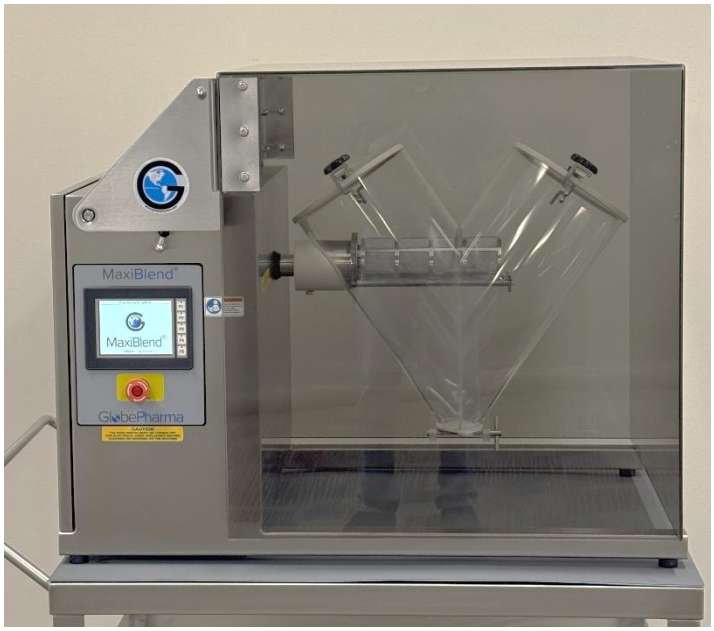
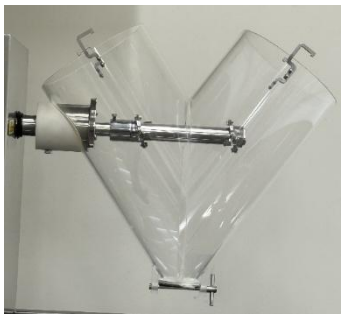
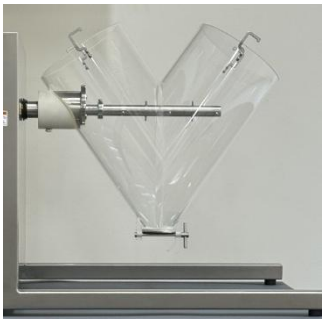
# MaxiBlend® Lab Blender




MaxiBlend® Lab Blender - shown with an acrylic shell for visibility only (316 SS shells are standard) & SIFT-N-BLEND® Intensifier (Patented)



High-speed Intensifier bar mounted in a 16 qt acrylic V-shell



Pin Intensifier bar mounted in a 16 qt acrylic V-shell

MaxiBlend® is a cGMP-compliant blender designed for homogeneous blending with optional intensifier bar drive arrangements. It accommodates interchangeable blending vessels of various shapes—including V-shells, bins, and double cones—and supports SIFT-N-BLEND® intensifier, high-speed intensifier bar, and pin intensifier bar attachments. With the intensifier option, liquid addition is also possible. The system is equipped with safety interlocks and PLC-based controls to ensure reproducible results.

Both the shell and the intensifier drives come with optional variable speed drives. SIFT-N-BLEND® intensifier attachment facilitates simultaneous sifting and blending of the powders and provides excellent homogeneity in the blend as the powders pass through the screen multiple times.

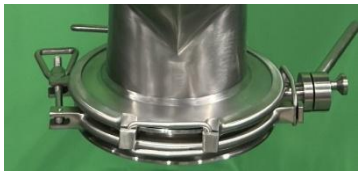
Shell sizes of 0.5 qt to 16qt can be interchangeably used. A bottle blending attachment is also available, which facilitates blending of small amounts in bottles.

## MiniBlend® Table-Top Blender

MiniBlend® designed for flexibility, accommodating blending needs ranging from 2 grams to 1 kilogram. Its compact design and versatile features make it ideal for various laboratory environments from pharmaceutical and compounding to nutraceutical and beyond.

0.5 qt, 1 qt, and 2 qt shells, and a small bottle blending attachment can be used interchangeably.
No intensifier option is available with this blender.

