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# **ADVANTAGES OF BEE HOMOGENIZERS for the PHARMACEUTICAL INDUSTRY**



# Advantages of BEEI Homogenizers for the Pharmaceutical Industry

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Over the past decade the pharmaceutical industry has been subject to vast change, much of it detrimental to the involved corporations and downstream consumers. While the cost of health insurance continues to rise, generic drugs are dominating an already saturated market, and the high cost of R&D has led to a severe decline in new 'blockbuster' drugs. To overcome such hurdles, pharmaceutical companies need to make smart business decisions through execution of developed strategies and accurate risk assessment. But most importantly, they must improve their drug development processes by obtaining equipment that will both function efficiently and output high-quality products. (1)

Homogenizers are the most efficient fluid processing equipment for processes such as cell disruption, particle size reduction, and emulsification, all of which are critical to development of most pharmaceutical products. Pharmaceutical corporations seeking to improve their processes should begin by selecting one that can synthesize the necessary products while also working efficiently to reduce long-term spending. BEE International Technology (BEEI) is renowned for their high-pressure homogenizers, as well as the support they can offer to pharmaceutical corporations working to transition from R&D to clinical trials to manufacturing.

Here we describe the advantages of BEEI homogenizers for the pharmaceutical industry by analyzing how product-specific details promote the synthesis of safe and efficacious drugs.



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# Pharmaceutical Applications for Homogenizers

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Today's pharmaceutical leaders are discovering and developing a wide range of new medicines to help people live longer, more productive lives. As a result, scientists require appropriate equipment to support synthesis of these medicines. Homogenizers have a wide variety of applications that are directly incorporated into common pharmaceutical drugs and treatments. Below are listed these applications and relevant pharmaceutical uses.

## 1. Particle Size Reduction

This feature has a significant impact on rate of absorption and total bioavailability, in addition to general drug appearance, particularly among tablet coatings and other external substances. Vaccines, vaccine adjuvants, nutraceuticals, and antibiotics are just some of the many pharmaceutical products affected by particle size.

Most drug products function better in terms of bioavailability, chemical stability, ease in swallowing, and physical appearance when they are comprised of smaller particle sizes that are uniform in consistency. Homogenizers are one of the few available technologies that can achieve both small particle size and uniform consistency, which will prepare your lab for production of a high quality drug product.



## 2. Micro & Nano Emulsions

Comprising a wide array of pharmaceutical products such as those intended for oral or topical use, emulsions are mixtures of two immiscible liquids that are stabilized by an emulsifying agent. Optimally functioning at reduced particle sizes, emulsions work to mask unpleasant tastes, increase absorption rate, enhance washability, optimize viscosity and minimize grease. Emulsions can be prepared as either water-in-oil or oil-in-water, and are responsible for the appearance of a single solution that does not separate out into layers; this is classically seen with homogenized milk, and to a lesser degree among pharmaceutical creams.

## 3. Dispersions

Dispersions are similar to emulsions in the establishment of a continuous phase; yet dispersions are distinct in that they comprise finely divided solid particles in a liquid, whereas emulsions comprise liquid particles.

Categorized as coarse dispersions (suspensions), colloids, or solutions, dispersions have a multitude of pharmaceutical uses, mostly as oral, parenteral, or inhalant/aerosol products. Antacids, antibacterials, anticonvulsants, and antifungal agents are just a small number of drugs that are comprised of dispersions. Critical to proper drug functioning, dispersions can improve chemical stability, minimize clotting, mask bitter tastes, control drug release, and increase rates of bioavailability.



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## 4. Cell Disruption / Cell Lysis

Interestingly enough, technology that is designed to reduce particle size is also suited for gently rupturing cells. Cell disruption is actually the first step in particle size reduction, and releases desired biomolecules from within the cell. Laboratory scientists require ability to rupture a wide variety of cells, such as *E. coli*, yeast, mammalian tissue, bacteria, algae, fungi and insect.

Cell disruption methods are typically deemed effective based on accessibility of intracellular proteins for extraction and solubility and process flexibility, e.g. ability to run a harsher or more gentle process based on the cell type.

