our company

DEVELOPMENT

INGREDIENTS

EDUCATION

SCIENTIFIC AFFAIRS

IMTech

THE SCIENCE CENTER
Innovative Material Technologies

• Value-added excipients

• Full technical support

• Our goal: to solve unique challenges

• Ingredients developed by formulation scientists for formulation scientists
Innovative Materials

• **MarCoat™ 125** – aqueous shellac solution for nutritional industry
  – Taste masking
  – Moisture barrier

• **MarCoat™ EC** – aqueous shellac-based, natural enteric coating solution for nutritional industry
  – pH dependent enteric release
  – Moisture barrier
  – Excellent for soft gelatin capsules

• **PlasACRYL® T20** – anti-adherent coating system additive
  – Stable GMS emulsion
  – Developed for EUDRAGIT® L30D55
  – May be used with most aqueous systems
  – Pan and Wurster coating
EUDRAGIT® Systems Using PlasACRYL™ T20

- Overview
- Need for anti-adherent
- Talc vs GMS
- Benefits of PlasACRYL® T20
- Case Studies
PlasACRYL® T20 Product Overview

- Manufactured by Emerson Resources in the USA, distributed exclusively by Evonik globally.
- Evonik provides technical support through their global laboratory network.
- A 20% emulsion of anti-tacking agent and plasticizer to ease the preparation of a robust spray suspension.
- Contains mono and di-glycerides (GMS) as an anti-tacking agent and triethyl citrate as a plasticizer.

PlasACRYL®

T = Tri Ethyl Citrate (TEC)
20 = 20% emulsion (solid content)
PlasACRYL® T20 Product Overview

• 20% emulsion of mono and di-glycerides (GMS) and plasticizer (triethyl citrate)

• Stable for 12 months

• Detackifier/glidant/anti-adherent

• Replaces talc in aqueous coating systems

• Developed for use with EUDRAGIT® L30D55

• Also used with IR films and drug layering

• Packaging in 5 and 15kg pails; 500g sample size bottles

• DMF in US and Canada
Why an Anti-Adherent?

Methacrylic Acid Copolymer Systems

• Low glass transition temperature
• Glass transition temperature related to and affected by necessary plasticizer level
• Results in:
  – High tablet-to-tablet cohesion
  – High tablet-to-equipment adhesion
  – Sensitivity to process temperatures
• Historically addressed by adding talc
  – Typical use levels 20%-50% of polymer by weight (often higher with pellets or spheres)
Talc

- Talc inhibits adhesion and cohesion
  - But must be used at high levels (20-50% of polymer)
    - Particle size ranges (6 – 30 micron typical)
    - Reduces film flexibility
    - Decreases the amount of polymer deposited per equivalent weight gain
    - Increases the required weight gain for acid resistance in most cases
  - And talc is an insoluble mineral powder that settles when suspension is stirred rigorously
    - Tank, lines, manifold, gun bodies
    - Lack of talc uniformity
    - Rigorous stirring required to suspend high talc levels and minimize sedimentation can cause shearing damage to acrylic emulsions, coagulation, and gun clogging
PlasACRYL® T20

- PlasACRYL® T20 (GMS) inhibits adhesion & cohesion
  - **And** Requires lower levels of inclusion than talc
    - Typically GMS level is 3-5% of polymer for tablets
    - 10 x less than talc
    - PlasACRYL® T20 increases the amount of polymer deposited per equivalent talc-system weight gain
    - Decreases the required weight gain required for acid resistance
  - **Also** PlasACRYL® T20 allows GMS to be readily incorporated into acrylic copolymer emulsions
    - Unlike talc PlasACRYL® T20 does not settle or separate out of the emulsion
    - Clear PlasACRYL® T20 systems require only the same gentle stirring used to mix methacrylic acid and plasticizer
    - PlasACRYL® T20 contains a portion of the plasticizer (triethyl citrate) necessary for film flexibility
  - PlasACRYL® T20 does not cause methacrylic acid coagulation
    - Does not require rigorous stirring like talc
    - Does not contain the ionic charges associated with talc
PlasACRYL® T20