## SimpleBlend®

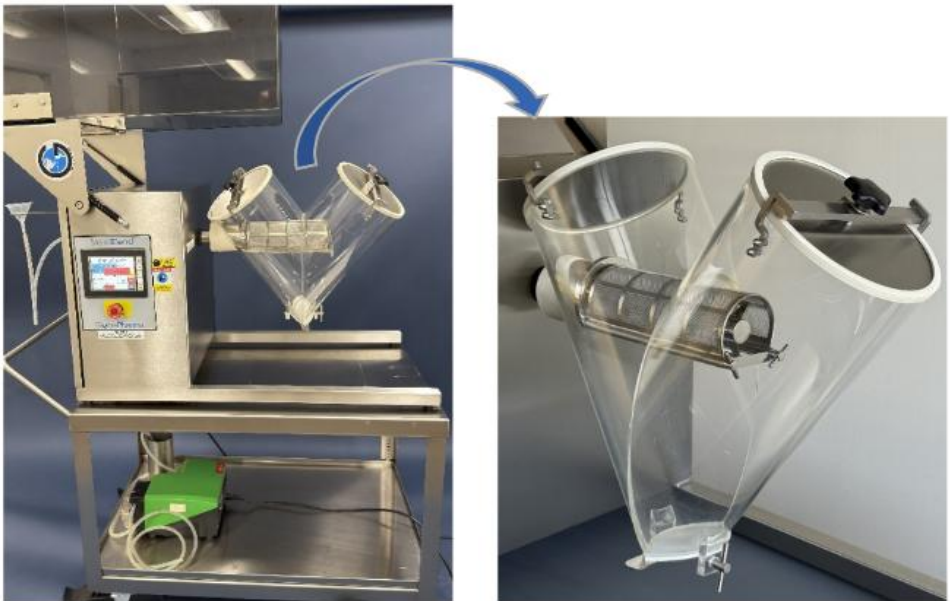


SimpleBlend® powder blenders are stand-alone pilot and small-scale production tumble blenders, featuring a direct-drive design, with the available GlobePharma's patented SIFT-N-BLEND® intensifier, high-speed intensifier bar, and variable speed drives for the shell and the intensifier bars.
The shells are made of 316 SS and provided with a sanitary butterfly valve.
Available in working capacities of 1, 2, 3, 5, and 10 cu.ft.
Safety-interlocked acrylic guards or laser guards are mandatory.

## SIFT-N-BLEND® Technology

GlobePharma's Patented (US 8,235,582; US 8,827,545; CA 2736942C; CA 2821188C & EP2703072B1) SIFT-N-BLEND® technology facilitates simultaneous sifting and blending in the blending vessel itself, thereby eliminating the need for separate sifting of ingredients, such as silicon dioxide, and provides excellent content uniformity of pharmaceuticals, especially low dose drugs, as well as food and cosmetic ingredients such as colors, flavors, sweeteners, etc. The SIFT-N-BLEND® attachment replaces the traditional intensifier bars, which are heavy, especially on commercial scale blenders requiring multiple operators to install and dismantle, and difficult to clean.

It consists of a semi-tubular screen, either made of wire mesh or a perforated stainless-steel sheet, a pair of mounting rods, and a paddle. This assembly is mounted on the trunnion hub inside the blending vessel, allowing the screen to rotate at the same speed as the shell (e.g., 25 rpm on a lab blender). A separate drive operates the paddle, which turns independently at variable speeds up to 2,500 rpm. As the paddle rotates, at each rotation some powder enters the screen and the paddle forces it through the screen, effectively breaking up lumps and any static agglomerates ensuring a uniform blend. The powder goes through screening multiple times, helping eliminate the need for pre-screening of the powder ingredients, and homogeneous blend is achieved.



SIFT-N-BLEND® intensifier mounted in a16 qt acrylic V-shell

## Sanitary Butterfly Valve

Sanitary Butterfly Valve is a cGMP-compliant valve available in models RC-RC, RC-WC, and WC-WC. It is constructed from 316L stainless steel and features an FDA-approved translucent silicone gasket along with a 316L stainless steel clamp. The center vane is polished to a mirror finish, while the remaining valve surfaces have a satin finish.

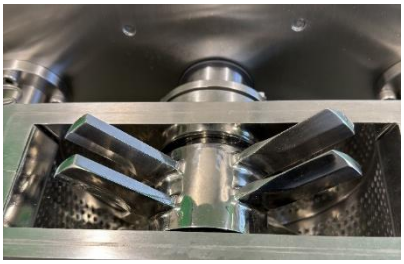
Valves with diameters of 6” (150 mm), 8” (200 mm), 10” (250 mm) and 12” (300 mm) are available from stock in USA. Nozzles for these valves are also available for welding on to the blender discharge end.

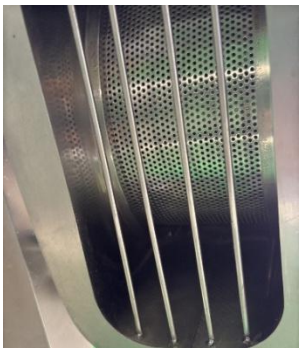
## Table-Top Hammer Mill


GP-Hammer Mill-1 is a compact, table-top mill designed for small-scale milling, capable of processing batch sizes as small as 5g, this R&D mill is ideal for de-lumping, pulverizing, and controlling particle size reduction of various materials.

Despite its small size, the GP-Hammer Mill-1 delivers the same process advantages as larger mills and can be seamlessly scaled up. Built with 316 stainless steel contact parts and housed in a 304 stainless steel enclosure, it meets the highest cGMP standards for product contact. The mill offers both impact (hammer) and cutting (knife) actions, easily selected by pushing a button. Both milling styles are integrated on the same rotor, and the unit's reversing motor enables either knives forward or hammers forward milling without the need to lift and reverse the milling chamber.

# GP Hammermill 2.5/5





The GP-Hammer Mill 5-2.5 is a hammer mill with capability of interchangeable milling chambers for R&D as well as pilot batches. This mill offers both impact (hammer) and cutting (knife) actions, easily selected by pushing a button on the unit.

The innovative design places both milling styles on the same rotor, and a reversing motor facilitates easy switching between hammers and knives, without the need for lifting and reversing the milling chamber. Switching between chambers is quick and effortless: simply unscrew the mounting bolts, slide out the existing chamber and blades, and secure the new configuration onto the same drive system. Users can seamlessly adjust the milling speed using the intuitive touchscreen HMI display.

