulation for the product different from that found in bottle 1.

^c Average (standard deviation) of bottles 1 and 2 only for Children's Dimetapp.

Table 5. Rheological Properties of Products.

Product's Name	Viscosity (Centipoise) Mean (Standard Deviation) ^a			
	Bottle 1	Bottle 2	Bottle 3	Mean
Children's Dimetapp ^b	14.56 (2.73)	2.96 (0.24)	3.04 (0.27)	3.00 (0.06) ^c
Hydrogen Peroxide Solution	0.93 (0.19)	0.97 (0.19)	0.94 (0.18)	0.95 (0.02)
Listerine	3.17 (0.27)	3.08 (0.26)	2.95 (0.23)	3.07 (0.11)
Magnesium Citrate Oral Solution	1.36 (0.12)	1.40 (0.15)	1.38 (0.11)	1.38 (0.02)
Saline Solution for Soft Contact Lenses	1.02 (0.08)	1.06 (0.11)	1.04 (0.09)	1.04 (0.02)
Scope	1.83 (0.15)	1.94 (0.17)	1.96 (0.20)	1.91 (0.07)
Vicks Nyquil Cold/Flu	24.58 (2.53)	24.30 (2.51)	22.84 (3.42)	23.91 (0.93)

^a Observations are the mean of four independent experiments each done six times.

^b Bottles 2 and 3 contained a new formulation for the product different from that found in bottle 1.

^c Average (standard deviation) of bottles 1 and 2 only for Children's Dimetapp.

Rheological Properties

The flow characteristic of the products was determined using either a capillary viscometer (Ostwald viscometer, Fisher Scientific) or a Brookfield viscometer (Model DV-1+, Brookfield, Middleboro, Massachusetts). For Newtonian fluids, an Ostwald viscometer was used; the time required for the test fluid to pass between two marks as it flowed by gravity through a vertical capillary tube was recorded. Purified water was used as a standard liquid. The viscosity of the product was determined from the following equation:

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

where η is the viscosity, ρ is the density and t is the time (1 is for the test fluid, and 2 is for water).

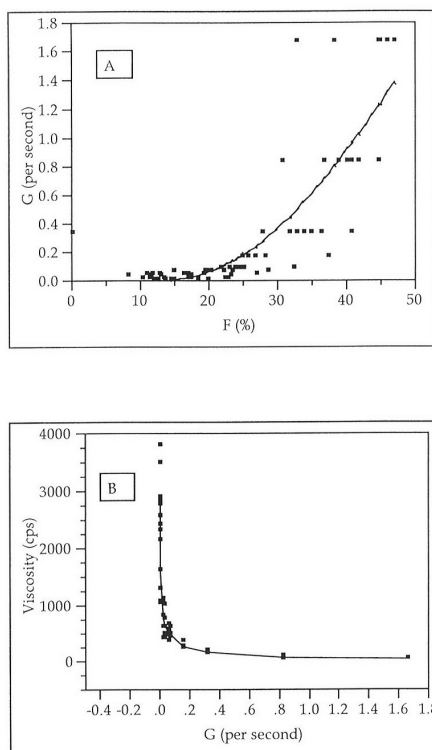
The rheological profile for non-Newtonian preparations was determined using a Brookfield viscometer.

Results and Discussion

The results of this study are presented in Tables 2 to 5. All products were heavier than water (volume to volume) except for