- Eliminates talc sedimentation
  - Minimizes coagulation and gun clogging
- Stable, ready to use, GMS emulsion product
- Lower weight gain and shorter run time
- Better quality film
- More effective anti-adherent
  - Less agglomeration; faster spray rates
- Improved tablet slip
- Facilitates inclusion of color in one step
Decrease Process Time

- Example (enteric coated tablet)
  - 10% wg required with talc (30kg solids on 300kg batch)
    » At 20% solids that requires 150kg of coating suspension
  - 8% wg required with PlasACRYL® T20 (24kg solids on 300kg batch)
    » At 20% solids that requires 120kg of coating suspension
  - At equivalent liquid delivery rates that is a savings of 20% process time

Note: This does not account for savings in process time due to faster spray rates and avoidance of down time caused by clogged equipment
Formulation Comparison

<table>
<thead>
<tr>
<th>Material</th>
<th>kg/batch</th>
<th>kg solids</th>
<th>% film</th>
<th>qty/24kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>560.00</td>
<td>168.00</td>
<td>83.29</td>
<td>19.99</td>
</tr>
<tr>
<td>PlasACRYL® T20</td>
<td>76.00</td>
<td>15.20</td>
<td>7.54</td>
<td>1.81</td>
</tr>
<tr>
<td>Triethyl citrate (TEC)</td>
<td>18.50</td>
<td>18.50</td>
<td>9.17</td>
<td>2.20</td>
</tr>
<tr>
<td>Water</td>
<td>354.00</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1008.50</td>
<td>201.70</td>
<td>100.00</td>
<td>24.00</td>
</tr>
</tbody>
</table>

Application of 24kg of the above coating results in the application of 19.99kg of acrylic polymer.

Application of 30kg of the talc suspension below results in the application of only 18.66kg of acrylic polymer.

<table>
<thead>
<tr>
<th>Material</th>
<th>kg/batch</th>
<th>kg solids</th>
<th>% film</th>
<th>qty/30kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>560.00</td>
<td>168.00</td>
<td>62.20</td>
<td>18.66</td>
</tr>
<tr>
<td>Talc</td>
<td>76.00</td>
<td>76.00</td>
<td>28.14</td>
<td>8.44</td>
</tr>
<tr>
<td>Triethyl citrate (TEC)</td>
<td>26.10</td>
<td>26.10</td>
<td>9.66</td>
<td>2.90</td>
</tr>
<tr>
<td>Water</td>
<td>688.40</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1350.50</td>
<td>270.10</td>
<td>100.00</td>
<td>30.00</td>
</tr>
</tbody>
</table>
Benefits of Switching from GMS to PlasACRYL® T20

• Example formulation for 100kg tablets

<table>
<thead>
<tr>
<th>Excipient</th>
<th>GMS formulation kg</th>
<th>PlasACRYL™ T20 formulation kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L 30 D-55</td>
<td>16.667</td>
<td>16.667</td>
</tr>
<tr>
<td>PlasACRYL® T20</td>
<td></td>
<td>2.500</td>
</tr>
<tr>
<td>GMS</td>
<td>0.250</td>
<td>-</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>0.100</td>
<td>-</td>
</tr>
<tr>
<td>TEC</td>
<td>0.500</td>
<td>0.250</td>
</tr>
<tr>
<td>Water</td>
<td>5.883</td>
<td>3.983</td>
</tr>
<tr>
<td>Total</td>
<td>23.400</td>
<td>23.400</td>
</tr>
</tbody>
</table>

*Preparation time reduced from 1 h 25 min to 35 min* (no high shear mixing or heating)

No homogenizing necessary, less preparation time = *decreased preparation costs!*
Benefits of Switching from GMS to PlasACRYL® T20

• No high shear mixing needed
• No heating of water required
• Less weighing steps
• Less investment of energy and time for preparation

Decreases complexity of

• Purchasing
• Raw material quality control
• Manufacturing processes
• Storage
Better Quality Film

• Better quality film with less weight gain
• Higher percentage of film is functional polymer
• Better acid resistance
• SEM demonstration
Moisture Uptake

81mg aspirin tablets, HPMC and TEC sub-coating to 1.2% wg and enteric coated to 10% weight gain.

