J. Soc. Cosmet. Chem., 35, 115–129 (March/April 1984)

A new method for measuring the viscoelastic parameters of pharmaceutical and cosmetic semisolids

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Received June 8, 1983. Presented at the Annual Scientific Seminar of the Society of Cosmetic Chemists, Cincinnati, Ohio, May 5–6, 1983. Abstracted in part from a dissertation submitted by Shivaji Purwar to the Graduate School, West Virginia University, in partial fulfillment of the Doctor of Philosophy degree requirements.

Synopsis

Pharmaceutical and cosmetic semisolids, besides being commonly described as non-Newtonian, have earlier been reported to be also viscoelastic. Unfortunately, semisolid viscoelasticity had hitherto been demonstrable only through the use of sophisticated and usually inaccessible devices such as the rheogoniometer or modified creep apparatus. A simple new method, initially developed for measuring absolute viscosity but later also found capable of revealing the viscoelastic nature of these materials, is discussed. The main device, consisting of two parallel plates between which material shaped in cylindrical form is pressed to obtain flow rate, is based upon application of normal stress rather than conventional shear stress. The originally developed equation of the system for measuring viscosity which converts observed data to compliance values (ratio of strain/stress) has been modified by partially incorporating the creep compliance equation to determine the viscoelastic parameters η_i, τ_i, J_i, etc. The values of these parameters for two common substances, petrolatum and PEG 1500, obtained by resolving the compliance curve via the residual technique, agreed favorably with values reported in the literature.

The method is assessed to possess several advantages over the modified creep apparatus, particularly, because of its simple engineering design, with ready accessibility. It appears to fill an existing gap in fundamental studies related to the viscoelastic analysis of semisolid materials.

INTRODUCTION

Pharmaceutical and cosmetic semisolids constitute a class of materials which are most difficult to characterize rheologically because they combine both liquid- and solid-like properties within the same material. According to Barry (1), much published work on the rheology of semisolids is incorrect or confusing in that the dominant "viscoelastic" nature of these materials has not been recognized. Such recognition is not only impor-

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tant from the point of view of a fundamental understanding of the nature of the system but it could provide a much more reliable means of characterizing these materials. Continuous shear methods most commonly used for evaluating semisolids provide apparent viscosities, loop areas, yield values, etc., which are non-fundamental as they depend at least in part on operating variables, i.e., instrumental effects contribute to their magnitude. These methods in fact examine the complex phenomena of structure breakdown where disruption is a function of the method of testing, and, therefore, true material constants such as viscosity and elasticity are not measured directly.

To allow one to gain a true insight into the nature and behavior of a semisolid, it is thus more appropriate to examine the material in its rheological ground state where experimental methods do not disrupt any organized structure and where at the completion of the test the material remains in its original state.

Although the Weissenberg rheogoniometer (2) and modified creep apparatus of Warburton and Barry (3) are the only devices utilized for viscoelastic evaluation of semisolids, their cost and inaccessibility have probably presented a major obstacle in their widespread use. In spite of existing methods, Barry (1) has clearly pointed out the need to develop a simple viscoelastic test suitable for on-line quality control procedures.

A new method, originally developed to obtain viscosity measurements (4), has been further extended in this study for viscoelastic analysis of materials. The method employed two parallel plates between which a sample specimen of definite size was pressed by application of a certain normal stress, while the rate of pressing was chart-recorded after amplification with a LVDT[1] unit. Using tensor analysis (5) for stress distribution and the rate of sample deformation (6) for shear rate, the following equation following Newton's equation was derived for viscosity measurement:

$$\frac{27\sqrt{\pi V}}{F}\left[K_1 - \left(H^{1/2} - \frac{H^{7/2}}{7a}\right)\right] = \frac{t}{\eta} \qquad (1)$$

(for symbols, see Glossary of Symbols in Appendix)

Assumptions such as uniform deformation of the sample; incompressibility (5,7) and isotropicity (5) of the material; minimal frictional resistance between moving parts of the equipment and between the material and the plates; as well as the absence of shear thinning with time, were considered in deriving the above equation.

Most of these assumptions were subsequently confirmed either experimentally or via documentation in the literature and have been discussed in detail elsewhere (4). The equation was thoroughly tested for viscosity involving all the variables present in it (4). In the present work, Equation 1 has been modified with the help of equations by Ferry (8) and Warburton and Barry (3) to incorporate the viscoelastic nature of the material.

THEORETICAL

The viscoelastic behavior of a material can be described by a general equation (5) such as

$$\sigma + p_1\dot{\sigma} + p_2\ddot{\sigma} + \ldots = K + q_1\epsilon + q_2\dot{\epsilon} + q_3\ddot{\epsilon} + \ldots. \qquad (2)$$

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[1] Schaevitz, Eng., Pennsauken, N.J.; Type 1000 HR; S/N 5599 CAS series.