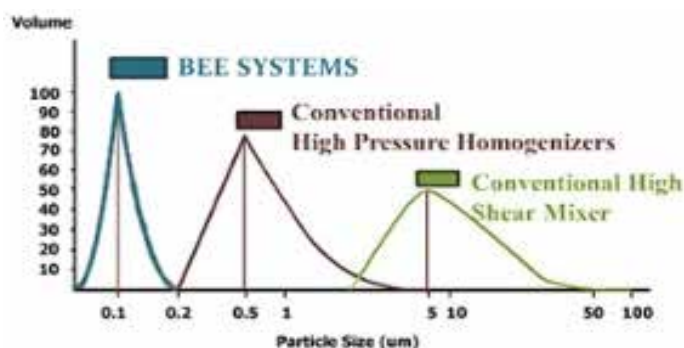
# BEEI Homogenizer Benefits

To support the range of pharmaceutical applications listed above, BEEI's products boast innovative technology that offers unique production benefits. For example, the sanitary design and features like validation procedures and documentation, data gathering, SCADA, and automated CIP ideally suit the in-line technology for pharmaceutical process equipment. Read further to better understand the unique benefits a BEEI homogenizer can offer your laboratory and drug development process.

## 1. Exceptional Particle Size Reduction

While most high-pressure homogenizers reduce particle size, BEEI's high-pressure homogenizers have applications where particles have been reduced to 0.01  $\mu\text{m}$ ! Conventional high-pressure homogenizers achieve maximum reductions of 0.5  $\mu\text{m}$  and conventional high shear mixers achieve reductions of 5  $\mu\text{m}$  on average. As an added bonus, BEEI's impressive particle sizes can also be achieved in fewer passes; in some cases, d90 (90% of the sample) is reduced to target size in just one pass, which improves overall efficiency and product quality.

Unlike other technologies that apply only one mechanical force to mix a product, BEE technology utilizes all available mechanical forces to achieve optimal results. These forces include turbulence, cavitation, high shear rates and impact. In addition, these mixing forces can be fine-tuned to the specific product, which can lengthen shelf life, improve sensorial properties (e.g. rapid penetration, merging textures) and improved biophysical properties (e.g. hydrating power). These features support many pharmaceutical applications, but a test run is suggested so that optimal product-specific settings can be determined.





## 2. Lysing Capability

Regarding homogenization, one of the central uncertainties among scientists in the pharmaceutical drug development space is the type of cell that can be lysed. While BEEI high-pressure homogenizers most commonly lyse E. coli and yeast, there are certainly other cell types that have been lysed with the equipment. Regardless of the cell type you want to use, always test it first to ensure that you are achieving the intended result.

## 3. Quality

BEEI's high-pressure homogenizers contain a wide array of capabilities that allow the user to customize his/her experiment, and which are infrequent among other homogenizer brands. For example, users can manually set their homogenizer to parallel or reverse flow and can run samples as many times as needed to achieve 100% particle reduction to target size.

In addition, multiple mechanical forces can be utilized and fine-tuned to produce the best results for a given product. Turbulent premixing can be replaced with a laminar flow, cavitation can be intensified or reduced, shear process time can be adjusted, impact can be maximized with the reverse flow setup, and process intensity can be adjusted with the simple turn of a dial.



## 4. Support & Warranty

On the quest to purchase equipment that is both critical to your drug's production and costly to repair, it is important to know that support and warranty details are helpful and customer-centered. BEEI's training and installation process help customers feel comfortable with both the equipment and the process; they also provide application-related support via phone as needed. Prior experience has informed BEEI support representatives, who can guide customers through issues or processes via telephone or even Skype.

The BEEI homogenizer warranty provides an impressive level of customer protection. In the first year after purchase, any injury to the machine that is not caused by the customer is 100% covered. See the BEEI Terms & Conditions for more on the terms and conditions of sale and warranty protection.

## Product Details

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Compared to other brands, BEEI is unique in its ability to recognize and cater to each stage of the drug development process.

Our homogenizers are categorized into one of the following stages: R&D, clinical trials, or manufacturing.

### 1. Research & Development

BEEI laboratory homogenizers can help R&D scientists achieve success through two major methods. First, their expanded experimentation options and product capabilities allow optimal results to be reached immediately. This can be seen through ease in handling technology, which allows processes to be quickly altered to accommodate a cell's sensitivity (or lack thereof).



Second, frequently used products like emulsions and dispersions are higher quality with smaller particle sizes. The products produced by the laboratory homogenizers in Table 1 match or even exceed that of other equipment, which can make the difference between adequate and remarkable drug testing results. Particularly when testing new innovations, improving existing products, or determining more efficient manufacturing options, these homogenizers will help achieve unmatched particle sizes to meet these goals. See Table 1 for a comparison of the BEEI laboratory homogenizers and each model's capabilities.