Comes with variable speed drive and integrated safety interlocks and protective grid underneath the milling chamber.

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# GP Cone Mill 197

GP-Cone Mill 197 is specifically designed for lab-scale conical milling. Each machine comes equipped with one screen and one impeller of customer's choice, with numerous available screens and impeller designs, providing process versatility and efficiency. This mill is portable, and the on-caster design allows for easy movement throughout any facility.

Milling is an operation which is used to reduce the particle size of the product being processed. Cone mills are used for reducing the size of dried granulations or for de-agglomeration or de-lumping because of its gentle milling nature.

Variable speed drive and safety interlocks are standard features.

## GP-HSG 1-6


GP-HSG 1-6 high shear granulator with interchangeable bowls from GlobePharma is a versatile, benchtop high-shear wet granulator designed for pharmaceutical formulation development applications, including mixing, wet granulation, and pelletization of powders.

Wet granulation is done with powders which have poor flow and inadequate compactability, usually with a binder solution. After wet granulation, the wet mass is dried and milled in separate equipment for further processing into dosage forms, such as tablets and capsules.

This versatile system features interchangeable 316 stainless steel bowls (0.5–6 L), each equipped with a variable-speed three-blade impeller and side-mounted chopper for making fine granulations.. An air purge design keeps operation clean, while the touchscreen HMI with PLC controls help provide reproducible results. Optional features such as liquid addition, jacketed bowls for heating or cooling, and a mobile stainless-steel cart make it highly adaptable to diverse laboratory needs.

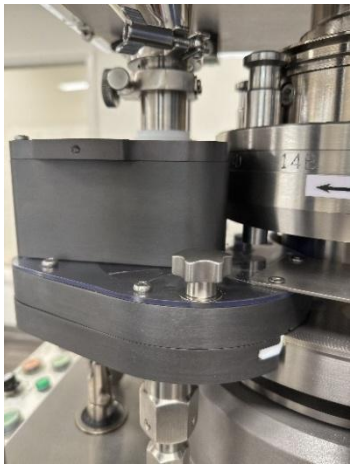
## GP-HSG 5


GP-HSG 5 high shear granulator with interchangeable bowls from GlobePharma is a versatile, high-shear wet granulator designed for pharmaceutical, nutraceutical and food formulation development applications, including mixing, wet granulation, and pelletization of powders. Compared to GP-HSG 1-6, this model is a more cost-effective option for wet granulation.

Wet granulation is done with powders which have poor flow and inadequate compactability, usually with a binder solution. After wet granulation, the wet mass is dried and milled in separate equipment for further processing into dosage forms, such as tablets and capsules.

Designed for efficiency and value, this compact, economical system offers interchangeable 316 stainless steel bowls in 1-, 3-, and 5-liter capacities, available in both standard and jacketed versions. Each bowl includes a variable-speed, three-blade impeller, with an optional top-mounted variable-speed chopper assembly forfor making fine granulations. For added flexibility, the system also offers optional liquid addition and jacketed bowls to enable precise heating or cooling during processing.

# VersaPress®

VersaPress® is an automatic, durable, cGMP compliant rotary tablet press with 316 stainless steel die table (product contact part of the turret), B, BD or D type multiple stations of a variable speed turret. 5 tons compression force and 2 tons pre-compression force help compacting difficult to compact powders. It offers exceptional versatility with multiple turret configurations, including the option of combining 7 stations each of B and D punches on a single turret. Variable speed turret allows running the press at slower speeds, which combined with use of just two stations makes it possible to run very small batches.

VersaPress® includes both gravity and force feeders for optimal flexibility with difficult to flow powders. With turret capacities of up to 18 stations for B tooling and 12 stations for D tooling, VersaPress® provides users with a wide range of R&D and pilot scale production capabilities.

Also available is an instrumentation package to monitor pre-compression, main compression and ejection forces.

# Manual Tablet Compression Machine

MTCM-I


MTCM-III

The Manual Tablet Compression Machine, Model **MTCM-I**, is designed for compaction of powders into tablets one at a time. It can also be used for compression of unit-dose powder samples obtained with GlobePharma's unit- dose powder samplers into tablets for submission to the analytical lab. This machine can produce double-layer tablets as well as tablet-in-tablet (core-in-shell) designs, one unit at a time. Compression is accomplished by means of hydraulic pressure applied with a manual hydraulic pump. A pressure gauge with 3000 lb., 5000 lb. or 10,000 lb. capacity is provided with the machine. The gauge is calibrated against a NIST certified load cell, and the calibration curve is provided with the machine. Accommodates standard "B", "D", and "DS" size tablet tooling without requiring any modifications or special tooling. Round-shaped as well as special-shaped tooling may be used. One set of punch holders (B, D or DS) is supplied with the machine. Additional punch holders and punches and dies are optional. The interchangeable aluminum punch holders help keep the tooling properly aligned during compression. The machine is compact in size (16" W x 12"D x 24"H) and is portable (65 lbs.).

**MTCM-III** helps compact multiple tablets simultaneously using custom-made split sample die and multi-tip tablet punch. This machine is equipped with a heavy-duty hydraulic piston. After compaction, the top part of the split die is removed, and the tablets are ejected into an ejection cup (not shown) using the same multi-tip punch.