100 tablets 10% wg submerged in pH 1.2 after 400 drops in friabilator

<table>
<thead>
<tr>
<th>Run #</th>
<th>Damaged</th>
<th>Acid uptake %</th>
</tr>
</thead>
<tbody>
<tr>
<td>SL13-14 (P)</td>
<td>0</td>
<td>2.10</td>
</tr>
<tr>
<td>SL13-15 (T)</td>
<td>2</td>
<td>3.27</td>
</tr>
</tbody>
</table>
### Enteric Disintegration

**USP enteric disintegration**

81mg aspirin tablets, HPMC and TEC sub-coating to 1.2% wg

<table>
<thead>
<tr>
<th>Run #</th>
<th>Weight gain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7%</td>
</tr>
<tr>
<td>SL13-14 (P)</td>
<td>100</td>
</tr>
<tr>
<td>SL13-15 (T)</td>
<td>67</td>
</tr>
</tbody>
</table>
Improved Film Quality

• PlasACRYL® T20 emulsion incorporates well into methacrylic acid emulsions
• Talc particles create disruptions in film continuity and integrity
• SEM photos demonstrate improved film quality through use of PlasACRYL® T20
Formulations for SEM Photos

- Formulations containing talc and PlasACRYL® T20 were coated in a Thomas Compulab 15" pan. Process parameters were equivalent.
- PlasACRYL® T20 coating was applied to 6.9% weight gain and talc coating was applied to 9.6% weight gain to achieve polymer weight gain of 6 mg/cm².
- GMS was included at 5% of polymer solids w/w.
- Talc was included at 50% of the polymer solids w/w.
- No sticking was observed.

<table>
<thead>
<tr>
<th>Material</th>
<th>g/batch</th>
<th>Solids g</th>
<th>% film</th>
<th>%poly</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>500.0</td>
<td>150.0</td>
<td>86.95</td>
<td>100.0</td>
</tr>
<tr>
<td>PlasACRYL® T20</td>
<td>75.0</td>
<td>15.0</td>
<td>8.70</td>
<td>10.0</td>
</tr>
<tr>
<td>Triethyl citrate</td>
<td>7.5</td>
<td>7.5</td>
<td>4.35</td>
<td>5.0</td>
</tr>
<tr>
<td>Water</td>
<td>280.0</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>TOTAL</td>
<td>862.5</td>
<td>172.5</td>
<td>100.00</td>
<td>--</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material</th>
<th>g/batch</th>
<th>Solids g</th>
<th>% film</th>
<th>%poly</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>500.0</td>
<td>150.0</td>
<td>62.50</td>
<td>100.0</td>
</tr>
<tr>
<td>Talc</td>
<td>75.0</td>
<td>75.00</td>
<td>31.25</td>
<td>50.0</td>
</tr>
<tr>
<td>Triethyl citrate</td>
<td>15.0</td>
<td>15.00</td>
<td>6.25</td>
<td>10.0</td>
</tr>
<tr>
<td>Water</td>
<td>610.0</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1200.0</td>
<td>240.00</td>
<td>100.00</td>
<td>--</td>
</tr>
</tbody>
</table>
SEM Photo Comparison

50% Talc, Tablet Dome (300X)

5% GMS, Tablet Dome (300X)
SEM Photo Comparison

5% GMS, Tablet Band (300X)

50% Talc, Tablet Band (300X)
Coating Parameters

- Eudragit systems with PlasACRYL® T20 can be applied at the same conditions as talc containing systems.
- Often, spray rates can be increased due to improved slip and lack of tackiness.
- Reduction of gun clogging, bearding, and other processing issues can save tremendous amounts time due to lack of down time.
- Inclusion of color in the enteric coating, reduction of necessary weight gains and reduction in down time have been demonstrated to save hours per pan from batch pan operations and make continuous coating operations much more efficient.
Reduce Agglomeration

Standard HPMC coating system
• 12% solids solution
• TEC at 10% of HPMC
• 15g/min spray rate

HPMC system with PlasACRYL®
• 12% solids solution
• TEC at 10% of HPMC
• GMS at 10% of Polymer
• 15g/min spray rate

Presented at AAPS, November 2006
Increase Spray Rates

Using PlasACRYL® in Wurster coating allows for faster spray rates while minimizing agglomeration.