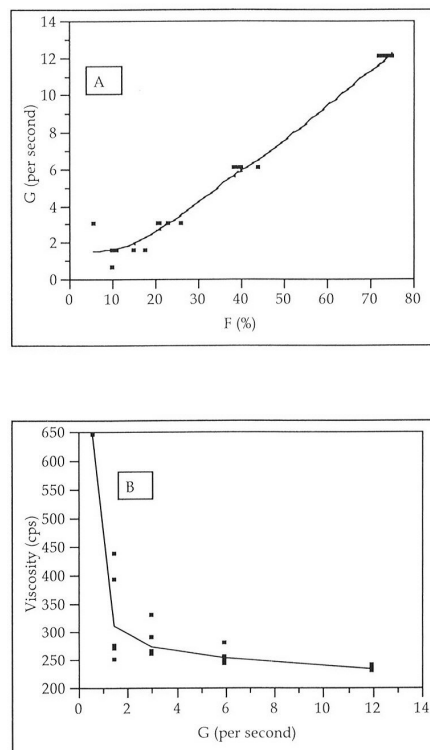
lotions, which exhibited equal or lower specific gravity values (Table 2). Saline solution for soft contact lenses had a pH similar to the physiological pH; the pH of the lotions was approximately neutral at room temperature (except for Fucerin Lotion, which had an acidic pH); Listerine was more acidic than Scope; Children's Motrin had a lower pH value than Children's Tylenol; however, both were acidic; all other preparations were acidic, except for Maalox and Dulcolax, which were alkaline (pH = 8.0 to 10.0) (Table 3). Hydrogen peroxide solution, saline solution for soft contact lenses and magnesium citrate oral solution were relatively dilute (the ratio of solutes is relatively small to that of solvent) and contained water as a solvent. They exhibited a surface tension very close to that of water (surface tension of water is 72.8 dynes/cm) (Table 4). The presence of alcohol and/or other surface-lowering agents in Children's Dimetapp, Listerine, Scope and Vicks Nyquil resulted in a lower surface tension for these products (Table 4). Ingredients in Children's Dimetapp, such as glycerin and

Figure 1. Dulcolax Rheological Profile.



Note: (A) shearing rate (G) versus shearing force (F %): a plastic flow was observed. (B) rate of shear (G) versus the viscosity coefficient in centipoises: a shear-thinning profile was observed. Data points are actual observations.

Figure 2. Caladryl Clear Rheological Profile.



Note: (A) shearing rate (G) versus shearing force (F %): a plastic flow was observed. (B) rate of shear (G) versus the viscosity coefficient in centipoises: a shear-thinning profile was observed. Data points are actual observations.

propylene glycol, made the solution very viscous ($\eta = 14.56$ cps for bottle 1 and 2.96 and 3.04 cps for bottles 2 and 3, respectively). The presence of high-fructose corn syrup in the formulation of Children's Dimetapp in bottle 1 resulted in a higher viscosity than the formulation in bottles 2 and 3 (high-fructose corn syrup was eliminated in this more recent formula). Vicks Nyquil formulation contained high-fructose corn syrup, propylene glycol and polyethylene glycol, which rendered the product very viscous (η was about 23.9 cps as an average for the three bottles tested). Sorbitol solution in Listerine and glycerin in Scope made these two products slightly viscous (an average of 3.07 cps for Listerine and 1.91 cps for Scope). Hydrogen peroxide (3%) in hydrogen peroxide solution resulted in a slight decrease in the surface tension (an average of 0.95 cps); polyethylene glycol in magnesium citrate oral solution was rendered slightly viscous. Saline solution for soft contact lenses had a surface

tension value similar to that of water (Table 5). Dulcolax, Maalox, Caladryl Clear, Children's Tylenol and Children's Motrin all showed shear-thinning properties. The rheological properties of Dulcolax were those of a plastic flow with an estimated plastic viscosity of 13.6 cps and a yield value of 27.7% (Figure 1). Similarly, the plastic viscosity of Caladryl Clear was approximately 250 cps with a yield value of 10% (Figure 2). Maalox, on the other hand, demonstrated a pseudoplastic flow profile (Figure 3). In addition, Children's Motrin and Children's Tylenol also showed a pseudoplastic profile (Figures 4 and 5).

Conclusion

Over-the-counter medications make up an important class of drugs in the United States. The young and the elderly especially depend on them for the treatment and control of minor illnesses.

Over-the-counter preparations may serve as a guide for the compounding pharmacist in attempts to customize dosage forms for patients. In this study, the physical characteristics of 16 OTC products were tested and reported.