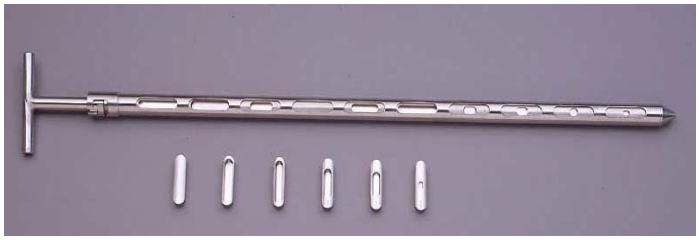
# Unit-dose Powder Samplers

Unit-dose powder samplers with interchangeable dies for unit-dose sampling are available in different diameters, lengths, and models. Made of 316 stainless steel, these samplers may have one sample port or multiple sample ports for simultaneous sampling at several locations. Any number of sample ports may be blocked with blank dies. Single, duplicate or triplicate sampling at each sample port is possible. Duplicate and triplicate samples are obtained from exactly the same spot at each sample port with just one insertion of the sampler into the powder bed. Segmented design samplers facilitate sampling from large blenders with roof height limitation. Stainless steel inner shaft is hollow (except in Model IB and 1BB) to make the sampler lighter. Inner shafts, custom-made of Delrin or Teflon - FDA approved white plastics), are available.

The samplers are passivated and easily cleanable with a removable conical end piece. Some sizes of standard models are stock items. Others are custom-made and have longer lead times.

**Model I (Patented):**

Standard single-sample design. 0.875" in diameter. One unit-dose sample is obtained at each sample port. The bottom most port starts at 1.5" from the tip. 40 different sizes of sample dies (0.1cc to 4.0cc in increments of 0.1cc) and 30 different sizes of split sample dies (0.1cc to 3.0cc in increments of 0.1cc) fit in this sampler. Stock sizes are 1ft with 5 ports, 2ft with 10 ports, 3ft with 6 ports, 4ft with 8 ports, 5ft with 10 ports and 6ft with 12 ports.



**Model I-A**:

Custom-made segmented single-sample design. 0.875" in diameter. Facilitates sampling from large blenders, with roof height limitation. Both segments may be used independently. Has a 1.5" diameter nut to join the segments. The bottom most port starts at 1.5" from the tip. Same dies as described under Model I fit in this sampler.

**Model I-B:**

Custom-made single-sample design. 0.5" diameter. One unit-dose sample is obtained at each sample port. The bottom most port starts at 1.0" from the tip. The inner shaft is solid. Custom-made dies from 0.1cc to 1.0cc fit in this sampler.

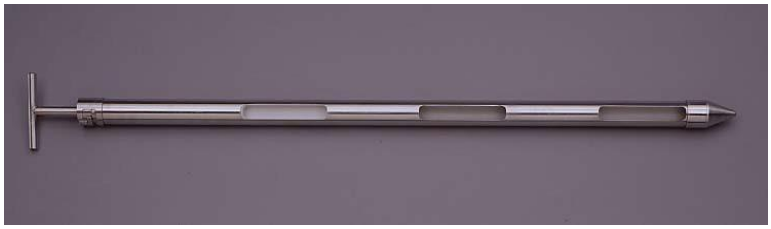
**Model I-BB**:

Custom-made single-sample design. 0.375" diameter. One unit-dose sample is obtained at each sample port. The bottom most port starts at 0.5" from the tip. The inner shaft is solid. Custom-made dies of 0.1cc, 0.2cc and 0.3cc fit in this sampler.

**Model I-C:**

Custom-made Spoon Sampler with a removable handle and interchangeable spoon-like sample die. The dies can be made to take any size sample. Especially suitable for sampling products where the particle surface cannot be disturbed, for example, coated non-pareils. Only one sample is obtained at a time.

**Model II:**



Custom-made single-sample design to accommodate dies up to 40cc in volume. 1.5" in diameter. One sample is obtained at each sample port. The bottom most port starts at 1.5" from the tip. Dies may be made of Delrin or 316 stainless steel, to accommodate up to 40cc with a 4" long die. More sample size can be obtained with longer, custom-made dies.

**Model III:**

Custom-made single-sample design to accommodate dies up to 200cc in volume. 2.0" in diameter. One sample is obtained at each sample port. The bottom most port starts at 4.0" from the tip. Dies may be made of Delrin or 316 stainless steel. Consideration should be given to the ease or difficulty of inserting a sampler of this diameter into the powder bed before placing an order.

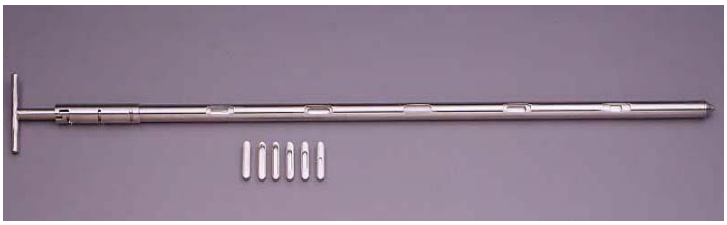
**Model III-A:**

Custom-made single-sample design. 0.875" diameter outer tube with a 1.5"/2.0" diameter chamber at the end to take a single sample. The chamber is interchangeable with other chambers, and each chamber can accommodate different size dies. Dies may be made of Delrin or 316 stainless steel. Samples sizes of up to 200cc may be obtained.