AAPS, November 2006
Reduce Agglomeration

EC coating system using talc
- Talc at 10% of polymer
- 15g/min in Vector FLM1 Wurster

EC system with PlasACRYL®
- GMS at 2% of polymer
- 15g/min in Vector FLM1 Wurster

Presented at AAPS, November 2008
Reduce Agglomeration

Drug Layering Acetaminophen (APAP)
- MCC spheres (Cellets 700)
- Drug:Film-former 3:1
- Screened through US Mesh 18 (1000 μm)

| Coating Formulation (% polymer weight) |  |  |  |  |
| Sample | APAP | HPMC | Talc | Plasacryl® T20 | TEC |
| HPMC Only | 300 | 100 | - | - | 10 |
| 50% Talc | 300 | 100 | 50 | - | 10 |
| 100% Talc | 300 | 100 | 100 | - | 10 |
| 10% GMS | 300 | 100 | - | 20 | - |
| 20% GMS | 300 | 100 | - | 40 | - |

Presented at CRS & AAPS 2011
Calculation of “Slip”

Comparison of “bed angle” for tablets coated with various formulations.

- HPMC only: 34 degrees
- GMS @ 1.8% of acrylic polymer: 30 degrees
- GMS @ 6.0% of HPMC polymer: 25 degrees
- Acrylic coating with carnauba: 20 degrees
- GMS @ 3.32% of acrylic polymer: 18 degrees

Presented at AAPS, November 2006
Single Coat Color

- Use of PlasACRYL® T20 as a talc alternative allows for trouble-free color inclusion in methacrylic acid coating systems
  - Pigments (aluminum lakes and iron oxide and titanium dioxide) pose the same problems as talc – sedimentation, mixing induced shear, coagulation, gun clogging, ionic charges
  - Systems containing both pigments and talc and stress a methacrylic acid system to the point of failure
  - By using PlasACRYL® T20, talc is eliminated thus better enabling the system to accept other problematic ingredients like pigments
One Step Pigmented System with PlasACRYL® and EUDRAGIT®

- 81 mg aspirin coated using EUDRAGIT®, PlasACRYL®, and SPECTRASPRAY Yellow SS-1243
- SPECTRASPRAY (Sensient) is a pigment dispersion; in this case, one specially formulated for use in aqueous acrylic coatings

- This PlasACRYL®, EUDRAGIT®, SPECTRASPRAY system has been successfully used with both dyes and lakes and a variety of colors including FD&C Yellow 6 Lake and Dye; FD&C Yellow 5 Lake; D&C Yellow 10 Lake and Dye; FD&C Red 40 Lake and Dye; FD&C Blue 1 Lake; and Titanium dioxide
Case Study for Enteric ASA

Subcoat formulation

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Function</th>
<th>Solids</th>
<th>% Soltn.</th>
<th>% Film</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectrablend*</td>
<td>Film, Plasticizer</td>
<td>96%</td>
<td>12.5</td>
<td>100</td>
</tr>
<tr>
<td>50857</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deionized Water</td>
<td>Medium</td>
<td>0%</td>
<td>87.5</td>
<td>0</td>
</tr>
<tr>
<td>Totals</td>
<td>Seal Coat</td>
<td>12%</td>
<td>100.0</td>
<td>100</td>
</tr>
</tbody>
</table>

*Spectrablend (Sensient Technologies, South Plainfield, NJ) is a 96% solids granulation of HPMC and includes plasticizer. In this case, the plasticizer is Triethyl citrate at 10% of the HPMC. This could be substituted with any HPMC and plasticizer blend. TEC is a recommended plasticizer.
## Stability Study for Enteric ASA

