

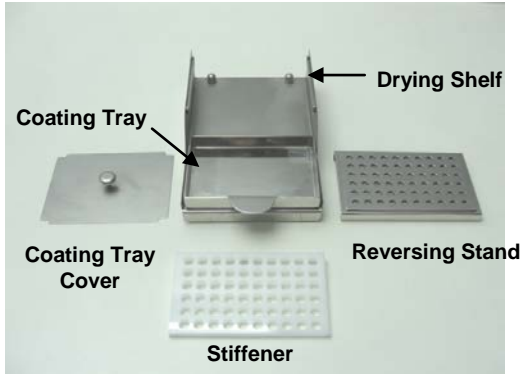


www.torpac.com/procoater

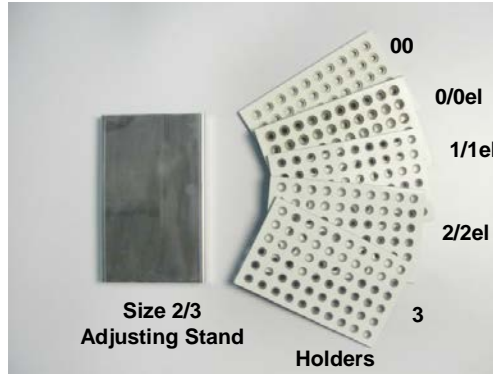
- ✓ Ideal for preparing small batches of enteric or film coated capsules in your laboratory
- ✓ Save time and money by eliminating set-up time for pan/spray coating
- ✓ Innovative dip apparatus for complete and uniform coating
- ✓ Used in hospitals and university pharmacies; clinical laboratories; drug development
- ✓ Works with solvent-based coatings as they dry quickly

Batch Size	Up to 60 capsules. Recommended batch size is 32 capsules.
Batch Time	About 60 minutes, including 50 minutes of drying time, for two coatings of capsule caps and body.
Coating Method	Dip using solvent based coatings.
Coating Solution	<ul style="list-style-type: none"> ▪ Contact Torpac for details of recipes ▪ You can use CAP from Eastman Chemical and Eudragit from Evonik (formerly Degussa, Huls or Rohm) ▪ Refer to the article Dodds, Ruth and Podczek, Fridrun "USING A SMALL-SCALE CAPSULE DIP COATER TO PRODUCE GASTRO-RESISTANT HARD CAPSULES". <i>Tablets & Capsules</i> Jan 2008. Purchase this article at http://www.tabletsandcapsules.com/Content/articleIndex.aspx. Enter Dodds in the search field.
Capsule Sizes	Holders sold individually for sizes 00, 0/0e1, 1/1e1, 2/2e1 & 3. Additional Size 2/3 Adjusting Stand required for sizes 2/2e1 and 3. For sizes 4 and 5, fill capsules and insert in a size 3 capsule that can be enteric coated.

Requires Capsule Holder for each Capsule Size. Sizes 2 and 3 also require a size 2/3 Adjusting Stand.



ProCoater Base Kit



Additional Items

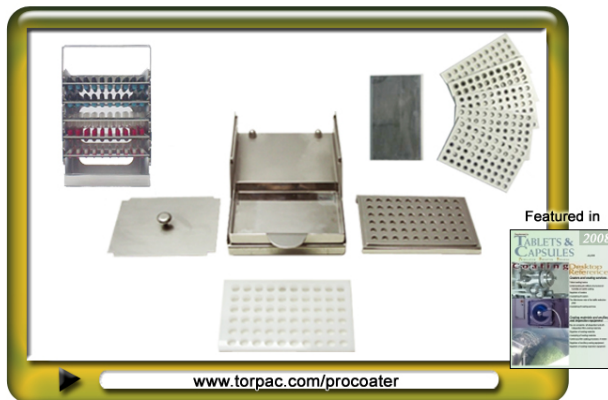


Drying Rack

Equipment Identification

Coating Stand	Contains drying shelf for Holder and place for Coating Tray.
Coating Tray	Pan with handle that holds coating solution.
Coating Tray Cover	Cover to minimize evaporation loss of coating solution.
Stiffener	White plastic sheet with 60 holes.
Reversing Stand	Used to reverse capsules after one-half of caplet/capsule is coated. For all sizes 00-3 & 0el -2el.
Size 2/3 Adjusting Stand	Used to further adjust size 2 and 3 capsules after reversing. Sold Separately.
Holder	Black & white plastic sheet with membrane and 60 holes. Holds capsules while dipping in solution. Sold individually by size.
Optional Drying Rack	Contains shelves for drying 5 Holders at a time (see page 6 for photo).

