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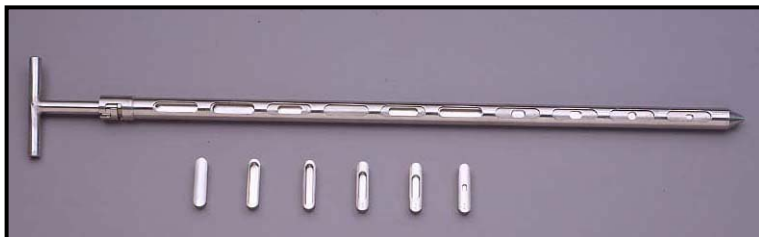
POWDER SAMPLERS

UNIT-DOSE POWDER SAMPLERS (PATENTED):

These 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.

Another unit-dose powder sampling technique, involving compaction of the powder sample in the sampling die itself, is described separately under "New Unit-Dose Powder Sampling Technique."

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:

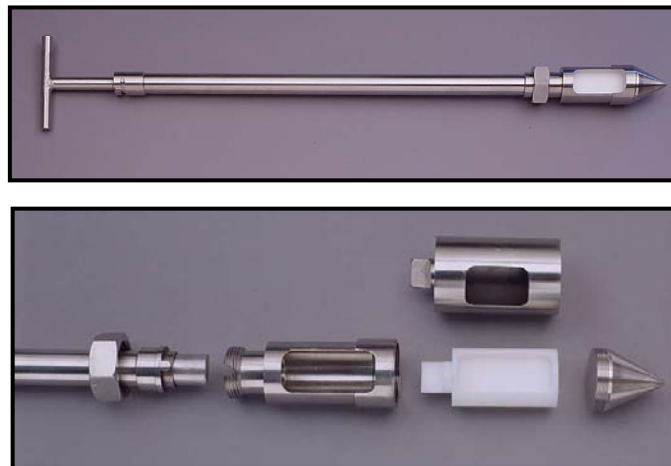
Custom-made single-sample design to accommodate dies up to 40cc in volume. 1.5" in diameter. One sample is obtained at each sample port. The bottom most port starts at 1.5" from the tip. Dies may be made of Delrin or 316 stainless steel, to accommodate up to 40cc with a 4" long die. More sample size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

Model III:



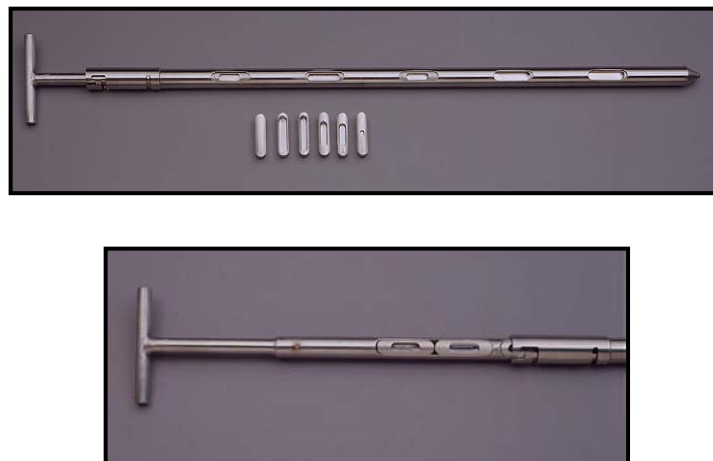
Custom-made single-sample design to accommodate dies up to 200cc in volume. 2.0" in diameter. One sample is obtained at each sample port. The bottom most port starts at 4.0" from the tip. Dies may be made of Delrin or 316 stainless steel. Consideration should be given to the ease or difficulty of inserting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