### Enteric Topcoat for 81 mg Aspirin

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Function</th>
<th>Solids</th>
<th>% Suspension</th>
<th>% Film</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>Film former</td>
<td>30%</td>
<td>49.22</td>
<td>73.66</td>
</tr>
<tr>
<td>PlasACRYL®</td>
<td>Detackifier</td>
<td>20%</td>
<td>4.91</td>
<td>4.90</td>
</tr>
<tr>
<td>Triethyl citrate</td>
<td>Plasticizer</td>
<td>100%</td>
<td>1.47</td>
<td>7.33</td>
</tr>
<tr>
<td>SPECTRASPRAY Yellow SS-1243</td>
<td>Color</td>
<td>41%</td>
<td>6.90</td>
<td>14.11</td>
</tr>
<tr>
<td>Deionized Water</td>
<td>Medium</td>
<td>0%</td>
<td>37.50</td>
<td>0.00</td>
</tr>
</tbody>
</table>

| Totals                     | Enteric        | 20%    | 100.00       | 100.00  |
PlasACRYL® T20 (Processing)

• Pigmented systems
  – Prepare lake/dye and opacifier premix (high-shear mixing with portion of water)
  – Mix EUDRAGIT® + PlasACRYL® T20 + additional plasticizer (Low-shear mixing for 30 minutes)
  – Combine pigment dispersion with additional materials and stir for approximately 15 min prior to coating
  – Continue gentle mixing during coating process

• Typical processing parameters
  – Same as a talc-based formula
## Stability Study for Enteric ASA

### Enteric Topcoat for 325 and 500 mg Aspirin

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Function</th>
<th>Solids</th>
<th>% Susp.</th>
<th>% Film</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDRAGIT® L30D55</td>
<td>Film</td>
<td>30.0%</td>
<td>49.22</td>
<td>73.78</td>
</tr>
<tr>
<td>PlasACRYL®</td>
<td>Detackifier, Plasticizer</td>
<td>20.0%</td>
<td>4.91</td>
<td>4.91</td>
</tr>
<tr>
<td>Triethyl citrate</td>
<td>Plasticizer</td>
<td>100.0%</td>
<td>1.47</td>
<td>7.35</td>
</tr>
<tr>
<td>SPECTRASPRAY Orange, D-489</td>
<td>Color</td>
<td>40.5%</td>
<td>6.90</td>
<td>13.96</td>
</tr>
<tr>
<td>Deionized Water</td>
<td>Medium</td>
<td>0.0%</td>
<td>37.50</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>Enteric</strong></td>
<td><strong>20.0%</strong></td>
<td><strong>100.0</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

- SPECTRASPRAY Orange D-489 is a dye-based system specially formulated for aqueous acrylic coatings
Stability Study -- Setup & Bottling

- Samples of each Aspirin dosage were placed in sealed bottles, with and without desiccant.
- Bottles of all types were designated for both room temperature (25±3°C and 60% RH) and accelerated (40°C and 75% RH) stability.
- Samples of each designation were set aside for monthly testing; initial, 1, 2, and 3; as well as a sample stored at 25°C and 60% RH for testing at 6 months (with and without desiccant).
Analytical Testing -- Overview of Tests

- All testing conducted within 7 days of sample pulls
- Samples tested for:
  - Description
  - Potency
  - Free SA
  - USP enteric coated dissolution
Aspirin Potency Test

- Tablets tested by HPLC assay according to USP monograph for delayed release aspirin

- Passing criteria is 95.0 – 105.0% of label claim
Limit of Free Salicylic Acid Test

- Using USP Salicylic Acid RS and according to the USP monograph for aspirin, assay results were obtained in terms of percentage of free SA
- Passing criteria is not more than 3.0%
USP Enteric Coated Dissolution

- Using USP test 724 Method B, 6 tablets of each sample were tested for enteric dissolution drug release specified in the USP monograph for delayed aspirin tablets.