Video Instructions



Our online video labels steps corresponding to the step in this manual. Please visit www.torpac.com/procoater to watch the video as you follow the steps if you are new to the enteric coating process.

A) Add Coating Solution

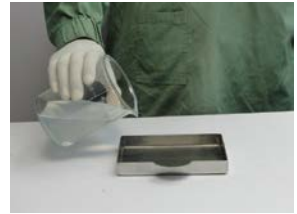
The amount of coating solution needed to fill Coating Tray is 180 ml to 200 ml.

Slowly pour the coating solution into the Coating Tray at corner as shown. This will help prevent bubble formation. Cover the tray. Replenish the solution as necessary, typically after every batch coatings of 32 capsules.

Tips

- 1: Use the ProCoater at chest height for easier viewing of capsules during coating (see photo).
- 2: The Coater works best with solvent-based coatings as they dry quickly.
- 3: The stainless steel tray is non-reactive with Acetone, Ethanol, Isopropyl alcohol and water.
- 4: Always coat the capsule body first to avoid bubbles near the capsule joint.

Contact information for two of the primary suppliers of enteric coating polymers is available on page 6.



B) Load filled capsules into Holder

Load the capsules as shown below. In this example, the capsule cap is green (darker color) and the capsule body is yellow (lighter color).



B1. Set up Stiffener:



- Place Stiffener on Standard Reversing Stand.

B2. Set up Holder:



- Place proper size Holder on Stiffener.
- Line up holes of Reversing Stand, Stiffener and Holder.

Tip: For best results use only 4X8 inner grid to coat just 32 capsules at a time.

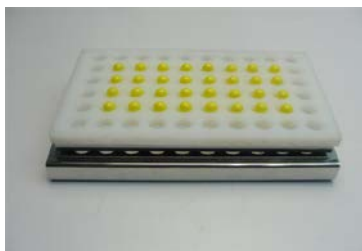
B3. Ready capsules for coating bodies:



- Insert capsules into Holder with cap up and body down.
- Press capsules down until body touches Reversing Stand.
- For sizes 00-1, follow steps B4-B6.
- For sizes 2 & 3, follow steps B4a-B6a.

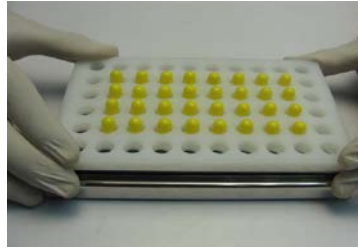
Sizes 00-1 Steps B4-B6

B4. Turn Over Holder:



- Turn over Holder with Stiffener onto Standard Reversing Stand so bodies face up.

B5. Press down Stiffener:



- Press down Stiffener.
- Remove Stiffener.

B6. Ready bodies for Coating:



- Hold the Holder at corners and turn over so bodies face down.
- Continue with Step C1 to coat bodies.

Sizes 2/3 Steps B4 - B6

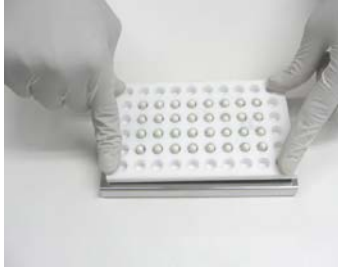
B4a. Turn over Holder:



- Turn over Holder with Stiffener onto 2/3 Adjusting Stand so bodies face up.

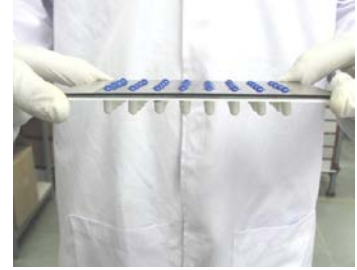
Note: Blue and white capsules are used in size 2 & 3 instructions.

B5a. Press Down Stiffener:



- Press down Stiffener.
- Remove Stiffener.