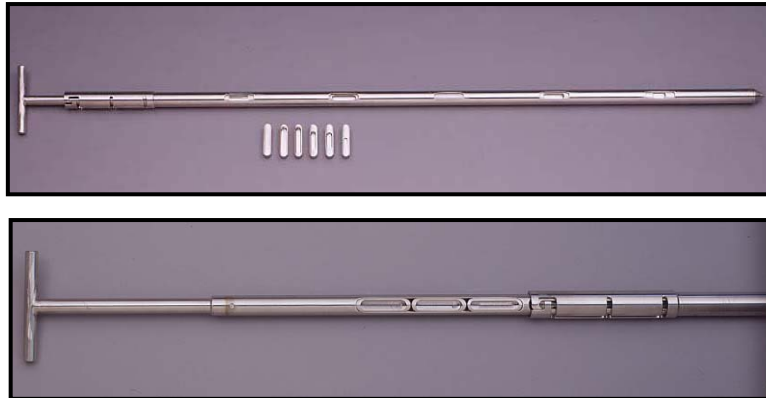
Model IV (Patented):



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

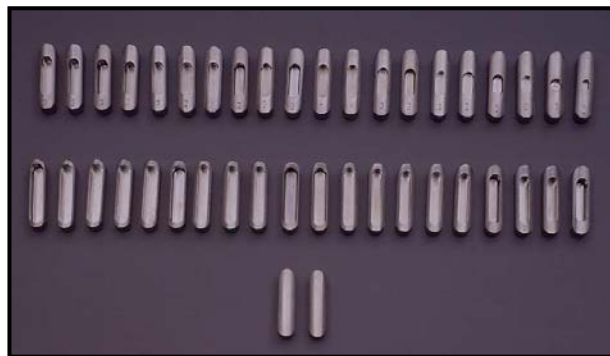
sample port requires either two sample dies or two blank dies. Same dies, which fit in Model I sampler also fit in this sampler. Hollow blank dies and Delrin inner shaft are recommended with this design. Stock sizes are 2ft with 5 ports, 3ft with 7 ports, 4ft with 8 ports, 5ft with 10 ports and 6ft with 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:

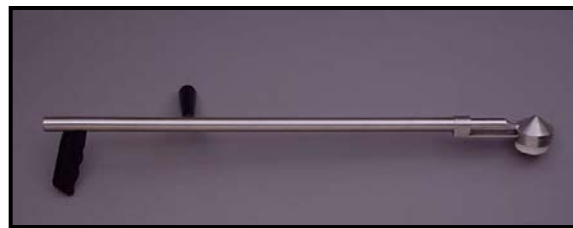
Split sample dies are used if the powder sample has to be compacted into a tablet in the die itself. Made of 316 SS, these dies are available in 30 different sizes from 0.1cc to 3.0cc in increments of 0.1cc. Please see under “New Unit-dose Sampling Technique” below for more details.

Model XVI – Vertical Sampling Compaction Sampler (Patent Pending):



Custom-made Model XVI Vertical Sampling Compaction Sampler, made of 316 Stainless Steel, 1.5" in diameter, accommodating dies from 0.1cc to 2.0cc (Model XVI-A) and from 0.1cc to 4.0cc (Model XVI-B). One sample is obtained vertically from the bottom of the sampler and the sample can then be compacted into a real tablet using GlobePharma's manual tablet compaction machine (MTCM-I or II), separate purchase of which is required.

Model V-A:



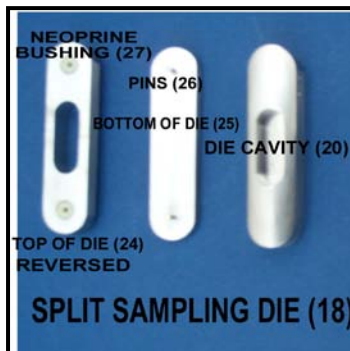
Custom-made stream sampler, 30" long, for unit-dose sampling, bulk sampling, or simultaneous unit-dose and bulk sampling while discharging the material. Up to ten unit-dose samples may be obtained at each sampling time point. Samples may be collected directly into empty gelatin capsules, thus eliminating the need to transfer the samples to vials. Or, the samples may be collected into cavities on the sample collecting disc, and then compacted into tablets using the manual tablet compression machine available from GlobePharma. The disc that holds the capsules and/or the sample bottle is made of 316 SS or Delrin, and is interchangeable with other discs for different size capsules/bottles. The disc that has the cavities for sample collection is made of tool steel and different discs are available for different size samples. Easy disassembling and cleaning.

