Dear reader,

You may have known ExAct for nearly three years as a customer’s newsletter with its main focus on pharmaceutical excipients.

This year the pharma active ingredients business within the BASF group has been reorganized in order to provide you with an intensified and integrated service fulfilling your needs.

BASF now provides a whole range of pharma ingredients from one source. By focusing on our comprehensive portfolio of actives, excipients and vitamins and offering a complete technical application and formulation support we guarantee process safety as well as freedom in application while enhancing our customers’ long-term product and market success.

The ExAct newsletter will continue to provide you with recent findings, application data and experience relating to our widened product range for the pharmaceutical industry.

Yours sincerely,

BASF Aktiengesellschaft
Marketing
Pharma Ingredients

Gabriel Tanbourgi

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Calendar

30th January to 2nd February, 2001
Informex
New Orleans*, USA

19th to 21st April, 2001
PM (Fair for Pharmaceutical Ingredients)
Kuala Lumpur, Malaysia

11th to 13th June, 2001
INTERPHEX Asia (International Exposition for the Pharmaceutical Industry)
Singapore, Singapore

23rd to 27th June, 2001
28th International Symposium on Controlled Release of Bioactive Materials
San Diego*, USA

10th to 12th July, 2001
CPhI, Pharmaceutical Ingredients China
Shanghai, China

3rd to 5th October, 2001
CPhI, Pharmaceutical Ingredients Worldwide
London*, United Kingdom

21st to 25th October, 2001
AAPS (American Association of Pharmaceutical Scientists) Annual Meeting
Denver*, USA

9th to 12th November, 2001
PHARMA INDIA (International Congress and Exposition for the Pharmaceutical Industry)
Mumbai, India

* BASF will be represented.
**Riboflavin 100**

**Vitamin B₂ in a new shape.**

U. Siedel

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**Introduction**

In general, direct-compressible actives have gained more and more importance. Expensive and time-consuming granulation steps are avoided – if possible – and replaced by direct compression. Therefore the demand for direct-compressible substances increased within the last years. This is especially the case for substances which are difficult to handle in their pure crystalline form like Riboflavin. Crystalline Riboflavin shows poor flowability and bad dissolution properties. Therefore BASF invested in new technology to produce an improved direct-compressible product specially designed for the food/pharma requests.

Direct-compressible Riboflavin formulations generally consist of granules with a certain amount of excipients to provide binding and disintegration properties. BASF offers a direct-compressible 100% grade which combines the advantages of improved powder properties and optimized release rates with the highest possible potency: Riboflavin 100.

**Manufacture**

Riboflavin 100 is manufactured by a natural fermentation process using a non-GMO microorganism, Ashbya gossypii. Since the soy products utilized for the fermentation are also not genetically modified we are able to supply our customer with a GMO-free product. The fermentation process guarantees a product of highest quality and purity.

**Technical advantages of Riboflavin 100**

- Homogeneous particle size
- Good flowability
- High purity
- Reduced dusting
- Good compressibility
- Excellent dissolution

**Particle form**

Many of the disadvantages in handling synthetic Riboflavin result from its particle form (2). Particles in form of needles show poor flow properties (6) and low bulk density (8). Especially the production of high potency Riboflavin tablets becomes difficult or even impossible. BASF’s Riboflavin 100 however consists of round particles (1) with a smooth surface leading to a higher bulk density (3).

**Flowability**

Due to the round particle form and its slightly coarser particle size (7, 8), Riboflavin 100 has an improved flowability compared to the synthetic material (5).

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**Outstanding product properties:**

- Reduced dusting
- Excellent dissolution

**Food fortification**

In addition to its excellent handling properties, Riboflavin 100 shows good mixing behavior with reduced tendency to subsequent segregation. A typical example in food fortification is the flour test. A four mixture containing three percent of Riboflavin is mixed thoroughly and sieved. The less flour mixture remains upon sieve 250 μm the better the mixture. As can be seen in picture (11), BASF’s Riboflavin 100 has considerably better mixing and sieving properties. These results can also be expected in the fortification of other food products like instant powders. The fortification of soft drinks or other liquids in the range of typical pH values can also be expected in the fortification of other food products like instant powders. The fortification of soft drinks or other liquids in the range of typical pH values with Riboflavin 100 results in the same color as with synthetic Riboflavin.

**Particle size distribution of Riboflavin 100** (7)

**Bulk density of Riboflavin 100** (2) [0.35 g/ml] and synthetic Riboflavin (4) [0.12–0.18 g/ml].

**Tableting properties**

Identical coloration compared to synthetic Riboflavin is also achieved for the use of Riboflavin 100 in pharma applications like tablets. Good flowability and homogeneous particle size distribution result in excellent tableting properties. Even formulations containing 50 mg and more of Riboflavin per tablet are easily compressible and show excellent dissolution. The dissolution in water has been improved compared to synthetic Riboflavin.
Dissolution profile of tablets containing 50 mg of Riboflavin 100. (12)

The USP requirement for the dissolution of tablets containing Riboflavin is 75% within 45 min. Figure (12) shows the dissolution profile of high-potency Riboflavin 100 tablets. The release rate of 75% even after 30 minutes indicates clearly a high reliability regarding dissolution speed in tablet formulations.

> Conclusions
Riboflavin 100 has demonstrated to be a product of high quality with good handling properties for food as well as pharma applications. Therefore it should be the product of choice for difficult formulations where excellent powder properties are required.
Kollicoat® SR 30 D

Influence of additives on the properties of films and coated dosage forms.

