# Opalux®

*Opaque Aqueous Color Dispersion*



Opalux is an opaque aqueous color dispersion of FDA certified aluminum lakes and/or other permitted pigments, and titanium dioxide in sucrose syrup. Effective color coating of sub-coated tablet cores is achieved in up to 90 minutes.

Advantages of using Opalux include:

1. Elegant end-product
2. Improved light stability over comparative dye shades
3. Guaranteed batch-to-batch color reproducibility and precision color matching
4. Relatively easy operator training
5. Production economies
6. Non-frosting qualities

**Pre-coloring Tablet Preparation**

Opalux is designed to be a fast coloring process applicable to tablets previously subcoated to almost the desired weight and size. Using Opalux for tablet build-up or rounding-off is uneconomical; these functions are best served by grossing syrups.

The efficiency of Opalux and the end product elegance is first determined by sub-coating qualities. Here, the emphasis is on evenness. Prominent tablet high spots or irregularities will require more coloring applications than would otherwise be needed. It is important that the surface perimeter of the tablet be sub-coated evenly, although this factor is much less critical than in soluble dye coating. Surface smoothness, on the other hand, is less important -- in fact, a slight coarseness is helpful in providing a better foundation on which the color solids will adhere. Therefore, smoothing costs for the most part can be eliminated.

Whenever possible, coloring should be scheduled to immediately follow the conclusion of sub-coating. The tablets at this time should be warm and, thus, better conditioned for Opalux coloring. If the pan interior is not excessively abrasive, up to six color coats can be applied in the same pan used in sub-coating. As the pan side becomes less smooth, color is worn off -- and time requirement and color expense increase. Also, of course, pre-polishing tablet smoothness is best attained in a smooth pan.

If a delay is required before coloring, the subcoated tablets should be stored in an oven room at approximately 90-100°F., and transferred to coating pans only when ready for processing. If an oven area is unavailable, place the tablets in the coating pan and position a flow of warm air directly on the product for approximately 30-45 minutes, half-turning the pan every five minutes. Such pre-warming of tablets is a desirable condition whenever practical, but is not a prerequisite in Opalux coating.

Tablet coaters accustomed to dye techniques will question warm air procedures. In Opalux coating, however, the principal interest is to get as much color on the tablet as quickly and as evenly as possible--smoothing will come later. Mottled areas will cover with added applications, developing a completely uniform and consistent color. Warm or dry air, therefore, becomes an efficient tool in fast color coating. Particularly with dark color coating, tinting the final sub-coating applications with Opalux is recommended to give a "head start" in the coloring process with insignificant added costs.

**Syrup and Color Solution Preparation**

The most important coating variables to prejudge are (1) size, speed and style of coating equipment, (2) tablet size, shape and load weight, and (3) the temperature and relative humidity of the coating room.

The judgment of the coater should always be considered in solution preparation and subsequent usage. Experience will teach the coater the procedure adjustments that will be required to produce the maximum efficiency and quality. To begin, the uncolored coating syrup should contain approximately 71% sugar solids by weight. This is easily prepared by: (1) heating one U.S. gallon of water to boiling, (2) removing or reducing the heat, and (3) stirring in 20 pounds of sugar until completely dissolved. Proportion accordingly for quantities needed. For deep edged tablets, or those of difficult coating shapes, some coaters are using a 75% solids syrup (24 pounds to one U.S. gallon). For color application, not less than 69% (18 pounds) syrup should form the base solution for efficient Opalux usage.

An important consideration to remember is that faster coloring requires larger applications, and lighter weight syrups containing more water will take longer to dry and will "rewash" previously applied color from edges and high spots. In contrast,

heavier syrups will dry more quickly and produce faster and more uniform color coatings. All Opalux formulae physically differ within themselves, some rather markedly. Solids and dye contents of each formula may be quite unlike the next. Also, other additives and combination methods may be dissimilar. Each Opalux color is individually developed to incorporate the best combined features of opacity, color strength, adhesion (in coating to tablets) and stability.

Because of the limited number of FDA certified and non-restricted colors available for use, some color blends may be somewhat more efficient than others. Therefore, new users may discover ratio adjustments that they may make in preparing their coating solutions--color for color. Color solutions made with heavier syrup do tend to form surface crystals while standing at room temperature. It is suggested that the solution be contained in a steam-jacketed kettle regulated for the temperature needed to keep such crystal formation from becoming excessive. Caution should be observed not to use aged and re-boiled solutions, as the increased inversion of the syrup may impair drying or smoothing qualities in coating application. Opalux with a pH under six increases the inversion of sugar and suspensions should not be heated above 140°F. Opalux is stirred easily into stock coating syrups to form color coating solutions. For new users, a ratio of one part of color concentrate to eight parts of syrup (by volume, not weight) is suggested. This color strength will serve in giving experience and product confidence to the coating personnel. Individual wants can then be guided, either by continuing this set procedure or adopting a modified approach. Opalux users' ratios range from 1-6 to 1-12, color to syrup.

