

ProCoater Base Kit

Additional Items

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

ldeal 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	 Contact Torpac for details of recipes You can use CAP from Eastman Chemical and Eudragit from Evonik (formerly Degussa, Hulls or Rohm) Refer to the article Dodds, Ruth and Podczeck, Fridrun "USING A SMALL-SCALE CAPSULE DIP COATER TO PRODUCE GASTRO-RESISTANT HARD CAPSULES". <u>Tablets & Capsules</u> Jan 2008. Purchase this article at <u>http://www.tabletscapsules.com/Content/articleIndex.aspx</u>. Enter Dodds in the search field. 	
Capsule Sizes	Holders sold individually for sizes 00, 0, 1, 2 & 3. Additional Size 2/3 Adjusting Stand required for sizes 2 and 3. For sizes 4 and 5, fill capsules and insert in a size 3 capsule that can be enteric coated.	

	Equipment Identification
Coating Stand	Contains drying shelf for Holder and place for Coating Tray.
Coating Tray	Pan with handle that holds coating material.
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.
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.

ProCoater

Enteric / Film Coat Capsules & Caplets

Enteric coat for lower intestine & colon drug release. Film coat for taste masking or appearance.

A) 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.

- Tip 1: The Coater works best with solvent-based coatings as they dry quickly.
- Tip 2: The Stainless Steel Tray is non-reactive with acetone
- Tip 3: 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 7.

B) Loading 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).

1. Set up Stiffener:



Place the Stiffener on the Standard • Reversing Stand.

Place the Holder on 2/3 Adjusting

Stand with bodies facing up.

Note: Blue and white capsules are used



2. Set up Holder:

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

Tip: For the best results use only 4X8 inner grid, i.e. coat only 32 capsules at a time.





3. Ready capsules for coating bodies:



- Insert capsules into Holder with cap side up and body side down.
- Press capsules down until body touches Reversing Stand.
- For coating size 2 & 3 capsules follow steps 4 - 6.
- For other sizes, capsule bodies are ready for coating. Skip to step 7.

4. Prepare size 2 and 3 capsules:	5. Position and Press down Stiffener:	6. Ready size 2/3 bodies for coating:

- Put Stiffener on Holder.
- Move Stiffener over Holder so that capsules align into holes of Holder.
- Press down Stiffener.



- Remove Stiffener.
- Hold the Holder at corners and flip so that body side faces down.
- Bodies are now ready for coating.

in size 2 & 3 instructions.

C) Coating Capsule Body

ProCoater

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

7. Coating bodies:



- Remove Coating Tray Cover.
- Hold the Holder at corners with capsule body facing down.
- Dip the capsule body plus a portion of the capsule cap into the solution (up to black line shown above).
- Perform the dipping and withdrawal operation in a steady motion.
 (Dipping and withdrawal time is a total of 10-15 seconds depending on viscosity).

8. Withdrawal and Rotation:



- Withdraw the Holder from Coating Tray, to the extent that body end just touches meniscus of the solution.
- Wait for 5 seconds or until the excess solution drips down from the body end.
- Lift the Holder up and flip over.
- To ensure uniformity of coating and to accelerate the drying process, slowly tilt and rotate Holder with capsules in all directions for about 1 minute. Avoid repeated rotation in one direction.

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



9. Drying:

- Flip the Holder so that the coated capsule bodies face up.
- Place the Holder on the drying rack of Coating Stand. The capsules will dry in about 25 minutes.
- Cover the Coating Tray to minimize solvent evaporation.



D) Reversing Capsules/Caplets.

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.

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



Reversing Stand (size 00-3)

15.



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

10. Prepare capsules for reversing:



 After drying, place the Holder on the standard Reversing Stand with bodies facing down.



- Put Stiffener on Holder.
- Move Stiffener over Holder so that capsules align into holes of Holder.

Position and Press down Stiffener:

Press down Stiffener.

14.



- Remove the Stiffener.
- For coating size 2 & 3 capsules follow steps 13 – 15.
- For other sizes, capsule caps are ready for coating. Skip to step 16.

Ready size 2/3 caps for coating:

13. Prepare size 2 and 3 capsules:



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

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



- Put Stiffener on Holder.
- Move Stiffener over Holder so that capsules align into holes of Holder.
- Press down Stiffener.



- Remove Stiffener.
- Hold the Holder at corners and flip so that caps face down.
- Caps are now ready for coating.

E) Coating Capsule Cap

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

16. Coating 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 the dipping and withdrawal operation in a steady motion. (Dipping and withdrawal time is a total of 10-15 seconds depending on viscosity).

17. Withdrawal and Rotation



- Withdraw the Holder from Coating Tray, to the extent that cap end just touches meniscus of the solution.
- Wait for 5 seconds or until the excess solution drips down from the cap end.
- Lift the Holder up and flip over.
- To ensure uniformity of coating and to accelerate the drying process, slowly tilt and rotate Holder with capsules in all directions for about 1 minute. Avoid repeated rotation in one direction.

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

18. Drying



- Flip the Holder so that the coated capsule caps face up.
- Place the Holder on the drying rack of Coating Stand. The capsules will dry in about 25 minutes.
- Cover the Coating Tray to minimize solvent evaporation.



Single coated gelatin capsules

F) Double Coating

Double coating is required unless the coating formula used has been validated for single coating. If double coating is necessary, follow these steps to second coat capsule bodies and then capsule caps.

1. Prepare capsules for reversing:



 After drying, place the Holder on the standard Reversing Stand with caps facing down.



- Put Stiffener on Holder.
- Move Stiffener over Holder so that capsules align into holes of Holder.
- Press down Stiffener.



- Remove the Stiffener.
- For coating size 2 & 3 capsules continue with step 4 on page 2.
- For other sizes, capsule caps are ready for coating. Continue with step 7 on page 3.

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) Propylene Glycol, Triethyl Citrate, Di-n-Butyl phthalate Standard plasticizers:

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.

Item Codes		Price (US\$)
ProCoater Base Kit ¹	MP Ctr Base	\$ 475
00 Holder	MP Ctr Hldr 00	\$ 50
0 Holder	MP Ctr Hldr 0	\$ 50
1 Holder	MP Ctr Hldr 1	\$ 50
2 Holder ²	MP Ctr Hldr 2	\$ 50
3 Holder ²	MP Ctr Hldr 3	\$ 50
Size 2/3 Adjusting Stand	MP Ctr Stand 2-3	\$ 40
Drying Rack	MP Ctr Rack	\$ 95



¹ Requires one or more Holders for use

² Requires Size 2/3 Adjusting Stand

Drying Rack

Chemical Suppliers

Base Kit

Size 2/3 Adjusting Stand

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Holders

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

EASTMAN

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

www.eastman.com

for research studies

http://www.evonik.com/

Other Products from Torpac