Model	Power Supply	Maximum Operating Pressure	Capacity (mL / min)	Processing Setups
Nano DeBEE 30	Electric	30,000 PSI	70	Parallel Reverse
Nano DeBEE 45	Electric	45,000 PSI	70	Parallel Reverse
Nano DeBEE 45-3	Electric, 220V only	45,000 PSI	115	Parallel Reverse
Micro DeBEE	Air	45,000 PSI	250	Parallel Reverse
Mini DeBEE 30	Electric	30,000 PSI	400	Parallel Reverse Dual Feed
Mini DeBEE 45	Electric	45,000 PSI	400	Parallel Reverse Dual Feed

**Table 1.** Comparison of typical performance ranges for laboratory homogenizers by BEE International.

## 2. Clinical Trials

Designed to test your drug’s specific process and production requirements, BEEI pilot plant high-pressure homogenizers can accomplish these in a small-scale, low-cost setting.

The pilot-scale high pressure homogenizer model typically includes a feed pump, hydraulic system to create flow, a proprietary intensifier system to create maximum operating pressures of up to 45,000 PSI, and a proprietary homogenizing system with digital display and heat exchangers.

Many more options are available to fit your needs, and can be customized to your schedule and budget. Similar to our laboratory homogenizers, the BEEI pilot-scale homogenizer also boasts unmatched particle sizes and results in fewer passes than those of competing homogenizer brands. See Table 2 for an enhanced scope of the pilot-plant performance parameters.

Power	Pressure	Capacity	Power Requirements
10 HP 7.5 kw	Up to 45,000 PSI	1-3 LPM	220 / 380 / 460 V 3 Phase 50 / 60 Hz Water (coolant) for product and hydraulic heat exchangers
20 HP 14.9 kw	Up to 45,000 PSI	2-6 LPM	220 / 380 / 460 V 3 Phase 50 / 60 Hz Water (coolant) for product and hydraulic heat exchangers

**Table 2.** Performance parameters for the customizable pilot-plant homogenizer by BEE International.

### 3. Manufacturing

BEEI industrial homogenizers are among the most powerful and versatile on the market for the manufacturing stage of drug development. With guaranteed scale-up from laboratory and pilot scale settings, BEEI industrial scale homogenizers produce unmatched particle size reduction with maximum efficiency for micro/nano emulsions and particles; they also produce cell rupture that is high yield in less time.

Such as with the pilot plant homogenizer, BEEI industrial homogenizers have a modular design in which standard components can be added and subtracted to create a custom solution. Additionally, the industrial model offers a user-friendly operator interface with touch screen display and proprietary software for ease in set-up, monitoring, operation, and data collection. See Table 3 for a comparison of the industrial homogenizer performance ranges, and to assess which will be the best fit for your laboratory's purposes.

Model	HP	Maximum Operating Pressure (PSI)	Capacity (Liter / Hour)
DeBEE 2000P-20/45	20	45,000	120
DeBEE 2000P-20/20	20	20,000	250
DeBEE 2000P-50/45	50	45,000	300
DeBEE 2000P-50/20	50	20,000	650
DeBEE 2000P-100/45	100	45,000	600
DeBEE 2000P-100/20	100	20,000	1300
DeBEE 2000P-200/45	200	45,000	1200
DeBEE 2000P-200/20	200	20,000	2700
DeBEE 2000P-250/45	250	45,000	1500

**Table 3.** Comparison of typical performance ranges for industrial homogenizers by BEE International.





## **Learn More about BEE International**

BEE International is a worldwide supplier of high pressure homogenizers for the pharmaceutical, biotech, chemical, cosmetic and food industries. In the laboratory, our systems process fluids producing uniform particle size reduction to nanoparticles, and high yield cell disruption.

All our systems produce the same results. Scaling up to pilot and clinical trial settings, our high pressure homogenizers consistently produce the same results and have a reputation for reliability. These qualities continue into manufacturing, where the in-line process reduces costs by achieving better results in less time.

**Contact us to learn more about our high pressure homogenization products and technology!**

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## **ABOUT BEE INTERNATIONAL**

BEE International was established in Israel in 1994 for the sole purpose of developing and bringing to the market innovative homogenizing technology and equipment.

The company began in cooperation with Technion University Israel Institute of Technology which is among the top science and technology research universities in the world.

In 1998 BEE International opened a US operation. Today, BEE International has representation and equipment installations worldwide.

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