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The mathematical complexity of solving such a differential equation may be viewed through a simplified 3-parameter fluid model—a combination of one Voigt unit and a dashpot in series.* The differential equation and the exact solution for this combination (5) is shown as:

$$\sigma + p_1\dot{\sigma} = q_1\dot{\epsilon} + q_2\ddot{\epsilon} \qquad (3)$$

$$J(t) = \frac{p_1q_1 - q_2}{q_1^2}\left(1 - e^{-q_1t/q_2}\right) + \frac{t}{q_1} \qquad (4)$$

and for an incompressible material, the solution becomes

$$J(t) = \frac{2(p_1'q_1' - q_2')}{3q_1'^2}\left(1 - e^{-q_1't/q_2'}\right) + \frac{2t}{3q_1'} \qquad (5)$$

In the above expression the quantity q_1' is equivalent to viscosity, η, in our case. Pharmaceutical and cosmetic semisolids are shown to be 6 to 10 parameter fluids (1) and the solution to their differential equations becomes inevitably more difficult. A 6-parameter fluid (5) for example, is expressed as:

$$\sigma + p_1\dot{\sigma} + p_2\ddot{\sigma} + p_3\dddot{\sigma} = q_1\dot{\epsilon} + q_2\ddot{\epsilon} + q_3\dddot{\epsilon} \qquad (6)$$

A simple alternative approach, however, as suggested by Ferry (8), was subsequently used by Warburton & Barry (3). According to this approach, the compliance J(t) for the Maxwell model is:

$$J(t) = J_0 + \frac{t}{\eta_0} \qquad (7)$$

and for the Voigt model:

$$J(t) = J(1 - e^{-t/\tau}) \qquad (8)$$

If several Voigt units with subscript i, where i = 1,2,3 . . . are present in the system along with a Maxwell unit all in series, then the compliance, being additive, is shown to be:

$$J(t) = \underbrace{J_0}_{A} + \underbrace{\sum_{i=1}^{n}\left[J_i\left(1 - e^{-t/\tau_i}\right)\right]}_{B} + \underbrace{\frac{t}{\eta_0}}_{C} \qquad (9)$$

where the last term (t/η_0) representing the terminal dashpot of the Maxwell unit is a characteristic of viscoelastic fluids and the viscosity it represents is known as the residual viscosity (1,5).

It may be noted that the quantity on the left-hand side of Equation 1 represents nothing but compliance J(t) with units of cm^2 $dynes^{-1}$ and thus a comparison of Equation 1 with Equation 9 shows that in our derivation, all we dealt with initially was the residual viscosity related to the dashpot of the Maxwell unit. Since our experimental data of

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* Viscoelastic materials can be very well represented by mechanical models like the Maxwell model which is a spring and dashpot in series, or the Voigt model which is a spring and dashpot in parallel, and/or their various combinations (1,5,8).

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compliance versus time showed a behavior similar to the creep compliance curve reported in the literature (5,8–10), it is convenient to incorporate the first two terms A and B on the right hand side of Equation 9 into Equation 1 to explain the entire experimental curve. This should be valid, since compliance is additive (3). Thus our equation for viscoelastic materials is finally modified as follows:

$$\frac{27\sqrt{\pi V}}{F}\left[K_1 - \left(H^{1/2} - \frac{H^{7/2}}{7a}\right)\right] = J_0 + \sum_{i=0}^{n} [J_i(1 - e^{-t/\tau_i})] + \frac{t}{\eta_0} \qquad (10)$$

where all the terms on right hand side have the same meaning as in Equation 9.

LINEAR VISCOELASTIC RANGE

The linear viscoelastic range is defined as the range of stresses within which the stress-to-strain relationship follows Hooke's Law and the viscous effect obeys Newton's Law (1,5). In this region, if a material is deformed under a given stress, it recovers totally when stress is withdrawn. Since the equation for viscoelasticity is based on both Hooke's and Newton's Laws, it is valid only when the experiments are performed in the linear viscoelastic range. The test for linearity could be based on either the recovery phase data of the creep compliance curve after stress is withdrawn, or by determining the strain/stress ratio (compliance) after a small time interval, e.g., 75 sec or less (1,11). Since it is not possible to obtain the recovery phase with our device, the latter method is used for determining the linear viscoelastic range in this study.

RESOLUTION OF COMPLIANCE CURVE

Although a method of analysis for resolving the creep compliance curve on the basis of Equation 9 has been reported (3), it is somewhat cumbersome and complex. A simple and straightforward method of analysis based on the "residual" technique (12) which ultimately leads to the same results is detailed in the Appendix.

EXPERIMENTAL

The tests were performed on petrolatum U.S.P.[2] and PEG 1500.[3] The material was melted to expel any entrapped air and set in trays[4] for at least two weeks prior to the test. This precaution was taken to ensure complete structural recovery which could require as much as 240 hours or more (13). The modified creep test, however, allows only 24 hours for such relaxation, presumably due to instrumental limitations.

At the time of the test, sample plugs were withdrawn with the help of a 1.2-cm inner diameter plastic syringe[5] with the top end cut open. The material was pushed out of the syringe with the help of the plunger and after discarding 2 to 3 mm of the top layer, a plug length of 0.7 cm (H_0) was sectioned off with the help of a floss. Three

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[2] Fisher Sci. Co. (lot #712418).

[3] Ruger (lot #1305).

[4] Ekco Housewares Company, Illinois.

[5] Monoject 5cc disposable plastic syringe.