**Color Solution Application**

Color shade and coating efficiency may also vary in accord with the percentage solids content of stock syrup. Heavier syrups will deposit more sugar during color coat formation in proportion to insoluble color solids and would suggest a lighter color shade in the finished tablet. Such color shade differences are usually slight and of notice only to the most observing critic. An adopted set procedure will assure consistent duplication of color from batch-to-batch.

The initial objective is to get as much color on the tablets as quickly and evenly as conditions will permit. At this stage, mottle or smoothness is not a concern. The first color application in Opalux pan coating should be in very heavy quantity--as much as pre-coloring tablet preparation and other conditions will permit. Warm tablets will accept more color solution and thus, permit a heavier initial "shot." The continued flow of warm or dry air directly on the tablet load, especially while color solutions are being applied, is important. A typical first application to a 38" pear shaped pan load will be from 12 to 18 ounces. Continue drying until dusting is observed (5 to 8 minutes).

The second color shot usually is of less quantity, but still as large as practical under allowable conditions. It is necessary to now consider with each subsequent application the possibilities of previously applied color "rewashing" from edges and high spots, especially with a heavy gross weight product load. Air should not be directed to the pan surface--roughness will develop too quickly and/or excessive and costly color build-up to the pan side may occur. Allow the tablets to dry as after the first color application. Usually, all subsequent coloring will follow the pattern of the second application, up to "finishing off" preparatory to polishing. Opalux coloring develops very quickly. As the full color cycle is reached, care should be given to surface smoothness. If the tablets are slightly rough, airflow should be reduced in volume and/or temperature, but only after an application has been completely dispersed throughout the batch and tablets begin to tumble more freely.

Some Opalux colors (particularly maroons) dry faster than others and airflow should be carefully guarded to prevent uneven drying. When sufficiently smoothed, "finish-off" with three applications of uncolored syrup--just enough to barely wet the tablet surfaces. This procedure will allow further smoothing and will form a skin covering over the solid color particles, precluding their transfer to the polishing pan side. Airflow should be avoided except in areas of very high humidity. If desired, lighter weight uncolored syrups can be used to finish-off.

Exercise every caution against an excessive application. Opalux coatings are thin and more critically affected by reactivation of color. For this reason, the tablet load should not be permitted to panslip in finishing; if needed, use an airflow to regulate.

Opalux coloring (up through "finishing-off") usually requires from one to two hours and should be attended to by coating personnel. If there is a break in the coating schedule, pans should be stopped until work resumes. Guard against any unnecessary tablet and pan motion at all times after coloring begins.

**Opalux Application**

Place tablets in a clean coating pan and warm to approximately 90°F. Tablets should be sub-

coated, grossed and smoothed so that surface is free from bumps or pits and the tablet edges are rounded.

Prepare syrup by heating 1 gallon water to boiling, then stir in 20 pounds sugar. Turn off heat and stir until sugar dissolves and syrup is clear. Place 1 pint Opalux in clean mixing container and add 1 gallon syrup while stirring. Do not heat above 140°F.

With pan started and warm, tablets rolling, direct warm air (about 100-100 °F.) upon tablets. Apply a generous amount of Opalux-syrup mixture, so that tablets are thoroughly wet. Be sure to stir tablets thoroughly while rolling in pan. As soon as dusting occurs make the next application. Designate this first amount of Opalux-syrup as "A" then apply the Opalux-syrup as follows:

| Application | Amount Applied | Conditions |
|---|---|---|
| 1 | A | Hot Air – Vacuum Drying interval 5-7 min. |
| 2 | 2/3A | " |
| 3 | 2/3A | " |
| 4 | 1/2A | Reduce air volume to keep drying interval 5-7 min. " |
| 5 | 1/2A | |
| 6 | 1/2A | " |
| 7 | 1/2A | " |
| 8 | 1/2A | " |
| 9 | 1/3A | No air blowing on tablets Vacuum only |
| 10 | 1/3A | " |
| 11 | 1/3A | " |
| 12 | 1/3A | " |
| 13 | 1/3A | No air -- No Vacuum |
| 14 | 1/3A | " |
| 15 | 1/3A | " |

*(Dry interval between applications 5-7 minutes)*

Fifteen applications as above should result in uniformly colored and smooth tablets. Finishing of these tablets is accomplished as follows:

Apply clear (16 lbs. or 20 lbs.) syrup, just sufficient to wet tablets and roll tablets until dry. Repeat above two more times. On the third application, as soon as the tablets change in appearance from a "shiny wet" to a "dull" shade, stop the pan, cover the front and jog the pan for 1/2 hour. At the end of 1/2 hour of jogging, remove cover and jog for another 1/2 hour without cover. Remove tablets from pan, place on trays and racks and polish next day.

**Abridged Coating Procedure**

Step 1. Prior to color applications, the sub-coated tablets should be warmed in the pan by a flow of warm air or removed from a rack oven just prior to color coating applications. This procedure will permit Opalux to adhere more readily and evenly, and whenever practical, should be employed.

Step 2. The sugar syrup should be approximately 71% solids (20 pounds of sugar and 1 U.S. gallon of water). The heavier syrup tends to give better adhesion of the color to the tablets and in application tends to reactivate less of the applied color.