**Model IV (Patented):**

Standard duplicate-sample design. 0.875" in diameter. Two unit-dose samples are obtained from exactly the same spot at each sample port. The bottom most port starts at 3.5" from the tip. Each sample port requires either two sample dies or two blank dies. Same dies, which fit in Model I sampler also fit in this sampler. Hollow blank dies and Delrin inner shaft are recommended with this design. Stock sizes are 2ft with 5 ports, 3ft with 7 ports, 4ft with 8 ports, 5ft with 10 ports and 6ft with 12 ports.

**Model V (Patented):**

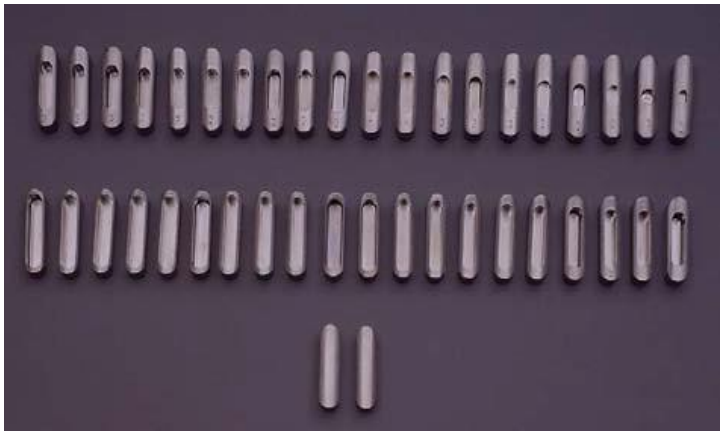


Standard triplicate sample design. Three unit-dose samples are obtained from exactly the same spot at each sample port. The bottom most port starts at 5.5" from the tip. Each sample port requires either three sample dies or three blank dies. Hollow blank dies and Delrin inner shaft are recommended with this design. Stock sizes are 3ft with 5 ports, 4ft with 7 ports, 5ft with 8 ports and 6ft with 10 ports. Consideration should be given to the location of the bottom most port in this model before placing an order.

**Standard Sample Dies:**

Standard sample dies and blank dies, made of 316 SS, are available in 40 different sizes from 0.1cc to 4.0cc in increments of 0.1cc to fit in Models I, I-A, IV, and V. Custom-made dies are available for other models. Custom-made Delrin or Teflon dies are also available.

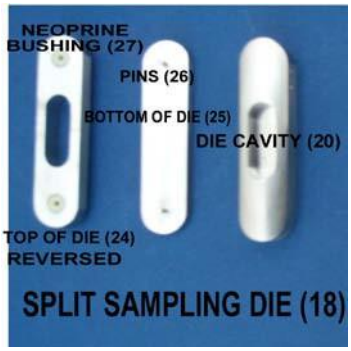
**Split Sample Dies**:



Split sample dies are used if the powder sample has to be compacted into a tablet in the die itself. Made of 316 SS, these dies are available in 30 different sizes from 0.1cc to 3.0cc in increments of 0.1cc. Please see under "New Unit-dose Sampling Technique" below for more details.

**Powder Sample Compaction Technique**

Samples are taken from powder blends to test for content uniformity before further processing, such as tableting or encapsulation. Integrity of the sampling technique is critical to ensure accuracy of the test results. Unit-dose sampling has been proven to improve the accuracy of the content uniformity results. However, there is still room for sampling error in unit-dose sampling if the samples are submitted to the laboratory in powder form. Combining unit-dose sampling with compaction of the powder sample into a real tablet in the sample die itself, reduces the error caused by handling of the loose powder samples. A manual tablet compaction machine is used for compaction of powder samples in the development and evaluation of solid dosage formulations. This technique is strongly recommended especially when you have a low dose directly compressible formulation. This technique requires GlobePharma's Unit-dose Samplers, Split Sample Dies (part number refers to the instructions in the manual) and Manual Tablet

Compaction Machine (MTCM-II or MTCM-I).

Each Split Sample Die is made of two 316 SS sections snapped together by hand to form the die. The upper section has a sampling cavity, and the lower section is blank. The split design allows ejection of the compacted tablet. These dies fit in Models I, I-A, IV and V, and cover a sample size range of 0.1cc to 3.0cc in increments of 0.1cc.

MTCM-II is used to compact the powder sample into a tablet in the sampling die by hydraulic pressure. A 3,000 lb capacity pressure gauge is provided. No electricity or compressed air is required. The machine is compact (8"D x 16"W x 16"H) and portable (30 lb) and works with standard tablet tooling. For customers' convenience, GlobePharma offers six standardized punch types and sizes, covering the full sample range from 0.1 cc to 3.0 cc. A table showing the sample size and corresponding punch type and size is given below:

| Sample Size, cc | Punch Type | Punch Size |
|---|---|---|
| 0.1 | IPT, B, Lower | 3/16" round |
| 0.2 | IPT, B, Lower | ¼" round |
| 0.3, 0.4, 0.5, and 0.6 | IPT, B, Lower | 3/8" round |
| 0.7, 0.8, 0.9, 1.0 and 1.1 | IPT, B, Lower | 9/32" x ¾" caplet |
| 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9 and 2.0 | IPT, DS3, Lower | 5/16" x 1.250" caplet |
| 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 and 3.0 | IPT, DS3, Lower | 3/8" x 1.500" caplet |

# Bulk Powder Samplers

Bulk powder samplers are available in different diameters with or without removable partitions. The removable partitions offer the advantage of providing separate top, middle, and bottom samples while making it easier to clean the sampler to GMP standards. These samplers are made of either 316 SS or FDA approved Nylon. The conical end piece is removable for ease of cleaning. Stock samplers are 3ft long with 3 sample ports. Custom-made samplers are available on special orders.

