A STUDY OF EMULSIONS.*

BY P. T. REES.[1]

The word Emulsion is derived from the Latin "Emulsus," meaning "To milk out." This class of medicaments is one of the oldest of pharmaceutical preparations, many products of this nature being in use before their structure was understood. Patent number 327,229 was issued to John Canrick in about 1884, covering a method for their manufacture.

In the light of modern research the complexity of the structure of emulsions has led to various definitions, but for pharmaceutical purposes they may be satisfactorily described as "Homogeneous products of two or more immiscible substances held by the intervention of an intermediate agent."

Again, from a pharmaceutical standpoint, emulsions of two types only need be considered, namely, Oil-in-Water and Water-in-Oil, with practically all of those intended for internal use being the Oil-in-Water type. All emulsions consist of three (3) parts or phases: (1) The continuous phase. (2) The dispersed phase. (3) The intermediate phase. In the Oil-in-Water type, the water being the continuous phase, oil the dispersed phase and the emulsifying agent the intermediate phase.

Many theories have been suggested for the behavior of these phases in the formation of emulsions:

(1) The Viscosity Theory which attempts to explain the stability of these products by a hindrance to coalescence due to the increased viscosity of the mixture.

(2) The Surface Tension Theory which states that emulsification is made possible by equalization of the surface tensions of the two liquid phases by intervention of the intermediate phase. In this manner inhibiting coalescence.

(3) The Hydration Theory which proposes that emulsification may occur only when the continuous phase can form hydrated compounds with the intermediate agent.

(4) The Adsorbed Film Theory which is, at present, the most generally accepted explanation and places the emulsifying agent as the third or intermediate phase. It advances the concept of adsorption of this phase, as a film about the oil, with both the continuous and the dispersed phases wetting this adsorbed film forming a difference in surface tensions on its two sides, thus causing it to bend to the side with the higher surface tension, becoming concave, and tending to enclose the liquid on that side. The mono-valent soaps, acacia, etc., which are more readily dispersed in water than in oil will enclose the oil globules and form the Oil-in-Water type emulsion. Di- and tri-valent soaps being more readily dispersed in oil will enclose the water and form the Water-in-Oil type emulsion.

The use of the Oil-in-Water type emulsion for internal administration is obvious, since water is the continuous phase, the finished product will be miscible with the aqueous body fluids, thus overcoming the objectionable taste of the oil phase.

In the field of Dermatology both types are employed but more commonly the Water-in-Oil. In the cosmetic industry approximately one-third of all items are in the form of emulsions. From the standpoint of these two fields alone, emulsions present not only efficacious preparations but also materially improve the appearance, usefulness and stability of these products.

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It is realized that the practical pharmacist rarely compounds extemporaneous prescriptions for emulsions, nevertheless he deals in many such products and is interested in their preparation and stability. The article by O. U. Sisson in the *Journal of the National Association of Retail Druggists* of June 1936, describes the modern technique for preparing emulsions and recommends the emulsification of many prescriptions which are frequently dispensed in a condition unsatisfactory to the physician, pharmacist and patient. His suggestions cover not only the eight official and various non-official emulsions but many ointments, dermatological prescriptions and professional cosmetics.

In general there are four (4) methods employed in Pharmacy for preparing emulsions, *e. g.*, trituration in a mortar, agitating in a milk-shake mixer, stirring in a mechanical mixer and recently by use of a Homogenizer. In investigating the practicability of the Homogenizer for pharmaceutical purposes it was decided to study the efficiency and speed of the other methods of manufacturing emulsions, out of which grew the material for this paper.

A hand-operated Homogenizer of about twelve (12) ounce capacity, suitable for small scale work, has recently been offered to the trade by International Emulsifiers, Inc., at a cost of $4.95. The apparatus is well constructed, durable and efficient. Tice, in the *American Journal of Pharmacy* of April 1935, reported on the advantages of the Homogenizer and compared products made with it to those prepared by the usual trituration method.

The present study has attempted to compare all of the generally used methods of emulsification on the basis of time, efficiency, economy, palatability and stability. The exhibit clearly shows the difference in stability of the products obtained by the four methods and their stability as related to the degree of dispersion of the dispersed phase as demonstrated by the micro-photographs.

Emulsion of Cod Liver Oil, U. S. P. Eleventh Revision, was chosen for these experiments since it is widely used, due to the present public demand for vitamin therapy, and the possibility of demonstrating the palatability of the finished products was considered.

Two hundred fifty (250) cubic centimeters of emulsion were prepared by each of the four methods of manufacture. In all cases the acacia was first mixed with the oil in starting the preparations and the alcohol added as a preservative to the finished product.

SPECIMEN "A" (HOMOGENIZER).

A primary emulsion was first prepared by passing the acacia in oil and water through the machine three (3) times. The syrup, methyl salicylate, final water and alcohol then added to the primary emulsion and the total volume again passed through the machine three (3) times.

Total time of manufacture being eight (8) minutes.