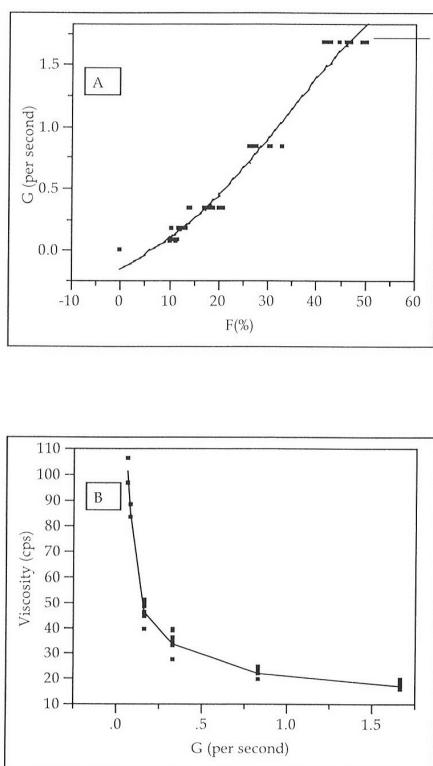
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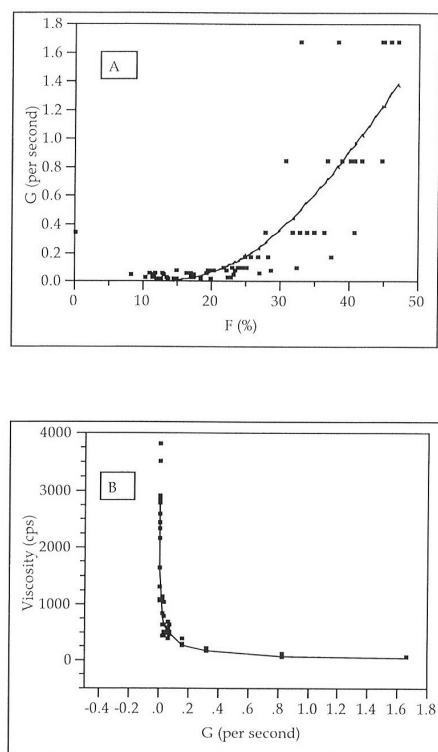
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Figure 3. Maalox Rheological Profile.



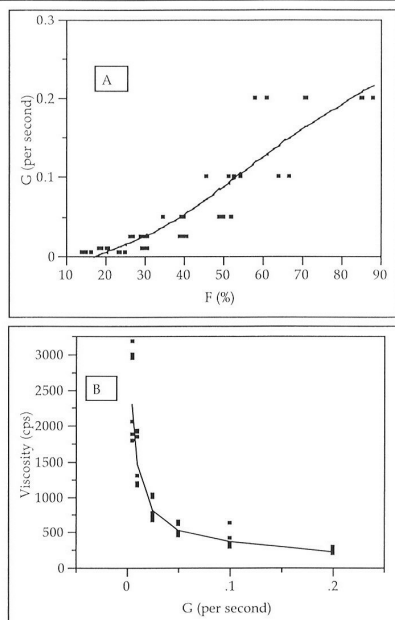
Note: (A) shearing rate (G) versus shearing force (F %) showing a pseudoplastic flow. (B) shear-thinning properties, the viscosity of Maalox decreases as the rate of shear (G) increases. Data points are actual observations.

Figure 4. Children's Motrin Rheological Profile.



Note: (A) shearing rate (G) versus shearing force (F %); a plastic flow was observed. (B) rate of shear (G) versus the viscosity coefficient in centipoises: a shear-thinning profile was observed. Data points are actual observations.

Figure 5. Children's Tylenol Rheological Profile.



Note: (A) shearing rate (G) versus shearing force (F %): a plastic flow was observed. (B) rate of shear (G) versus the viscosity coefficient in centipoises: a shear-thinning profile was observed. Data points are actual observations.

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