**Model VI:**

Standard bulk powder sampler. Made of 316 SS, 0.875" diameter, 3ft long with three 0.5625" W x 8.0" L non-partitioned (communicating) sample ports. Each port holds about 40cc sample. The end piece is removable for easy cleaning. Also, the top end of the inner tube has been modified to open in order to facilitate emptying of the powder sample directly into a bottle.

**Model VI-A (Patented):**

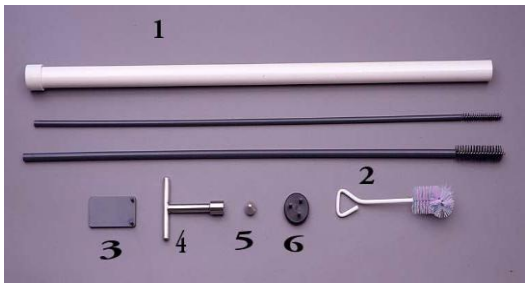
Just like Model VI, except that the ports are partitioned (non-communicating) with removable partitions. However, this sampler can also be used as a core composite sampler if the partitions are not used (communicating).

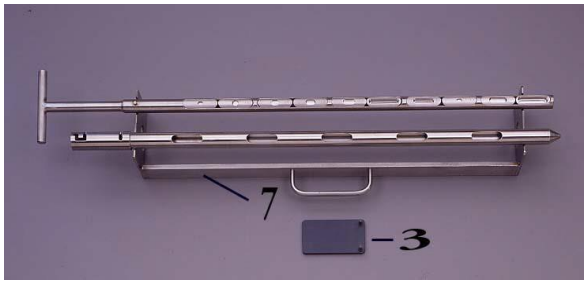
**Model VI-B (Patented):**

Standard bulk powder sampler. Made of 316 SS. 1.5" diameter. 3ft long sampler with three 1.125"W x 4.0"L sample ports are readily available. The sample ports are partitioned (non-communicating) with removable partitions. Each port holds about 90cc of powder sample. The same sampler may also be used as a core composite sampler if the partitions are not used (communicating).

**Sampling Accessories:**

1. **PVC Storage Tube**: Available in different lengths for storage of the samplers when not being used. These tubes protect the samplers from being damaged.
2. **Brush Kit**: Two Nylon brushes with long PVC handles to clean the outer and the inner tubes of the samplers.
3. **Die Retrieval Tool**: Made of PVC, this tool is required to be able to retrieve the dies from the sampler.
4. **Loose Handle**: Made of 316 SS, it is required with any segmented design sampler to be able to use the lower segment as an independent sampler.
5. **Conical End Piece**: Spare end piece for samplers. Available for all relevant models.
6. **Capsule Ejection Tool for Stream Sampler (Model V-A):** Made of PVC, this tool is required to push the capsules up from the cavities in the sample collecting disc.
7. **Stand:** Made of PVC, available in 10", 22" and 42" lengths. The stand holds the outer tube and inner tube separately. It is a required item with the improved design of the sampler to be able to retrieve the dies from the sampler.



# Liquid Samplers

**Model VIII: Sampler with a Sterile Disposable Syringe (Patented)**

This sampler is available for use with 5cc and 60cc sterile disposable syringes. The top of the sampler has exactly the same scale as the syringe so that unit-dose samples or bulk samples may be taken. 60cc syringe comes with a catheter tip (5mm ID bore) to facilitate sampling of suspensions and semi-solids. The body of the syringe is completely enclosed, and only the tip is exposed to the material. The sampler is all made of 316 stainless steel, sterilizable, easily cleanable, and is ideal for sampling from drums, tanks, mixers, reactors, etc. 2ft, 4ft, and 6ft long samplers are readily available. Other sizes are custom-made. Custom-made segmented samplers are available for sampling from very large tanks.

**Model IX: Sampler with a Single Cup:**

Model IX is a custom-made and it takes one sample into a glass or plastic bottle. The bottle is enclosed in a stainless-steel cup and does not get wet outside. Different size bottles may be used by simply changing the adapter that holds the bottle inside the cup. The sealing plug is made of Teflon or Delrin (FDA approved white plastics) and is removable for easy cleaning. The rest of the sampler is made of 316 stainless steel. Three different sizes of cups, as described under Model VII above, are available. Custom-made segmented samplers are available for sampling from very large tanks. Ideal for bulk sampling (20cc and up) from drums, tanks, mixers, reactors, etc.

**Model XI - Stainless steel Pipette Type Liquid/Semi-solid Sampler:**

Model XI-B Liquid Sampler, 48" long, 1.0" OD, made of 316L stainless steel with RA 10 finish (mirror finish) on the inside, electropolished, and passivated as per ASTM A-967 standards. This sampler comes with one 316 SS interchangeable tip with a bore size of 0.5mm to 12mm (customer to specify bore size). The top end of the sampler has a removable Delrin (FDA approved white plastic) sleeve which seals against the stainless-steel tube and accommodates the 140mL syringe. One syringe with FDA/USP VI PVC tube piece (to provide proper seal) fitted on the tip of the syringe is supplied with the sampler. This sampler meets GMP standards and is easily and thoroughly cleanable. 2ft, 4ft and 6ft lengths are standard stock items. Longer samplers are custom-made with longer lead times.