- A passing result for the intestinal (buffer) portion of the test is not less than 75% dissolved.
### Results: 81 mg Aspirin Stability 9% Weight Gain

<table>
<thead>
<tr>
<th>Stability</th>
<th>Desiccant</th>
<th>Time</th>
<th>Potency</th>
<th>Free SA</th>
<th>Diss. Acid</th>
<th>Diss. Buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>0 (initial)</td>
<td>98.3%</td>
<td>0.1%</td>
<td>0.4%</td>
<td>100%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>With</td>
<td>3 months</td>
<td>97.3%</td>
<td>0.1%</td>
<td>1%</td>
<td>104%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>3 months</td>
<td>97.3%</td>
<td>0.2%</td>
<td>0%</td>
<td>102%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>6 months</td>
<td>96.8%</td>
<td>0.4%</td>
<td>0%</td>
<td>95%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>1 month</td>
<td>97.6%</td>
<td>0.3%</td>
<td>0.7%</td>
<td>100%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>3 months</td>
<td>98.4%</td>
<td>0.7%</td>
<td>0%</td>
<td>103%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>1 month</td>
<td>98.7%</td>
<td>0.5%</td>
<td>0.9%</td>
<td>97%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>3 months</td>
<td>96.9%</td>
<td>1.7%</td>
<td>1%</td>
<td>103%</td>
</tr>
</tbody>
</table>

**All 81 mg Aspirin test results are passing**

<table>
<thead>
<tr>
<th>Passing Criteria</th>
<th>95-105%</th>
<th>NMT 3%</th>
<th>NMT 10%</th>
<th>NLT 75%</th>
</tr>
</thead>
</table>

---
## Results: 325 mg Aspirin Stability 8% Weight Gain

<table>
<thead>
<tr>
<th>Stability</th>
<th>Desiccant</th>
<th>Time</th>
<th>Potency</th>
<th>Free SA</th>
<th>Diss. Acid</th>
<th>Diss. Buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>0 (initial)</td>
<td>99.1%</td>
<td>0.1%</td>
<td>0.3%</td>
<td>98.0%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>With</td>
<td>3 months</td>
<td>101.2%</td>
<td>0.1%</td>
<td>1%</td>
<td>104%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>3 months</td>
<td>99.6%</td>
<td>0.1%</td>
<td>0%</td>
<td>103%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>6 months</td>
<td>101.6%</td>
<td>0.1%</td>
<td>1%</td>
<td>98%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>1 month</td>
<td>99.3%</td>
<td>0.2%</td>
<td>1.3%</td>
<td>99%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>3 months</td>
<td>102.7%</td>
<td>0.6%</td>
<td>1%</td>
<td>103%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>1 month</td>
<td>101.7%</td>
<td>0.2%</td>
<td>0.9%</td>
<td>100%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>3 months</td>
<td>102.4%</td>
<td>0.5%</td>
<td>1%</td>
<td>102%</td>
</tr>
</tbody>
</table>

All 325 mg Aspirin test results are passing

<table>
<thead>
<tr>
<th>Passing Criteria</th>
<th>95-105%</th>
<th>NMT 3%</th>
<th>NMT 10%</th>
<th>NLT 75%</th>
</tr>
</thead>
</table>
## Results: 500 mg Aspirin Stability 7% Weight Gain

<table>
<thead>
<tr>
<th>Stability</th>
<th>Desiccant</th>
<th>Time</th>
<th>Potency</th>
<th>Free SA</th>
<th>Diss. Acid</th>
<th>Diss. Buffer</th>
</tr>
</thead>
<tbody>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>0 (initial)</td>
<td>98.5%</td>
<td>0.04%</td>
<td>0.3%</td>
<td>94%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>With</td>
<td>3 months</td>
<td>99.3%</td>
<td>0.1%</td>
<td>1%</td>
<td>99%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>3 months</td>
<td>101.8%</td>
<td>0.1%</td>
<td>1%</td>
<td>97%</td>
</tr>
<tr>
<td>25° C/60%RH</td>
<td>Without</td>
<td>6 months</td>
<td>98.5%</td>
<td>0.2%</td>
<td>1%</td>
<td>93%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>1 month</td>
<td>97.4%</td>
<td>0.1%</td>
<td>1.6%</td>
<td>95%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>With</td>
<td>3 months</td>
<td>101.7%</td>
<td>0.2%</td>
<td>1%</td>
<td>99%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>1 month</td>
<td>98.5%</td>
<td>0.2%</td>
<td>1.1%</td>
<td>98%</td>
</tr>
<tr>
<td>40° C/75%RH</td>
<td>Without</td>
<td>3 months</td>
<td>98.1%</td>
<td>0.8%</td>
<td>1%</td>
<td>100%</td>
</tr>
</tbody>
</table>