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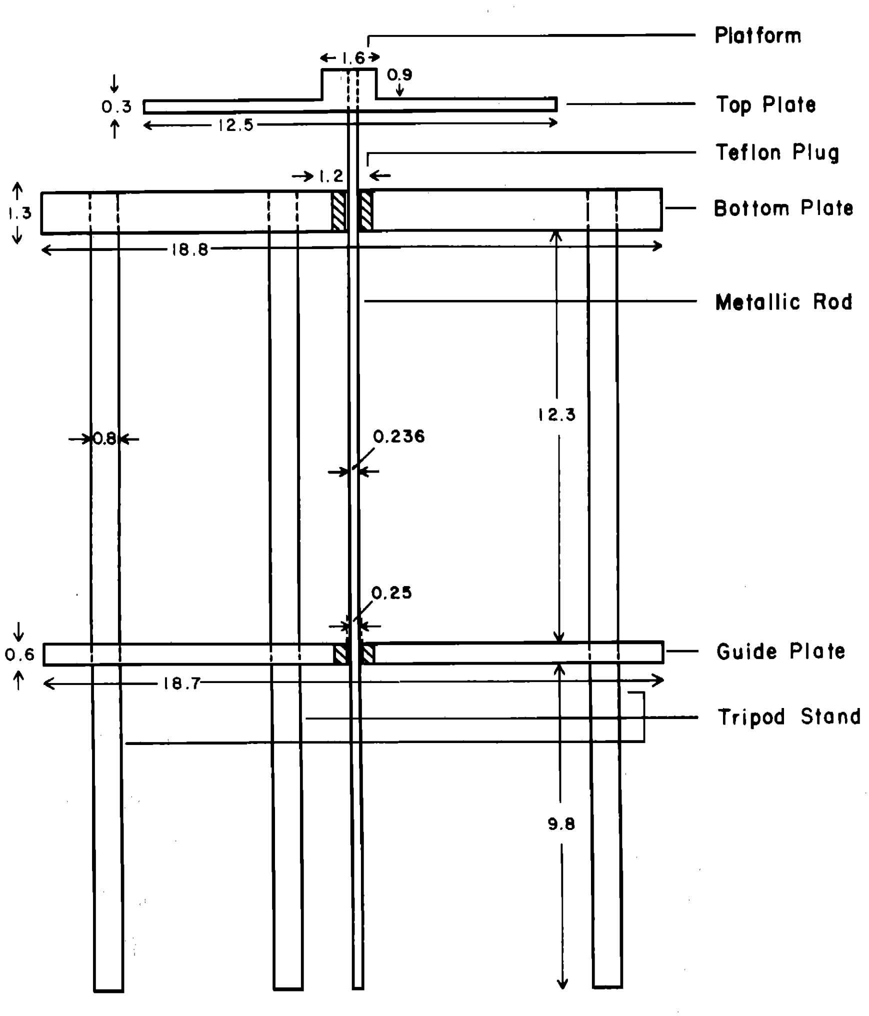
such plugs of equal dimensions were drawn before every run and an electronic thermometer probe[6] was inserted for monitoring the temperature of the material during the experiment. The pressing rate of the material placed between two horizontal circular plexiglass plates under a known stress was magnified with the help of a LVDT unit mounted on the top plate and was chart-recorded directly. Sample plugs were loaded onto the bottom plate, which was permanently affixed on a tripod. The top plate, with a guide rod attached underneath it, moved freely vertically through the central hole of the bottom plate (Figure 1). Additional plexiglass plates could be

APPARATUS



All dimensions are in cm.

Figure 1.

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[6] Electronic Digital Thermometer, Fisher Scientific Co.

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mounted over the fixed bottom plate for ease in handling and cleaning. Any level of stress could be applied simply by placing the desired weight on the top plate in addition to that of the LVDT unit. Since magnification of the LVDT unit was already established, the extent of sample deformation, h, represented by the height traveled by the top plate for a given time, t, could be obtained from the chart recordings. It may be noted that the quantity H in Equation 1 or Equation 10 is equal to (H_0 − h).

RESULTS AND DISCUSSIONS

Figure 2 shows the chart recordings representing the extent of sample deformation, h, (see above) of five separate single runs (with 3 sample plugs in each run) for petrolatum using five different stress levels. These stress levels were applied by using 48.44-, 53.88-, 58.44-, 63.88-, and 68.44-gm weights on 1.2-cm-diameter samples. The engineering strain (h/H_0) after 65 sec was calculated for each stress using the respective h values as shown by the vertical dotted line in Figure 2. A plot of the calculated

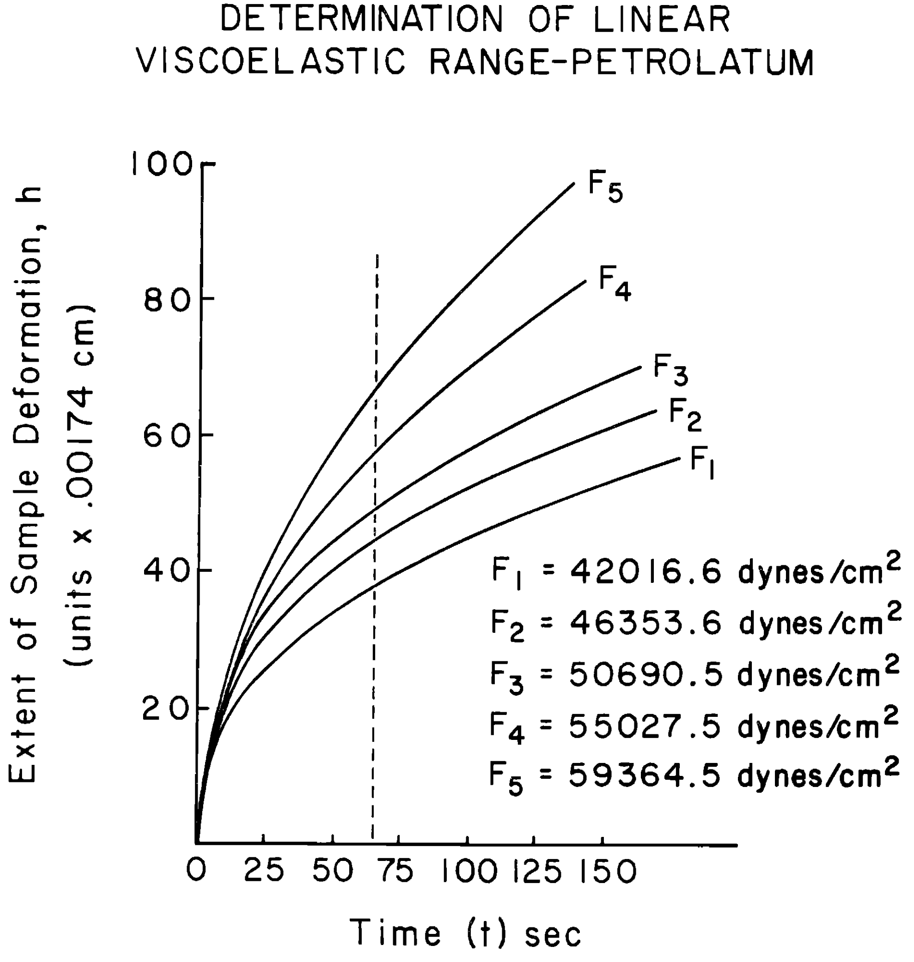

Figure 2.