B6a. Ready bodies for Coating:



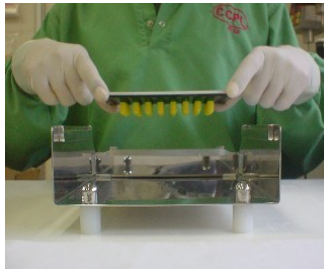
- Hold the Holder at corners and turn over so bodies face down.
- Bodies are now ready for coating.
- Continue with Step C1.

C) Coat Capsule Bodies

Dip entire capsule body plus a portion of capsule cap. Black line indicates length to be dipped in coating solution.

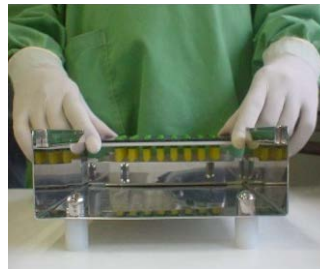


C1. Coat bodies:



- Remove Coating Tray Cover.
- Hold the Holder at corners with capsule body facing down.
- Dip capsule body plus a portion of capsule cap into solution (up to black line shown above).
- Perform dipping and withdrawal operation in a steady motion. *(Dipping and withdrawal time is a total of 25-30 seconds depending on viscosity).*

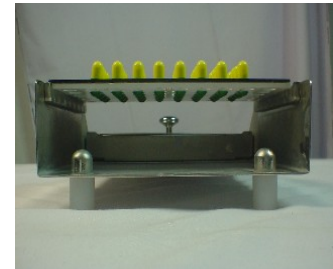
C2. Withdraw and Rotate:



- Withdraw Holder from Coating Tray **to the extent that body end just touches surface of solution.**
- Wait for 5 seconds or until the **excess solution drips down from body end.**
- Lift Holder up and turn over.
- To ensure uniformity of coating and to accelerate the drying process, **slowly tilt and rotate Holder with capsules in all directions for about 35-45 seconds.** Avoid repeated rotation in one direction.

Alert: High viscosity (more than 310 cps.) solution promotes a thick coating or drop formation at the tip of the capsule cap or body. Rotate Holder to prevent this.

C3. Dry:



- Turn over Holder so coated capsule bodies face up.
- Place Holder on Drying Shelf of Coating Stand. Capsules dry in about 25 minutes.
- Cover Coating Tray to minimize solvent evaporation.



See Online video for Step C1-C3 at www.torpac.com/procoater

D) Reverse Capsules

The Reversing Stand is used to initially set up the capsules, and to reverse the position of capsules for coating i.e. to change from coating the body to coating the cap.

Standard Reversing stand is common for all sizes 00 to 3. Coating sizes 2 and 3 requires an Adjusting Stand also.

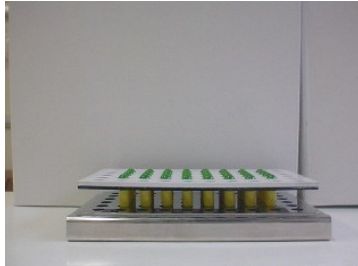


Reversing Stand
(size 00-3)



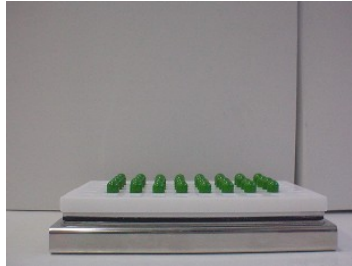
Size 2/3 Adjusting Stand
(size 2-3)

D1. Prepare capsules for reversing:



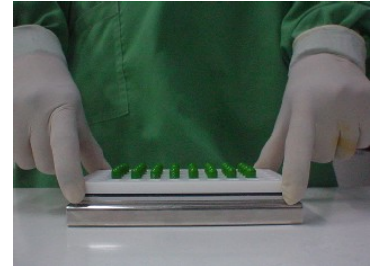
- After drying, place Holder on standard Reversing Stand with caps facing up.

D2. Position and press down Stiffener:



- Put Stiffener on Holder.
- Line up holes of Reversing Stand, Holder, and Stiffener.
- Press down Stiffener.

