TRANSLUCENT OIL-IN-WATER NANOEMULSIONS

BACKGROUND

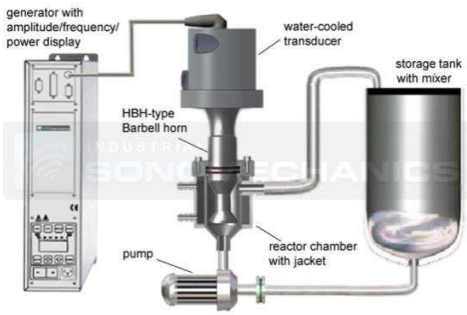
Cosmetic and dermatological industries use nanomaterials, such as nanoemulsion and nanocrystals, as delivery systems for active lipophilic compounds and drugs. Translucent nanoemulsions are a special class of nanoemulsions that have extremely small droplet sizes (below 100 nm) and narrow droplet size distributions. These materials have special properties, including optical translucency, low viscosity, and long-term kinetic stability. Due to their extremely small droplet sizes and very large dispersed phase surface-to-volume ratios, translucent oil-in-water nanoemulsions are especially attractive for cosmetics, ophthalmological and dermatological industries, as they are readily absorbed by the skin, easily sterilized by filtration, and can deliver exceptionally high concentrations of active oil-soluble substances.

Due to the similarity in appearance, translucent nanoemulsions are sometimes confused with microemulsions, which belong to another class of stable (thermodynamically) and optically clear colloidal systems. Microemulsions are spontaneously formed by "solubilizing" oil molecules with a mixture of surfactants, co-surfactants, and co-solvents. The required surfactant concentration in a microemulsion is several times higher than that in a translucent nanoemulsion and significantly exceeds the concentration of the dispersed phase (generally, oil). Because of many undesirable side-effects caused by surfactants, this is disadvantageous or prohibitive for many applications. In addition, the stability of microemulsions is easily compromised by dilution, heating or changing pH levels.

PRODUCTION WITH HIGH-AMPLITUDE ULTRASOUND

Industrial Sonomechanics, LLC (ISM), offers bench and industrial-scale high-power ultrasonic processors for the production of translucent nanoemulsions. The processors are based on our patented Barbell Horn Ultrasonic Technology (BHUT), which, as explained below, makes it possible to directly implement laboratory accomplishments in a production environment, guaranteeing reproducible and predictable results at any scale.

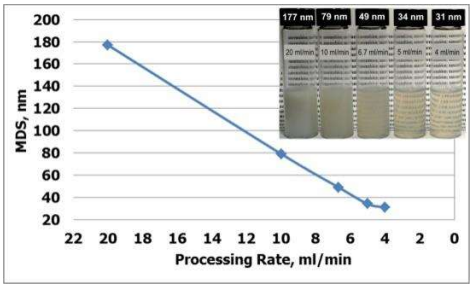
Very high ultrasonic amplitudes are required for the efficient production of translucent nanoemulsions. The necessary shear forces are created by ultrasonic cavitation, which produces violently and asymmetrically imploding vacuum bubbles and causes micro-jets that break up the original oil droplets down to sizes below 100 nanometers. Known for many decades, this effect of high-amplitude ultrasound has been extensively studied and successfully used in laboratory-scale research. However, prior to the introduction of BHUT, none of the existing ultrasonic liquid processors could generate the required amplitudes on the industrial scale. Commercial implementation of high-power ultrasound has, therefore, been limited to processes for which low amplitudes are sufficient (cleaning, simple deagglomeration, mixing, macro-emulsification, etc.).



Why ISM's Ultrasonic Technology?

Conventional high-power ultrasonic technology inherently forces all processes to run either at a small scale and high amplitude or a large scale and low amplitude. ISM has successfully overcome this limitation by developing BHUT, which permits constructing industrial-scale ultrasonic processors able to operate at extremely high amplitudes. The processors are directly scalable and can be used in the commercial production of high-quality translucent nanoemulsions for the cosmetics and dermatological

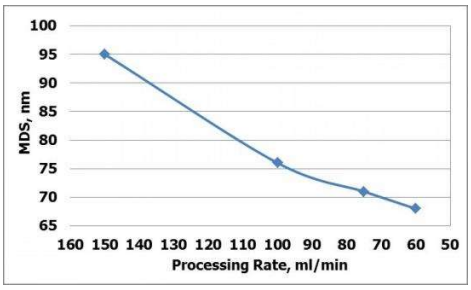
industry. Our equipment is compact and relatively low-cost, needs little technical support, includes very few wetted parts, generally requires no special pre-treatment of precursors, and is potentially self-sterilizing due to antibacterial properties of high-intensity ultrasound.



Examples of Produced Translucent Nanoemulsions

Target nanoemulsion parameters were: soybean oil content - 10 %; surfactant concentration - 6%, mean droplet size (MDS) - 75 – 80 nm. The ingredients were pre-mixed using a magnetic stirrer at 500 rpm for 2 min. MDS values were measured using Beckman Coulter N4 Plus Particle Size Analyzer.

Lab Scale: Nanoemulsions were first prepared using ISM's 1200 W flow-through ultrasonic processor, BSP-1200, operating in a laboratory-scale configuration. This setup utilized a common horn (CH) and a small reactor chamber. The horn's output diameter was 15 mm and its operation amplitude was 90 microns. Nanoemulsion samples were prepared at the processing rates of 20, 10, 6.7, 5, and 4 ml/min. MDS decreased as the processing rate was lowered, and the nanoemulsion became increasingly translucent. Target MDS was achieved at the processing rate of 10 ml/min. The acoustic power deposition under these conditions was 130 W.



Pilot Scale: The process was subsequently upgraded to pilot scale by switching to a Half-wave Barbell horn (HBH) and using a larger reactor chamber. The horn's output diameter was 35 mm and its operation amplitude was 90 microns, same as in the previous lab experiment. Nanoemulsion samples were prepared at the processing rates of 150, 100, 75, and 60 ml/min. The results presented on the left show that the closest match to target parameters in terms of the final required MDS was obtained at the processing rate of 100 ml/min. This corresponds to a scale-up factor of 10. The acoustic power deposition, in this case, was 1,150 W, which is consistent with the obtained scale-up factor.

This process may be further scaled up by using ISM's 3000 W industrial-scale ultrasonic processor system, ISP-3000, equipped with a larger HBH and/or by using a series multi-reactor arrangement. Ultrasound is a simple and effective technique for producing translucent nanoemulsions. With the use of BHUT, the process is directly scalable, making it possible to implement in an industrial production environment.

The data presented above was collected in collaboration with Allied Innovative Systems, LLC (ALLIS).

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