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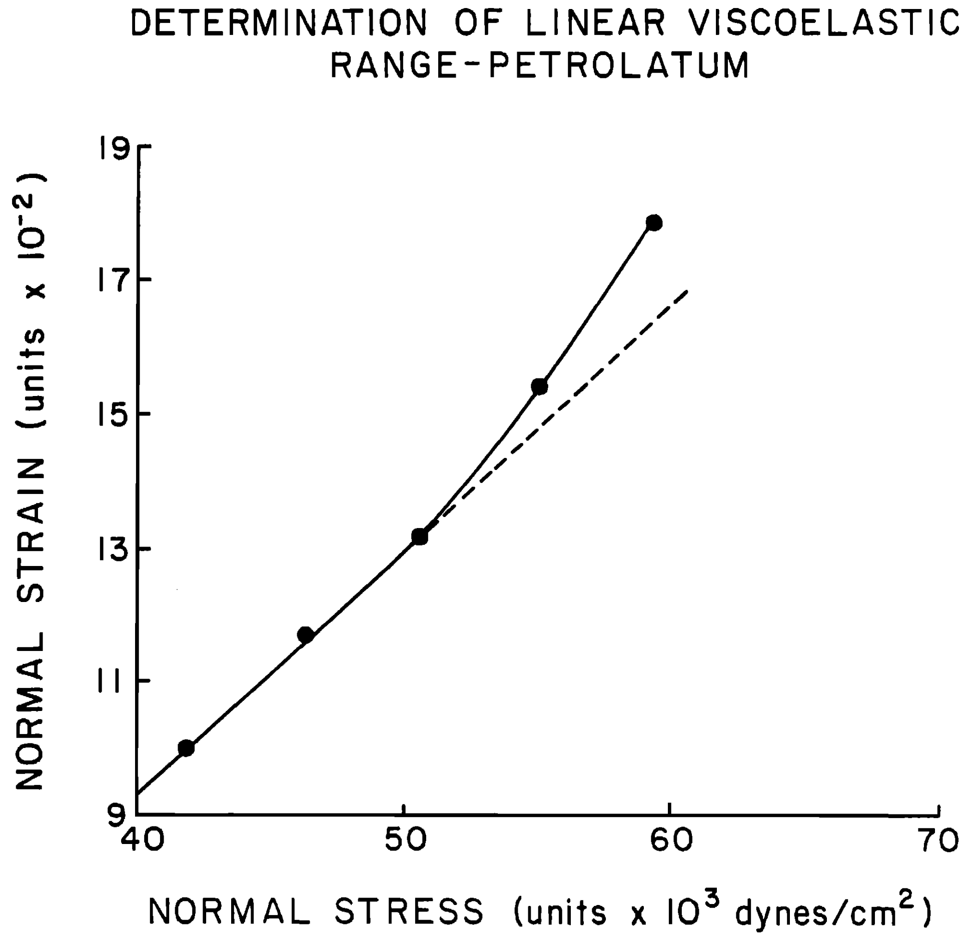

Figure 3.

strains with the respective stresses (Figure 3) shows initially a linear relationship, thus providing the linear viscoelastic range.

The final data were obtained for a period of approximately 10,000 sec at 24.52 × 10^{3} dynes cm^{-2}-stress which was well within the linear viscoelastic range. These data were converted by computer,[7] using Fortran language into compliance values on the basis of left hand side of Equation 10 (Figure 4). The curve thus generated was resolved according to the method described in the Appendix in order to obtain the viscoelastic parameters τ_i, η_i, J_i. The resolution took 3 steps to exhaust the data completely (Figures 5–7), suggesting the presence of three Voigt units. The model shown as an inset in Figure 4 agrees with the literature model for petrolatum (14). The values for various viscoelastic parameters obtained in this manner (Table I) are found to be of approximately the same orders of magnitude as the reported values (3, 15). It must, however, be borne in mind that these values are not only material-dependent but temperature-dependent as well.

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[7] AMDAHL 470 V/7A.