All 500 mg Aspirin test results are passing

<table>
<thead>
<tr>
<th>Passing Criteria</th>
<th>95-105%</th>
<th>NMT 3%</th>
<th>NMT 10%</th>
<th>NLT 75%</th>
</tr>
</thead>
</table>

Passing Criteria: 95-105% NMT 3% NMT 10% NLT 75%
Case Study Conclusion

• The analytical results for all three dosage forms (81 mg, 325 mg, and 500 mg Aspirin), including both those stored at room temperature and those stored under accelerated stability conditions, with and without desiccant, were within the specified criteria for passing results.

• Positive results demonstrate the advances that have been made in acrylic polymers coating systems used in conjunction with PlasACRYL® T20 for aqueous enteric coatings.
Paracetamol Tablets

Paracetamol tablets coated with 5 mg EUDRAGIT® L 30 D-55 / cm²

Time [min]

Drug dissolved [%]

Talc formulation
standard GMS formulation
PlasACRYL T20 + TEC
PlasACRYL T20 + TEC + Polysorbate 80

Using 10% PlasACRYL T20 without any addition of TEC led to brittle surfaces

Data Supplied Courtesy of Evonik Industries
Analytical Results

Paracetamol tablets coated with EUDRAGIT® L 30 D-55 (PlasACRYL T20 formulation with TEC and Polysorbate 80)

Drug dissolved [%] vs Time [min]

- Initial
- 6 month 25°C/60% r.h.
- 6 month 30°C/65% r.h.
- 6 month 40°C/75% r.h.

Data Supplied Courtesy of Evonik Industries
Aspirin Crystals

**ASA crystals coated with EUDRAGIT® L 30 D-55 (15% polymer applied)**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Drug dissolved [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc</td>
<td></td>
</tr>
<tr>
<td>GMS</td>
<td></td>
</tr>
<tr>
<td>PlasACRYL T20 + TEC</td>
<td></td>
</tr>
<tr>
<td>PlasACRYL T20 + TEC + Polysorbate 80</td>
<td></td>
</tr>
</tbody>
</table>

- **Talc**
- **GMS**
- **PlasACRYL T20 + TEC + Polysorbate 80**
- **PlasACRYL T20 + TEC**

Data Supplied Courtesy of Evonik Industries
Aspirin Crystals – Dissolution Stability

ASA crystals coated with EUDRAGIT® L 30 D-55 (PlasACRYL T20 formulation with TEC and Polysorbate 80)

Data Supplied Courtesy of Evonik Industries
Diclofenac Na Tablets

Diclofenac Na tablets coated with 5 mg EUDRAGIT® L 30 D-55 / cm²

Drug dissolved [%]

- GMS
- PlasACRYL T20

Time [min]

Data Supplied Courtesy of Evonik Industries
Diprophylline Tablets

Diprophylline pellets coated with EUDRAGIT® FS 30 D (10% polymer applied)

Drug dissolved [%]

Time [min]

GMS
PlasACRYL T20 + TEC + Polysorbate 80
PlasACRYL T20

Data Supplied Courtesy of Evonik Industries
Next Generation PlasACRYL®

• All inclusive product
  – Contains full amount of plasticizer

• Flexible product
  – Contains no plasticizer
  – Able to use custom plasticizer of choice
  – Idea for use with EUDRAGIT® NE30D and other very low glass transition polymers
In Summary

- PlasACRYL® T20 inhibits adhesion and cohesion
  - Requires lower levels of inclusion than talc; 10x less
  - GMS disperses readily in acrylic copolymer emulsions; will not settle out; less clogging
  - Is shelf stable for 12 months
  - Provides dramatic time savings
  - Increases the amount of polymer deposited per equivalent weight gain because of lower use level and required weight gain for acid resistance in most cases
  - More effective for less agglomeration with faster spray rates
  - Ideal for one step color coating
Thank You

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