

## ***STRATEGIES AND TECHNIQUES FOR TROUBLE-FREE MANUFACTURING OF COSMETIC EMULSIONS***

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### **Introduction**

Faced with fierce competition and ever-changing market demands, cosmetic chemists are increasingly under pressure to formulate large numbers of new products quickly. Frequently, insufficient time is allowed for conducting stability tests and pilot batch experiments which are essential to assure sufficient shelf life and trouble-free manufacturing operation. Among the various types of cosmetic preparations, emulsion-based products, including suspensions, are most vulnerable to batch-to-batch variations in product quality and stability. Such variations often result in QC rejection, causing time-consuming reprocessing, inevitable delay in new product introduction or even expensive product recall. To reduce processing costs, many manufacturers have increased batch size, and a batch failure can be very expensive, not only in terms of the raw material cost but also the expense of disposing of the rejected bulk. Clearly, the ability to ensure consistently uniform product quality in manufacturing a wide range of emulsion-based products is more important than ever for our industry.

### **Defining the Problem and Understanding the Causes**

Key to developing a sound strategy for consistently producing trouble-free batches of diverse emulsion products is defining problems clearly and seeking to understand their true causes. Some problems, such as pH value of a certain batch not meeting specifications, are usually not very difficult to define and the extent of deviation from the norm can be measured objectively and accurately. Since there are only a limited number of ingredients in the product which can contribute to the pH variation, isolating possible variables and investigating the cause may not be very difficult.

However, there are other more complex problems involving certain visual characteristics such as "product texture" which are more difficult to define and measure objectively. A sample of a cream from a certain production batch may pass all measurable specifications such as pH, viscosity, specific gravity, and yet its texture may appear different from that of the laboratory sample or previous batches. Whether this variance should be sufficient to cause alarm may depend on the chemist's perception. An inexperienced worker may ignore it whereas an experienced formulator may see it as a sign of something going wrong with the batch and suggest further investigation. Ignoring signs of a potential problem can invite an expensive product recall in the future. However, an error in identifying a non-problem as a problem can also cause unnecessary delay in production – and resulting expense. Clearly, accurate definition and evaluation of the problem is a very important first step in solving the often complex problems involving cosmetic emulsions.

Batch failure can result from many possible factors, and identifying the correct cause or causes requires good understanding of the effects of key variables. Since consumer satisfaction is essential for cosmetic products, any change in product properties that can affect consumers' perception of quality, safety, or effectiveness needs to be controlled. For cosmetic emulsions these properties may include product appearance including color, opacity, and texture, as well as other sensory properties such as fragrance, odor and skin feel. Control of rheological properties is essential for emulsion products as they can strongly affect consumer perception of product qualities like "richness," "smoothness," and "stickiness"(1). In addition, change in rheological properties of an emulsion can strongly affect product stability as, for example, a reduction in yield value can cause serious phase separation which will almost certainly be interpreted by consumers as a sign of an inferior or defective product.

### **Investigating and Identifying Factors Affecting Emulsion Quality**

Precise control of chemical composition in the production batch is crucial, as inaccurate weighing or the use of the wrong raw materials can certainly cause variations in many important chemical/physical properties related to product quality and shelf life. Equally important, however, are "Process Variables," which can also exert strong influence on perceived product quality. Most cosmetic emulsions on the market are processed by a batch process, using kettles and mixers. By nature, batch processing is accompanied by numerous process variables which are difficult to control precisely, and which may affect emulsion quality. Process variables are those variables introduced during the manufacturing process including emulsification temperature, mixing speed, the rate and the order in which the two phases are combined, cooling rate and even filling speed. Depending on the type of product and formulation, some process variables can be very important while others may be insignificant. Better control of process variables can often be attained by adopting a continuous process, but this method is not often used in cosmetic production because of the high engineering and equipment costs and the lack of flexibility.

### **Understanding the Nature of Emulsion Products**

One reason why so many emulsion products are tricky to manufacture and pose difficulty in controlling the quality of every batch is that most emulsions, except microemulsions, are non-equilibrium systems. As such, they are subject to the Second Law of thermodynamics and there is a strong tendency for the oil phase to become separated from the water phase, even when surfactants and polymers are used to retard this process. In general, a non-equilibrium product such as an O/W cream, consisting of incompatible oil and water phases, is much more susceptible to process variables and more troublesome to process than is a single phase product like a toning lotion consisting mainly of water and ethanol in an equilibrium state. Many process variables, such as shear stress from mixing and even the speed of adding one phase to another, if not carefully controlled, can affect emulsion properties and shelf life. Thus, a 1000 gram sample of a new cream made in a beaker in the product development laboratory may have a shelf life of 3 years while the first production batch from the same formula, produced in a 1000 gallon tank, may end up having only a 6-month shelf life. If the shortened shelf life is not detected before shipment, a costly product recall could result. Scaling-up of a new product from the laboratory to production is a very important step in prudent emulsion product development and carefully controlled pilot batch experiments go a long way in preventing production disasters.

### **Manufacturing Trouble Prevention Program**

To avoid problems in manufacturing a new emulsion formulation, it is essential for the development chemists, quality control staff and process engineers to work together to develop an effective trouble prevention program. Early detection and identification of potential manufacturing problems is crucial. The product development chemists in charge of the new product should be alert to communicating potential processing problems to the QC and engineering staff. Since each emulsion formulation is unique and may be affected differently by different process variables, it is often advisable to carry out pilot process experiments to determine the best way of processing and scaling up a new emulsion.

The importance of staff training cannot be overemphasized in our fast-changing industry. Companies are expanding production by installing larger kettles and bigger mixers. Changing batch size often means introduction of many process variables which can affect product quality and stability. It is not surprising that some emulsions made in a new larger kettle can often produce batches having lower quality or shortened shelf life. An experienced staff may be able to detect signs pending trouble from the appearance of a batch sample and take corrective, or at least cautionary action. Proper staff training and open communication among manufacturing staff, QC and development chemists are very important in formulating a sound strategy for trouble-free manufacturing of cosmetic emulsions.

### **References**

- (1) T. J. Lin, *Rheology Fundamentals and Applications in Cosmetics Formulation, Manufacturing and Quality Control*, *The Chemistry and Manufacture of Cosmetics*, M. L. Schlossman, editor, Allured Publishing Corp. volume1, pp 341-371 (2000)