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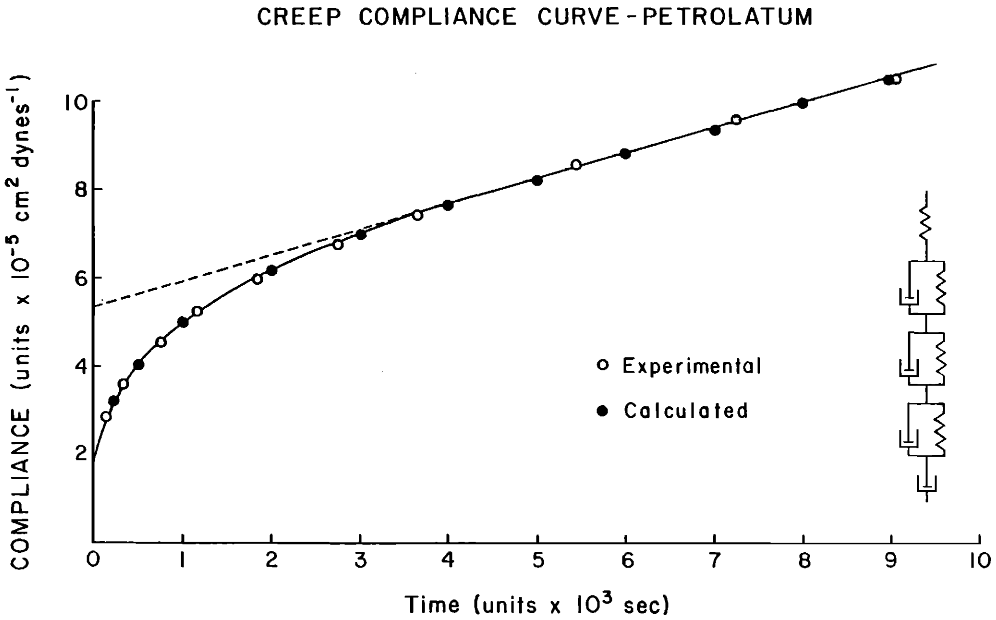

Figure 4.

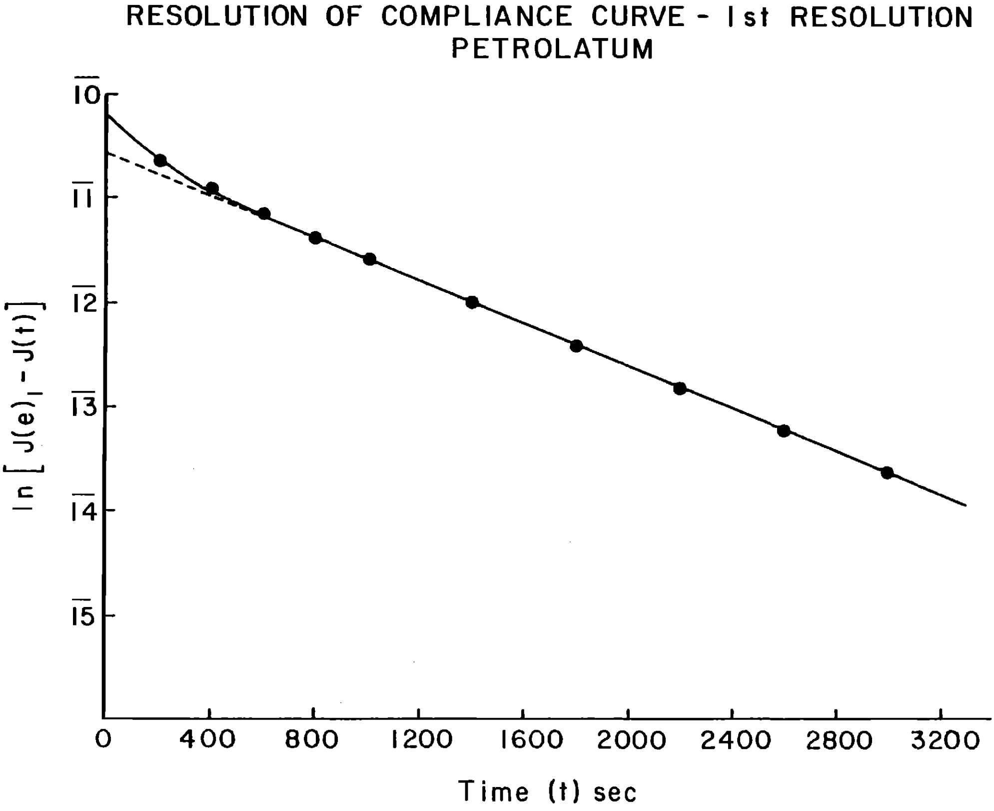

Figure 5.

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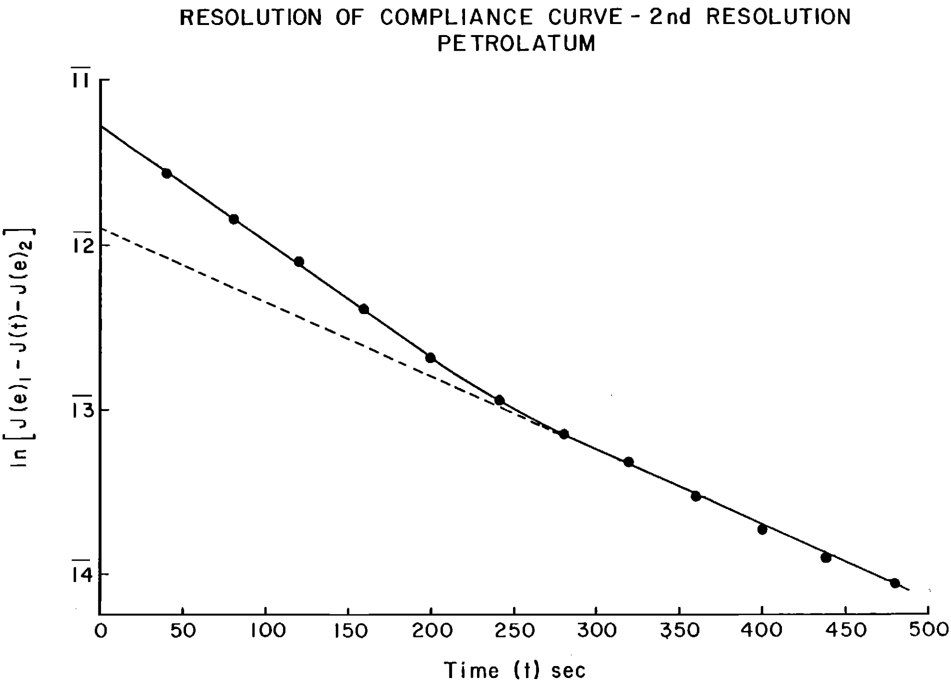

Figure 6.