NEW UNIT-DOSE POWDER SAMPLING TECHNIQUE (PATENTED):

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 in order 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. This New Unit-dose Powder Sampling Technique further reduces the sampling error by combining unit-dose sampling with compaction of the powder sample into a real tablet in the sample die itself. Compaction of the powder samples into tablets may reduce the sampling error because the samples are in compacted form and handling of the loose powder samples by the operator or the analyst is completely eliminated. Indeed, several major pharmaceutical companies have already successfully utilized this technique in situations where the blend samples were failing the content uniformity test while the tablets compressed from the same blends were passing the test. This technique is strongly recommended especially when you have a low dose directly compressible formulation. Why wait until you have a problem?

This technique requires GlobePharma's Unit-dose Samplers, Split Sample Dies and Manual Tablet Compaction Machine (MTCM-II or MTCM-I). Split sample dies and the manual tablet compaction machine are described below and the unit-dose samplers are discussed under "Unit-Dose Powder Samplers."

Split Sample Dies:



Each Split Sample Die is made of two 316 SS sections snapped together by hand to form the die. The upper section has the 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.

Manual Tablet Compaction Machine-II (MTCM-II):



This machine is used to compact the powder sample into a tablet in the sampling die itself 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. GlobePharma offers, for the sake of customers' convenience, six different types and sizes of standardized punches covering the entire sample size range of 0.1cc to 3.0cc. 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 | 1/4" 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 3/4" 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 be 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 is 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).

Model VI-C:



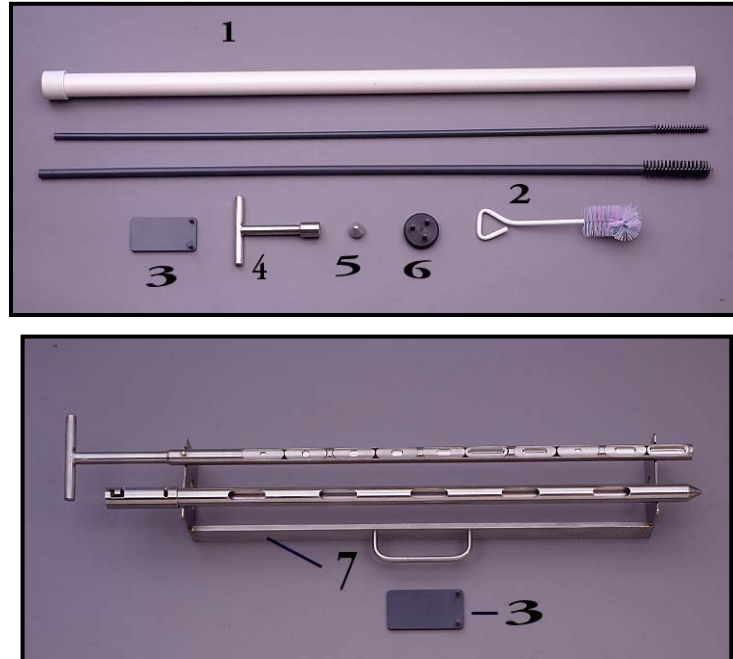
Standard bulk powder sampler. Made of FDA approved Nylon. 1.5" diameter. 3ft long sampler with three sample ports is standard. Ideal for raw material sampling. It can be used with or without dies.

Model VI-D:



Same as Model VI-B, except the diameter is 2.0" and each sample port accommodates about 180cc of powder.

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.