A creamy white preparation was obtained which showed no signs of stratification until after one (1) month. After ten (10) months of ordinary shelf-storage stratification may be noted at the bottom of the container. Approximately twenty (20) cc.

The product is noticeably free from included air-bubbles and shows a very uniform, finely divided dispersion of the oil phase.

SPECIMEN "B" (MORTAR).

The Continental Method, as specified in the U. S. P. Eleventh Revision, was used in the manufacture of this product.

Total time of manufacture being sixteen (16) minutes.

The fresh preparation appeared very satisfactory, being slightly more yellow and fluffy than Specimen "A" due to air enclosure during the trituration. After one (1) week there was evidence of stratification with about thirty (30) cc. of separation at the bottom of the container. After one (1) month stratification was decidedly apparent with the primary emulsion occupying about two-thirds of the container. Little change was noted between the one- (1) and ten- (10) month storage period.

The product shows oil globules of irregular sizes and of a fairly coarse and uneven dispersion.

SPECIMEN "C" (MILK-SHAKE MIXER).

The primary emulsion was prepared in the shaker and the balance of the ingredients added.

Total time of manufacture being sixteen (16) minutes.

A three- (3) layer stratification was noted within twelve (12) hours.

It is believed that but very little actual emulsion was formed by this method of manufacture, it being the thin white central layer of the finished product which shows an uneven dispersion of the oil globules and difficulty is experienced in identifying the continuous or the dispersed phase.

SPECIMEN "D" (MIX-MASTER).

The primary emulsion was first prepared in the mixer and the other ingredients added.

Total time of manufacture being eight (8) minutes.

The freshly prepared product appeared very satisfactory; the color and viscosity approaching that of Specimen "B." Stratification of approximately four (4) cc. appeared after one (1) week storage. After one (1) and ten (10) months' storage the stratification approximated that of Specimen "B."

The product shows a more uniform oil dispersion than seen in Specimen "B" but the size of the particles is larger than those of Specimen "A."

An opportunity was afforded to demonstrate, rather briefly but conclusively, clinical tests to show the direct relationship between the size of the dispersed phase particles and the palatability of the finished emulsion.

The three products "A" (Homogenized), "B" (Mortar), and "D" (Mix-Master) were administered to individuals with the following results:

Case No. 1. Adult (Male). Age 45 years. Occupation: Doctor of Medicine.

SPECIMEN "A" (HOMOGENIZED).

Palatability: Excellent.
Regurgitation: None.
Miscibility: All traces of emulsion removed from the mouth by drinking water.

SPECIMEN "B" AND "D" (MORTAR AND MIX-MASTER).

Palatability: Taste of oil.
Regurgitation: From 4–6 hours after administration.
Miscibility: Water failed to remove all traces of emulsion from the mouth.

Case No. 2. Child (Female). Age 12 years.

SPECIMEN "A" (HOMOGENIZED).

Palatability: Excellent.
Regurgitation: None.
Miscibility: All traces of emulsion removed from the mouth by drinking water.

SPECIMEN "B" AND "D" (MORTAR AND MIX-MASTER).

Palatability: Claimed taste of oil and nausea. Refused further administration.

Case No. 3. Child (Male). Age 9 years.

SPECIMEN "A" (HOMOGENIZED).

Palatability: Excellent.
Regurgitation: None.
Miscibility: All traces of emulsion removed from the mouth by drinking water.

SPECIMEN "B" AND "D" (MORTAR AND MIX-MASTER).

Palatability: Claimed taste of oil and nausea. Refused further administration.

SUMMARY.

In comparing the time of manufacture and the stability of the finished product the Homogenizer produced the best emulsion, requiring only eight (8) minutes. The Mix-Master required but eight (8) minutes for manufacture, producing a satisfactory emulsion for immediate use, but showed stratification in one (1) week. The Mortar emulsion required sixteen (16) minutes for manufacture and produced a satisfactory product for immediate use, but showed stratification after one (1) week storage. The Milk-Shake Mixer proved unsatisfactory in that no emulsion was formed after sixteen (16) minutes of agitation.

CONCLUSION.

The practice of using the ever-ready and handy Milk-Shake Mixer for the manufacture of extemporaneous emulsions is emphatically condemned.

For the manufacture of a satisfactory emulsion the following methods are recommended in the order based upon their palatability and stability. (1) Homogenized. (2) Mix-Master Mixed. (3) Mortar and Pestle.

Further study is needed in order to establish the full value of the Homogenizer to the modern practice of Pharmacy.

PHYSICIANS, PATIENTS AND PRESCRIPTIONS.*

BY CHESTER I. ULMER,[1] M.D.

For several years I worked in the L. L. Walton Pharmacy, Williamsport, Penna. I give you this rather drab bit out of my autobiography, not that it particularly interests you nor to give any unsolicited publicity to the Walton Pharmacy, but rather because it may serve as a protective buffer for some of the remarks I shall now make. Any criticisms I may make of either profession are purely constructive ones and are made with no belligerent spirit, I assure you.

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