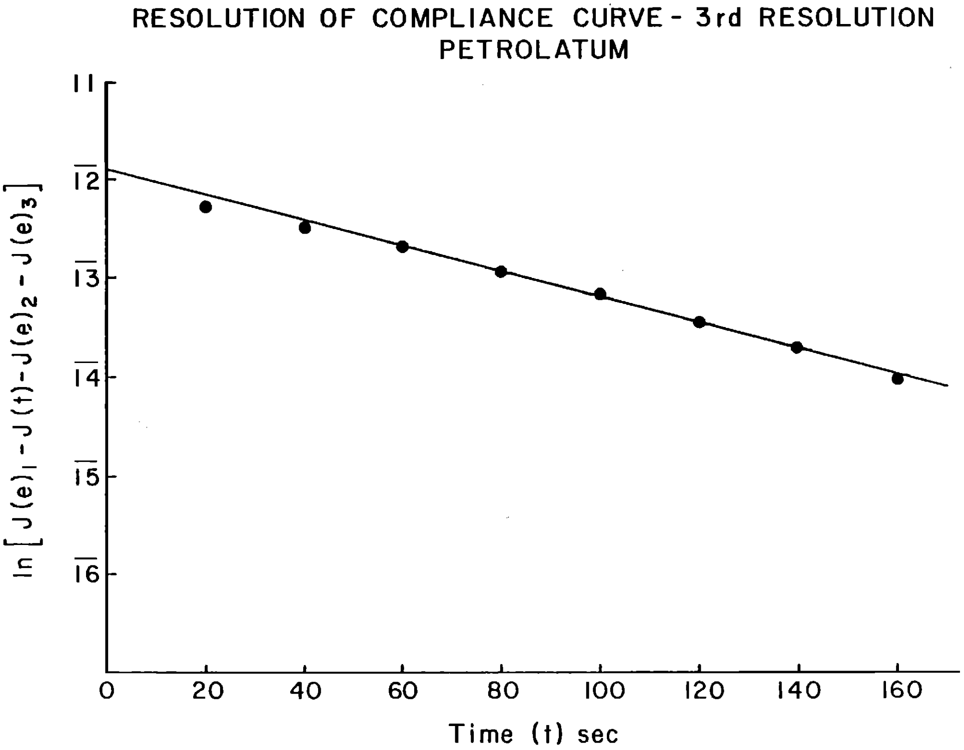

Figure 7.

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Table I
Comparison of Viscoelastic Parameter Values for Petrolatum*

Parameter	Literature**	Literature***	Experimental
	τ_i Values (seconds)		
τ_1	1360–2059	1230.0	914.7
τ_2	38–487	245.0	222.2
τ_3	2–57	58.8	76.9
	η_i Values (poise $\times$ 10^{-8})		
η_0	19.00–278.00	0.132	1.74
η_1	13.50–55.70	0.059	0.35
η_2	0.98–33.40	0.024	0.33
η_3	0.06–6.13	0.024	0.11
	J_i Values (cm^2 $dynes^{-1}$ $\times$ 10^6)		
J_0	0.757–0.355	42.2	13.8
J_1	0.315–1.050	93.5	25.9
J_2	0.100–0.452	41.5	6.79
J_3	0.024–0.388	24.7	6.79

* Melting point 38–39°C.
** Reference 15.
*** Reference 3.

To check the model and the resolved values of the various parameters, the compliance values at different times were calculated back with the help of Equation 10. These values are superimposable on the experimental curve (Figure 4), thus confirming the model and the resolved values.

A similar study was performed on PEG 1500, and the compliance curve obtained is shown in Figure 8. The resolution of this curve required only two steps, suggesting the presence of only two Voigt units in contrast to three such units with petrolatum. The model is shown as an inset in Figure 8, while the various parameters obtained are shown in Table II. The regenerated compliance curve, shown as filled circles in Figure 8, is again superimposable.

COMPARISONS WITH THE MODIFIED CREEP APPARATUS

As mentioned earlier, besides the rheogoniometer (2) which is used mainly in testing engineering materials, the modified creep apparatus test (3) is so far the only other method capable of demonstrating the viscoelastic nature of semisolid materials. It is basically a rotovisco-type viscometer with a concentric bob-cup geometry and differs from other bob-cup type viscometers, e.g., the Stormer viscometer, in its unique ability to use very low levels of stress because of the air-bearings in its design. The following points provide a comparison of our method with those of the modified creep apparatus test.

1. Since the cup and bob of the creep test are an integral part of the instrument and the material needs to equilibrate in the cup after filling, the number of observations which may be taken with this device in a given period is limited.