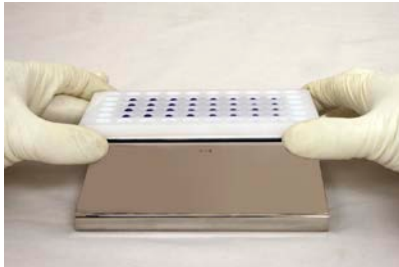
D3. Ready caps for coating:



- Remove Stiffener.
- For sizes 00-1, capsule caps are ready for coating. Skip to step E1.
- For sizes 2 & 3, follow steps D4-D6.

Sizes 2/3 Only

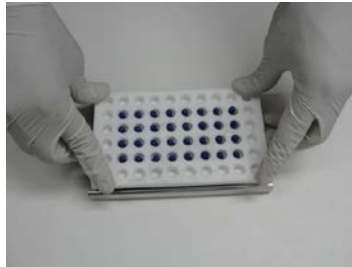
D4. Place on 2/3 Adjusting Stand:



- Place Holder on 2/3 Adjusting Stand with caps facing up.

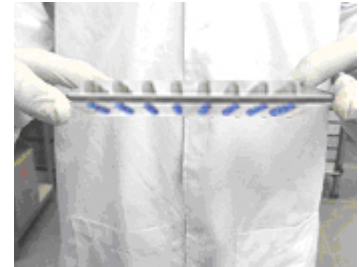
Note: Blue and white capsules are used in size 2 & 3 instructions.

D5. Position and Press down Stiffener:



- Put Stiffener on Holder.
- Line up holes of Reversing Stand, Holder and Stiffener.
- Press down Stiffener.

D6. Ready caps for coating:



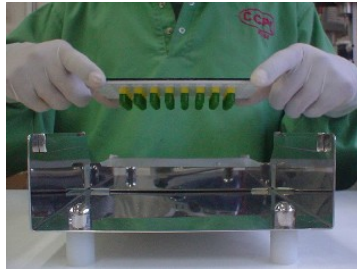
- Remove Stiffener.
- Hold the Holder at corners and turn over so that caps face down.
- Continue with Step E1 to coat caps.

E) Coat Capsule Caps

Dip the entire capsule cap plus a portion of the capsule body. Black line indicates the length to be dipped in coating solution.



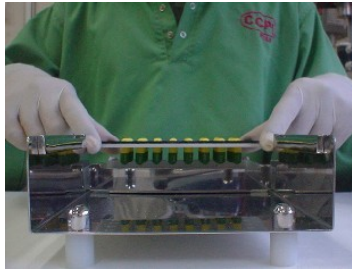
E1. Coat Caps:



- Remove Coating Tray Cover.
- Hold the Holder at corners with capsule cap facing down.
- Dip the capsule cap plus a portion of the capsule body into the solution (up to black line shown above.)
- Perform dipping and withdrawal operation in a steady motion.

(Dipping and withdrawal time is a total of 25-30 seconds depending on viscosity).

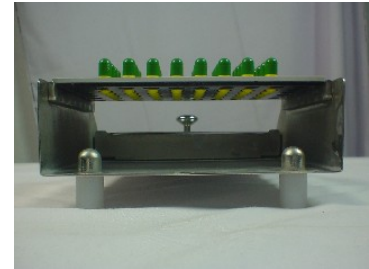
E2. Withdraw and Rotate:



- Withdraw Holder from Coating Tray, **to the extent that cap end just touches surface of solution.**
- Wait for 5 seconds or until the **excess solution drips down from cap end.**
- Lift Holder up and turn over.
- To ensure uniformity of coating and to accelerate the drying process, **slowly tilt and rotate Holder with capsules in all directions for about 35-45 seconds.** Avoid repeated rotation in one direction.

Alert: High viscosity (more than 310 cps.) of solution promotes a thick coating at tip of capsule cap or body. Rotate Holder to prevent this.

E3. Dry:



- Turn over Holder so coated capsule caps face up.
- Place Holder on Drying Shelf of Coating Stand. Capsules dry in about 25 minutes.
- Cover Coating Tray to minimize solvent evaporation.