Optional interchangeable tips made of 316 SS, with orifice sizes of 0.5, 1, 2, 3, 4, 5, 6, 8, 10, and 12 mm are available.

# Remote Swabbing & Microbiological Sampling Tools

Made of anodized aluminum (for light weight), standard tool extendible up to 10 ft with optional extensions to 25 ft, to take swab or microbiological samples from distant locations such as surfaces of large mixers, blenders, dryers, reactors, etc. without someone getting inside of the equipment. At the tip of this tool there is an anodized aluminum adjustable angle adapter which can be bent up to 90° to gain access to the location to be swabbed. Five different types of clips may be attached to the tip of the adjustable angle adapter to hold a swab (with or without a handle), a wipe, a microbiological sampling plate (agar plate) or a swab from a microbiological sampling tube (Swube). This tool can be completely dismantled and reassembled in a few minutes and is sterilizable. The plastic collars inside the tool segments can be sanitized with alcohol. An optional mirror attachment with sizes of plastic mirrors (3" x 3" and 6" x 6") and a flashlight attachment are also available.

**Teflon Template Tool**

It is just like the tool described above except that a Teflon template holder with a Teflon template having an opening of desired dimensions is attached to it and is used in conjunction with the swabbing tool for swabbing a pre-determined surface area.
Teflon templates are available with custom-made sizes, shapes, and surface area.

## Accessories

**Suction Cups –** are required to be used in conjunction with the swabbing tool for microbiological sampling with agar plates. 2" in diameter and individually packaged, two different types are available:

(Rodak plates are not sold by GlobePharma)

- Made of PVC, cannot be steam sterilized, may be sanitized with alcohol, and disposable.
- Made of silicone and can be steam sterilized and reusable.

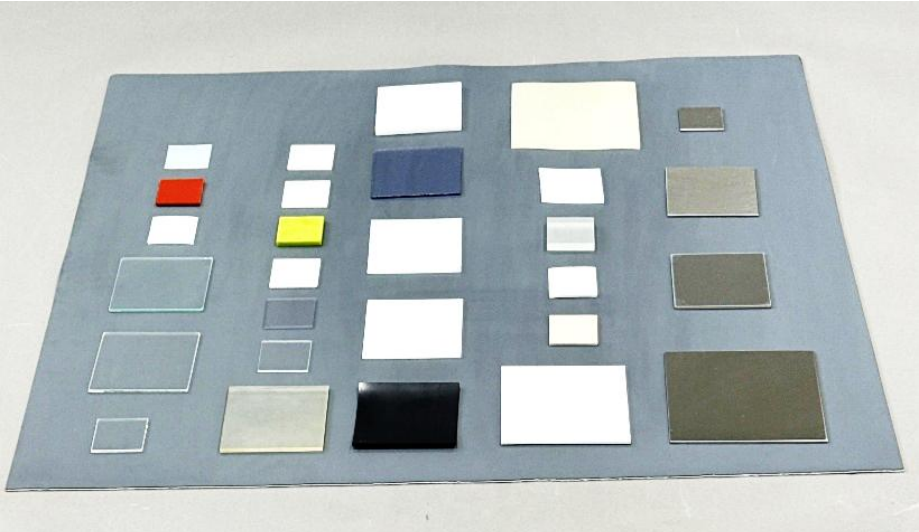
**Clips** – Five different types of clips are available:

- Made of 316 stainless steel and electropolished for microbiological sampling using agar plates. Steam, dry heat, ETO, and gamma radiation sterilizable.
- Made of 316 stainless steel and electropolished for swab sampling using swabs with or without handles, filter paper, or wipes. Especially suitable for Texwipe Alpha Swabs TX761 and TX714A (available from VWR Scientific). Steam, dry heat, ETO and gamma radiation sterilizable.
- Made of FDA approved white plastic, for same application as described in (b) above. May be sanitized with alcohol, but not sterilizable. Designed to avoid scratching the surface being swabbed.
- Made of an FDA approved amber colored special plastic, for microbiological sampling using swabs from microbiological tubes (Swubes). Steam, dry heat, ETO, and gamma radiation are sterilizable.
- Made of 316 stainless steel, for microbiological sampling using Culture Swab from DIFCO Laboratories.

## Cleaning Validation Coupons

Cleaning validation coupons are precision cut pieces of different materials and different finishes to specified dimensions, cleaned and passivated (if stainless steel) and packaged. These coupons are used in a laboratory to validate a swabbing technique on a matching surface of the production equipment. The swabbing technique must be validated to make sure the target residue is recovered from the surface to an acceptable level before swabbing of the actual production equipment surface is carried out.

GlobePharma offers cleaning validation coupons of many different materials, with different finishes with some metals, in different dimensions.



