NINE SIGMA REQUEST # 68787

Pharmaceutical Formulations for Oral Medications
hydrophobic organic molecule
water soluble at pH < 3

CRS TECHNOLOGIES INC.

SUMMARY

In the processing of foods and pharmaceuticals and a host of other industries) it is often necessary to disperse, emulsify, homogenize, and/or reduce particle sizes. Ultrahigh shear mixers are used for these tasks.

Although a large number of both ultrasonic and hydrodynamic devices have been developed for these and other uses, there are fundamental limitations to their use. Most importantly, they have not been optimized for any particular application. Once developed, they are marketed to many end users, with a variety of needs. Often times, because of this 'one size fits all' marketing strategy, the end user ends up with a device that is ill suited for his particular task, and the device ends up in a corner gathering dust. Or, almost as bad, the device works at some level, but inefficiently. The end user is then forced to work with a processor that needlessly wastes raw resources (and thus, money).

Scaling a high shear processor for a particular application is one example. Shearers are often scaled up or down to accommodate a new material through output requirement, or new end user. However, the performance of the shearer changes as it is scaled. In order to maintain efficiency and functionality, or to optimize it, a good understanding of the physical mechanisms is needed.

Until now, there has been no attempt from the industry to systematically study or optimized high-shear processors for these industries that takes trial and error out of the equation, and instead allows a systematic approach to understanding the mechanisms and optimization strategies. For example, the efficiency of a fluid being emulsified in a processor depends on how quickly and how often the fluid particles can pass through the shearing stage. If there are significant dead spaces, the efficiency and product quality drops.

Modeling and optimization is expensive and time consuming and once developed can also be used to quickly adapt the technology to new uses, and significantly improve existing techniques.

The CRS process is an industrial optimized hydrodynamic system that utilizes in part of the process a mechanism that is common to the industry (see companies such as Silverson, Ross, IKA, etc.). However, it is unique in its ability to produce stable emulsion with the resulting phytonutrients released in a highly bioavailable form.

After 12 years of research, the company is currently engineering an industrial optimized system to recover highly bioavailable antioxidants as a drug target for addressing viruses, cancers and other wellness applications. The science and process protected with various PCT applications, is validated by USDA, Covance Laboratories and other academic institutions. Further scientific investigations are being undertaken in 2013 with academic investigators in South Africa, India and Europe. A key factor in the science is hydrogen bonding

Because of these unique characteristics of the technology and process, the possibilities of addressing the improved bioavailability challenges of the hydrophobic organic molecule could be investigated singularly or by using a Host.

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