Step 3. Opalux is used by most operators at a ratio of one part of Opalux to eight parts of 71% solids sugar syrup by volume.

Step 4. Color applications should thoroughly wet the tablets. A typical charge may be 12 ounces of coating color suspension to a full 38" pan.

Step 5. A flow of warm, dry air throughout the entire coloring process is strongly recommended, especially while color is being applied. After full color is attained and if the tablets should not be properly smoothed, then the airflow may be moderated accordingly.

Step 6. "Finish-off" with three small applications of plain syrup for further smoothing and to preclude the transfer of the solid color particles to the side of the polishing pan. After the third application has thoroughly covered tablets, cover pan opening and jog as usual until tablets are dry. Transfer to polishing pan, apply wax solution and polish as usual.

No more than three or four finishing applications of plain syrup should be attempted; otherwise, the skin thickness may increase to sufficient solids-free depth that the "frost" preventing qualities of Opalux are lost. For the same reason, soluble dyes should not be used in color shading an Opalux color base.

The last finishing shot of plain syrup should be thoroughly dispersed throughout the tablet batch, and when free of tackiness, stop the pan and cover immediately. Quarter-jog every two minutes for ten minutes and every five minutes thereafter for one-half hour, or as otherwise is required to prevent surface fusion of the moist tablets. Remove the pan cover.

If early polishing is then desired, direct a flow of cool air (or half-flow of warm air) upon the tablet batch and half-jog the pan every ten minutes for one hour (the dark colors for one and one-half hours). The tablets are now ready for polishing, Opalux guards against moisture "frosting."

In Opalux coating, there are inefficient practices to guard against:

1. *EXCESSIVE COLOR DUSTING:* This is the most common mispractice, and is identified by color dust surrounding the pan area not equipped with exhaust ducts, or chipping during polishing or future transportation; it is usually caused by overdrying between applications. Opalux coatings dry faster due to the increased solids content.

2. Excessive dusting may also result from a rough pan interior, where an abrasive action occurs. In the end analysis, it is cheaper in time and materials to continue coloring in a smooth pan.

3. If excessive dusting is prematurely evident within two to four minutes after a color application (pan size, load and other conditions determined) then the airflow quantity or temperature should be reduced. Warm air is an effective aid in Opalux coating, but be cautioned against drying too quickly and unevenly--the coating may fracture off and uniform color formation may be impaired.

4. *IMPROPER FINISHING:* The thin Opalux color coat can be ruined by over application of plain syrup, whereupon the tablet load pan-slides or color is otherwise "washed" or worn off. Excessive or hard turning of the pan during the critical "sweating-out" period may also cause an abrasion of color from tablet surfaces. These inefficiencies result in a mottled or spotted product.

Coating inefficiencies are sometimes created by faulty equipment installations which may result in coating pans that rotate too slowly, or at excessive speeds. For instance, a filled 38" or 42" pear shaped pan turning at 25 RPMs or less invites mottled coloring and excessive time and color costs--particularly if the tablets have high spots, defined edges or are capsule shaped. The slower movement and gross tablet weight may force considerable reactivation of previously applied color before there is sufficient drying exposure, and uniform coloring may not be obtained. This inefficiency is, of course, further extended as the pan surface becomes more abrasive.

There may be debate that a more heavy syrup, additional air use and/or pan baffles will correct the above conditions. Two "wrongs" can become one "right," however, chances for error are more probable. Setting the pan speed at 28 or 30 RPMs will present fewer problems.

Angulated ("Hex") pans, or smaller tablet loads, will provide faster tablet rotation in proportionate pan revolutions and, therefore, slower speeds are suitable--26 to 28 RPMs.

Finer elegance and more production economy can be realized by proper selection of colors for appropriate tablet shapes. Whatever the color or source of preparation (dyes or Opalux), some colors are more efficient than others for tablet coating. For example, dark green or maroon is usually less efficient than pink, yellow or cherry red and, therefore, should influence judgment when a heavy ingredient and difficult tablet shape is presented for color specifications. If a difficult color should be required, users will appreciate even more the time savings, color consistency and frost resisting advantages of Opalux over dyes.

Opalux coatings are recognized as offering considerably more resistance to light fading than comparative dye shades. Light pastel shades, however, will tend to fade and, if selected, the end product should be packaged in light-protective containers. Since Opalux is an opaque coloring process, pastel colors will not necessarily shorten coating time requirements and, therefore, should not be the sole basis of selection.

A deep concavity of the tablet punch is very helpful in reducing time in subcoating and coloring, as the shallow edges are more readily evened-over. When compared to standard punch, many hours of precoloring tablet preparation are eliminated. For the most elegant product at lower cost, the deep concave punch is a valuable investment, regardless of color selection.



For more information, contact your Colorcon representative or call:

North America **+1-215-699-7733**

Europe/Middle East/Africa **+44 (0)-1322-293000**

**Latin America** **+54-11-5556-7700**

**India** **+91-832-6727373**

**China** **+86-21-61982300**

You can also visit our website at **www.colorcon.com**



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