# DYNASEG™

## Dynamic Powder Segregation Tester

An innovative apparatus, "**DYNASEG**™ (Patent Pending), and method for segregation testing of powder blends are introduced by GlobePharma after 30 years of research and five prototypes, enabling determination of segregation potential under stressed dynamic conditions. It empowers pharmaceutical formulation scientists to evaluate, during the formulation development stage, which powder blend formulations are most resistant to segregation during large-scale manufacturing. By identifying robust formulations at the formulation development stage, manufacturers can mitigate content uniformity failures and align with the "Quality by Design" (QbD) principles for consistent, cGMP compliant production.


A small sample (30 cc) of the powder blend is introduced into a stainless tube having a series of baffles. The powder flows with gravity over the baffles and collects onto a split sample die with 30 unit-dose cavities. The powder on the split die is scraped even with a spatula and the individual powder samples in the cavities are compressed into tablets individually with a standard tablet punch or simultaneously with a multiple punch, the top part of the split die with the tablets is separated and the tablets are ejected using the same punch. The tablets are then analyzed for active ingredients using standard analytical techniques, and content uniformity is calculated.

Vibration may be added as an additional stress factor while the powder is flowing over the baffles to evaluate how resistant the blend is to segregation under stressed conditions. This is akin to stability testing of pharmaceuticals under accelerated conditions, providing a QbD approach for blend optimization.

# SIFT-N-BLEND® TECHNOLOGY

## Simultaneous Sifting & Blending in a Closed Environment

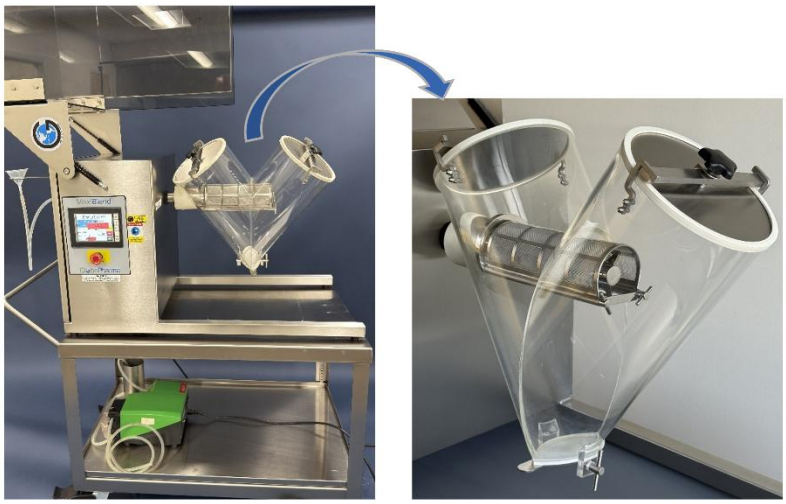
GlobePharma's Patented (US 8,235,582; US 8,827,545; CA 2736942C; CA 2821188C & EP2703072B1) **SIFT-N-BLEND®** technology facilitates simultaneous sifting and blending of the powders in the blending vessel itself, eliminating the need for separate sifting of the ingredients, such as silicon dioxide, and provides excellent content uniformity of pharmaceuticals, especially low dose ones, nutraceuticals, cosmeceuticals and beverage pre-mixes. In addition, the blends prepared using **SIFT-N-BLEND®** are dynamically stable, as tested by GlobePharma's newly developed dynamic powder segregation tester (**DYNASEG®**), thus mitigating the possibility of segregation on production-scale machines. Dynamically stabile blend is achieved by repeatedly passing the blend through a screen while simultaneously blending. As compared to the traditional intensifier bars, **SIFT-N-BLEND®** is much lighter and easy to install, clean, and maintain. Interchangeable screens with different mesh sizes are available. Segmented design for the screen and the paddle, offered for large scale tumble blenders, helps make installation, cleaning and maintenance easier. **SIFT-N-BLEND®** would also achieve homogeneous blending of food and cosmetic ingredients such as colors, flavors, sweeteners, etc., and in any other field where powders are blended.

**SIFT-N-BLEND®** technology facilitates simultaneous sifting and blending in an enclosed environment, eliminating the need for separate sifting of ingredients, thus saving time and money, prevents exposure of operators to dust and provides a highly homogeneous blend (if formulation is good), thus avoiding costly content uniformity problems in manufacturing.

Combined with GlobePharma's DYNASEG™ Dynamic Powder Segregation Tester, it helps optimize solid dosage formulations at the R&D development stage itself.

Existing tumbling blenders (v-blenders, double-cones and bin blenders) may also be retro-fitted with **SIFT-N-BLEND®** attachment, as long as these blenders have an intensifier bar drive already on the machine.

## DESCRIPTION



**SIFT-N-BLEND®** attachment mounted in a 16 qt acrylic V-shell

The **SIFT-N-BLEND®** attachment replaces the traditional intensifier bars, which are very heavy, especially on commercial scale blenders, requiring multiple operators to install and dismantle. It consists of a semi-tubular screen, either made of wire mesh or a perforated stainless-steel sheet, a pair of mounting rods, and a paddle. This assembly is mounted on the trunnion hub inside the blending vessel such that the screen turns at the same speed as the shell (25 rpm on lab blender) while the paddle is operated by a separate drive and turns independently at a variable speed of up to 2500 rpm and, as it turns, some powder enters the screen, and the paddle inside the screen pushes the powder through the screen breaking any lumps in the powder. The powder goes through screening multiple times, helping eliminate the need for pre-screening of the powder ingredients, and homogeneous blending is achieved.