Single coated gelatin capsules

F) Second Coat Caps and Bodies

Double coating is required unless the coating formula used has been validated for single coating. If double coating is necessary, second coat the capsule caps, reverse the capsules, then second coat the capsule bodies. Follow steps beginning on page 3, section C. **Note that capsule caps and bodies are now switched around.**

Cleaning Instructions

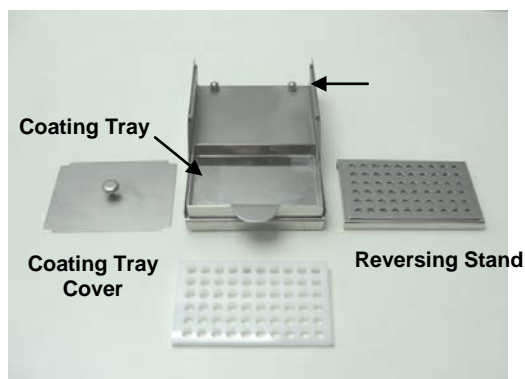
For easy cleanup, DO NOT ALLOW COATING SOLUTION TO HARDEN on parts.

Follow these cleaning procedures when working with the following materials:

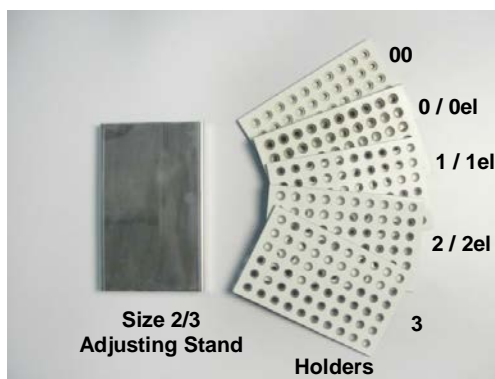
Standard coating polymers: Eudragit L100, L100-55, S100 & CAP (Cellulose Acetate Phthalate)
Standard plasticizers: Propylene Glycol, Triethyl Citrate, Di-n-Butyl phthalate

Soak parts in warm water (30-36° C or 86-97° F) for 5 to 10 minutes, then clean using a nylon brush under running tap water at preferably 30-36° C (86-97 ° F).

If coating solution has hardened on the parts and the instructions above do not work, soak parts in a solution of 10% sodium bicarbonate and warm water (30-36° C or 86-97° F) for 10 to 15 minutes. Rinse under warm water. Repeat if necessary.



ProCoater Base Kit ¹



Additional Items



Drying Rack

Item Codes	
ProCoater Base Kit ¹	MP Ctr Base
Size 00 Holder	MP Ctr Hldr 00
Size 0/0el Holder	MP Ctr Hldr 0
Size 1/1el Holder	MP Ctr Hldr 1
Size 2/2el Holder ²	MP Ctr Hldr 2
Size 3 Holder ²	MP Ctr Hldr 3
Size 2/3 Adjusting Stand	MP Ctr Stand 2-3
Drying Rack	MP Ctr Rack
★ ProCoater Combo ³	MP Ctr Combo

¹ Requires one or more Holders for use.

² Requires Size 2/3 Adjusting Stand.

³ Includes ProCoater Base Kit, Size 2/3 Adjusting Stand and 1 holder for each size 00-3.

Chemical Suppliers



For information on **Eudragit line of coatings from Evonik** (formerly Degussa, Huls, Rohm).

<http://www.evonik.com/>



For information on **Cellulose Acetate Pthalate, "C-A-P"** from Eastman:

www.eastman.com

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Technical Support

Please contact your distributor or: www.profiller.com

E-mail: help@profiller.com

Emails are typically received and responded to within 24-48 hours.

ProFiller[®] 1100



Hand-held filler up to 2000-3200 capsules/hour. Sizes 000-5 and el, sizes.

ProFiller[®] 3600



Hand-held filler up to 4500-6900 capsules/hour. Sizes 000-4.

ProFiller[®] 3700



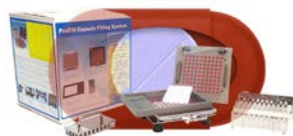
Bench-Top filler up to 7200-9000 capsules/hour. Sizes 000-5 and el, sizes.

ProFiller[®] 3800



Bench-Top filler with Semi-Automatic (European Style) Orienter. Same output as 3700. Sizes 00-4.

ProFill 100 OE



Hand-held filler for capsules sizes AAA-D.

ProFiller[®] 3700 OE



Bench-Top filler for capsules sizes AAA-D.

ProFunnel



Fast & accurate way to single fill capsules without spillage. Ideal for research studies

Rat & Mouse Dosing Kit



Kit includes: Dosing Syringe, Filling Funnel & Stand, tamper, 100 Capsules, and video CD.