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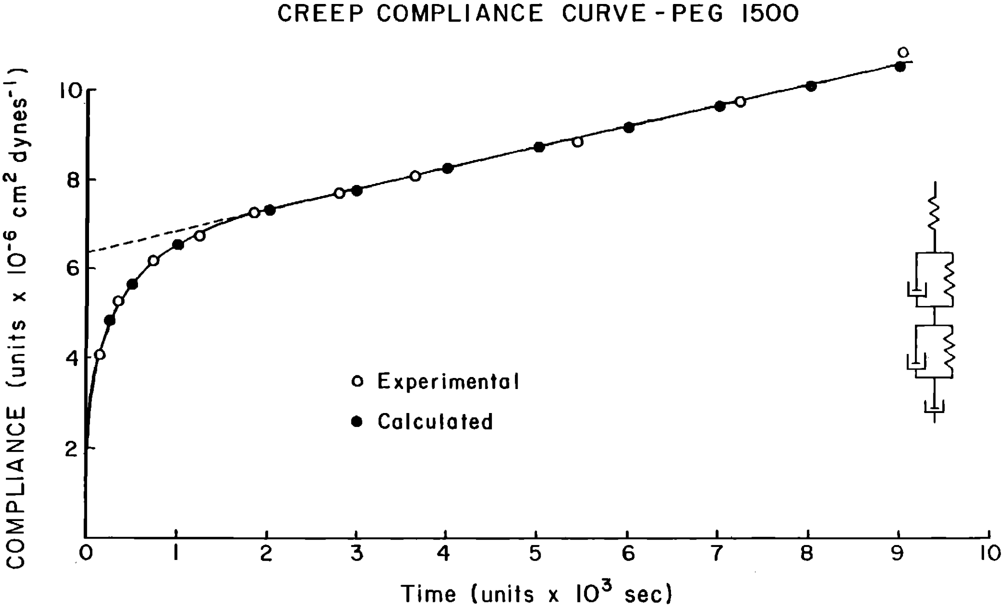

Figure 8.

Table II
Experimental Viscoelastic Parameter Values for PEG 1500*

τ_1	441.70 seconds
τ_2	58.62 seconds
η_0	21.70×10^8 poise
η_1	1.52×10^8 poise
η_2	0.36×10^8 poise
J_0	1.82×10^{-6} cm^2 dynes^{-1}
J_1	2.90×10^{-6} cm^2 dynes^{-1}
J_2	1.64×10^{-6} cm^2 dynes^{-1}

* Melting point 37–38°C.

Our device has replaceable bottom plates and therefore more frequent runs are possible.

2. Although the creep test allows 24 hours for relaxation, this time is probably not sufficient for a complete relaxation (13).

With our device, the material is almost undisturbed when loaded on the plate, and therefore no waiting period is necessary.

3. Although it is not possible to obtain the recovery phase with our device as a check for the linearity of the viscoelastic range, it could easily be determined by examining the initial strain for a range of stresses (see text). In fact this is a preferred method because it is less time-consuming. The whole process of determining this range with the new device requires 2–2½ hours as compared to several days with the creep test (inclusive of a 24-hr waiting period before each observation).

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4. For day-to-day comparison studies or quality control where measurements in the linear viscoelastic range are not essential, our device could provide data in less than 100 sec (4).

5. With this device, sample specimens are visible throughout the test, and therefore, slippage or fracture (resulting in plug flow) are clearly visible; thus doubtful results are conveniently avoided.

6. Only very small quantities of sample are needed for the test (three plugs of less than 1-cc each).

7. The new device is far less expensive than either the rheogoniometer or the modified creep apparatus.

8. One of the limitations of the device is that being an open system, measurements can only be taken at ambient room temperature unless a controlled environmental chamber is available.

9. Material for testing should be firm enough to retain its shape prior to the taking of measurements.

CONCLUSION

A simple device and method have been developed which reveal the viscoelastic nature of pharmaceutical and cosmetic semisolid materials, hitherto possible only through such unaccessible devices as the rheogoniometer or the modified creep aparatus. Various viscoelastic parameters can be obtained which characterize the material more specifically than with currently employed parameters such as apparent viscosity, yield value, area of hysteresis loop, etc., the magnitudes of which are partly influenced by the method used.

As indicated by Barry and Grace (15), such small strain tests are sensitive enough to even distinguish variations in the official grades of raw materials which are otherwise undetectable with current devices. Thus the accurate specifications of raw materials could possibly lead to smooth processing in manufacturing and ultimately a better product. Fundamental viscoelastic parameters such as residual viscosity which reflect the true nature of materials could also be used more effectively than apparent viscosities when assessing drug diffusion in topical bases (1). In addition, these kinds of tests may also help in elucidating on a molecular level the nature and rates of configurational rearrangements of structural entities within semisolid materials (1,16).

APPENDIX

The equation for a typical creep compliance curve (Figure 9) is as follows:

$$J(t) = J_0 + \sum_{i=1}^{n} [J_i (1 - e^{-t/\tau_i})] + \frac{t}{\eta_0} \tag{1}$$

which in expanded form can be written as

$$J(t) = J_0 + J_1 + J_2 + J_3 + \,.\,.\, + \frac{t}{\eta_0} - J_1 e^{-t/\tau_1} - J_2 e^{-t/\tau_2} - \,.\,. \tag{2}$$

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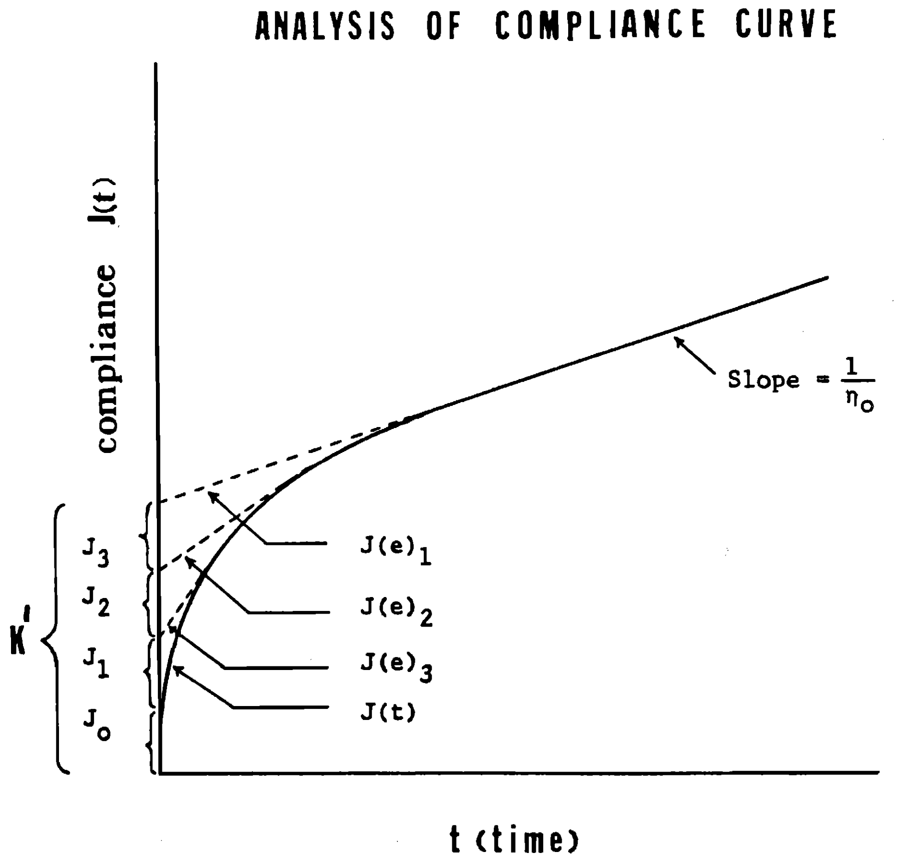

Figure 9.

Since $J_0 + J_1 + J_2 + J_3 +$ ---- is a constant quantity, K′ (Figure 9), by substitution and rearrangement, we have

$$K' + \frac{t}{\eta_0} - J(t) = J_1 e^{-t/\tau_1} + J_2 e^{-t/\tau_2} + \text{-----} \tag{3}$$

where quantity $(K' + (t/\eta_0))$ is the extrapolated linear part of the creep curve and may be represented as $J(e)_1$ (Figure 9). For conditions of $\tau_1 \ll \tau_2 \ll \tau_3 \ldots$ etc., at the larger times and smaller τ_i, quantities (e^{-t/τ_1}) and (e^{-t/τ_2}) etc. become less dominant compared to higher terms (e^{-t/τ_3}). Thus Equation 3 for larger times can be approximated as

$$\left(K' + \frac{t}{\eta_0}\right) - J(t) = J_3 e^{-t/\tau_3}$$

or,

$$J(e)_1 - J(t) = J_3 e^{-t/\tau_3} \tag{4}$$

If $[J(e)_1 - J(t)]$ is represented as x, then by taking the natural log, we get

$$\ln x = \ln J_3 - t/\tau_3 \tag{5}$$

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which is the equation for a straight line. Since quantity x at different time intervals can be graphically obtained from the creep curve, a plot of ln x versus t should provide a negative slope of $1/\tau_3$ and an intercept of $\ln J_3$ from which τ_3 and J_3 can be obtained.

It should be noted that in the plot obtained with Equation 5 at smaller times, we have a curve rather than straight line because of the dominance of τ_1, τ_2 in this region. The equation for this part of the curve in nonlogarithmic form would be

$$x = J_1 e^{-t/\tau_1} + J_2 e^{-t/\tau_2} + J(e)_2 \tag{6}$$

where term $J(e)_2$ is the extrapolated portion of the plot obtained with Equation 5. Again, with the same argument as before, the first term is less dominant than the second term in Equation 6. Thus,

$$x = J_2 e^{-t/\tau_2} + J(e)_2$$

or,

$$x - J(e)_2 = J_2 e^{-t/\tau_2}.$$

If $[x - J(e)_2] = Y$, then

$$Y = J_2 e^{-t/\tau_2}$$

or,

$$\ln Y = \ln J_2 - t/\tau_2 \tag{7}$$

from which J_2 and τ_2 can be obtained. This analysis can be continued in a similar manner such that

$$Y - J(e)_3 = J_1 e^{-t/\tau_1} \tag{8}$$

from which J_1 and τ_1 can be calculated.

Values for J_0 could be obtained from the value of K', other J_i values and the relationship $J_0 = K' - (J_1 + J_2 + J_3 + \dots)$. While the terminal linear portion of the creep curve provides the value for η_0, other η_i values could be obtained from the relationship $\eta_i = \tau_i/J_i$.

GLOSSARY OF SYMBOLS

V = volume of sample specimen (cm^3)
H_0 = initial height of sample specimen (cm)
H = height of sample at time t (cm)
t = time (sec)
F = applied force (= applied weight × 981 g cm/sec^2)
a = $4V/\pi$ (cm^3)
$K_1 = \left(H0^{1/2} - \dfrac{H0^{7/2}}{7a}\right)$ ($cm^{1/2}$)
η = viscosity (g/cm sec or poise)
$J(t)$ = compliance as a function of time (cm^2 dynes^{-1})
J_0 = compliance of Maxwell unit (cm^2 dynes^{-1})
η_0 = residual viscosity of the Maxwell unit (poise)

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J_i = compliance of the Voigt units (cm^2 dynes^{-1})
τ_i = retardation times of Voight units (sec)
η_i = viscosity of Voigt units (poise)
σ = normal stress (dynes cm^{-2})
ϵ = normal strain
P_i, q_i = various constants
P'_i, q'_i = various constants for incompressible material
K = bulk modulus (dynes cm^{-2})

ACKNOWLEDGEMENTS

The authors wish to express their sincere appreciation to the Society of Cosmetic Chemists for their scholarship grants (1980, 1981) in supporting the research, and also Dr. William R. Powell, formerly Associate Professor of the WVU Department of Mechanical Engineering and Mechanics, for his encouragement and assistance in the initial development of the apparatus.

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