K. Kolter, T. Rock

Introduction
Controlled release film coatings generally do not consist only of the controlled release polymer but also contain various excipients such as plasticizers, coloring agents, antitack additives, pore formers or suspension stabilizers. These additives have differing degrees of influence on a variety of film properties, the dissolution rate and the film coating process. Kollicoat SR 30 D is a new polyvinyl acetate based polymer dispersion for the manufacture of controlled release coated dosage forms [1]. While the influence of plasticizers on the mechanical film properties has already been described [2], no data are yet available concerning the other excipients.

Purpose
This study was performed to determine the influence of additives commonly used in coating formulations on the coating process and film properties. This knowledge can be used to optimize coating formulations and to improve and expedite their development.

Materials and Methods
Materials
Kollicoat SR 30 D is a polyvinyl acetate dispersion stabilized with polyvinylpyrrolidone and sodium lauryl sulfate (BASF AG); caffeine (Knoll AG), Pharsil (dimethicone, Wacker); Aerosil 200 (Degussa), Granulac 230 (lactose, Meggle).

All ingredients were blended in a Diosna-mixer for 5 minutes, moistened with water until a readily mouldable mass was obtained (approx. 48% water). The mass was then mixed thoroughly for another 3 minutes extruded in an Alexanderwerk apparatus with a vertical 1.5 mm sieve and the resulting granules were transferred to a spheronizer (Heller) and rounded for 10 minutes. The still moist pellets were dried in a fluidized bed granulator and then sieved to obtain the required particle size (0.7–1.4 mm).

The recommended addition rate of 1,2 Propylene glycol is 10% referred to the dry polymer. Propylene glycol was first added to the given amount of water. Then Kollidon SR 30 D was stirred in. The pigment dispersion was homogenized using a corundum mill and added slowly to the polymer dispersion while stirring.

Table 1: Composition and preparation of the pellets

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Parts by weight (g)</th>
<th>Composition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine powder</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Avicel PH 101</td>
<td>43.75</td>
<td>43.75</td>
</tr>
<tr>
<td>Granulac 230</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Kollidon VA 64</td>
<td>47.00</td>
<td>47.00</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Composition and preparation of the spray suspension

<table>
<thead>
<tr>
<th>Polymer dispersion</th>
<th>Parts by weight (g)</th>
<th>Composition (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kollicoat SR 30 D</td>
<td>190.00</td>
<td>47.0</td>
</tr>
<tr>
<td>(dry polymer)</td>
<td>(57.00)</td>
<td>(14.1)</td>
</tr>
<tr>
<td>1,2 Propylene glycol</td>
<td>5.66</td>
<td>1.4</td>
</tr>
<tr>
<td>Water</td>
<td>141.37</td>
<td>36.6</td>
</tr>
</tbody>
</table>

Table 3: Coating process

The coating was applied on 0.5 kg caffeine pellets in a fluidized bed coater (Aeromatic Strea 1) under the following conditions:

- Inlet air temperature: 60 °C
- Outlet air temperature: 35 °C
- Atomizing pressure: 1.0 bar
- Spraying rate: 11.5 g/min
- Drying: 40 °C / 3 min
- Coating level: 3 mg/cm²
- Spraying time: about 35 min
- Solids content of the spray suspension: 20 %
Results and Discussion

The use of different plasticizers resulted in very similar dissolution rates (Figure 1). No differences were apparent between propylene glycol 10% and triethyl citrate (5% and 10%), while triacetin (5%) and ATBC (5%) produced slightly slower dissolution rates.

The excipient talc – widely used in coating preparations – accelerated dissolution with increasing concentration (Figure 2) at constant coating level. It should be noted, however, that especially at very high talc concentrations the polymer content was much lower and was no longer sufficient to completely bind the solids.

Very fine particulate solids like Aerosil 200, magnesium stearate or tricalcium phosphate in higher concentrations interfere greatly with film formation, since dissolution occurs very rapidly (Figure 3). Lipophilic antitack additives like glycerol monostearate or dimethicone slow down dissolution in the lower concentration range and accelerate it at higher concentrations (Figure 4).

The additives had no impact on the curing behavior of the pellets. Even after high thermal stress (24 h/60°C) dissolution was almost unchanged. Coating formulations with several additives also showed the same behavior (Figure 5).

Conclusions

- The type of plasticizer used has almost no influence on dissolution.
- Antitack additives in low to medium concentrations also hardly affect dissolution.
- Fine particulate solids markedly accelerate dissolution, especially at higher concentrations.

References

An excellent dry binder.
D. Flick, K. Kolter

Purpose
Dry binders are intended to improve tablet formation by direct compression with the main emphasis on improving the mechanical properties \[1\], i.e. the hardness and friability of the tablets. Apart from microcrystalline cellulose and the cellulose ethers, polyvinylpyrrolidone is probably the best-known dry binder. An almost unknown dry binder is Kollidon VA 64 (copovidone), a vinylpyrrolidone vinyl acetate-copolymer. An almost unknown dry binder is Kollidon VA 64 (copovidone), a vinylpyrrolidone vinyl acetate-copolymer \[1\].

Experimental Methods
Materials
Dry Binder: Kollidon 30 (povidone), Kollidon VA 64 (copovidone) (BASF AG); Avicel PH 101 (microcrystalline cellulose (MCC); Pharmacoat 606 (hydroxypropylmethylcellulose 2910) (Shin Etsu); Maldex 18 (maltodextrin) (Amylum).

Methods
The dry binders were tested in several formulations (Table 1). A dicalcium phosphate tablet (A), with excipients which are not soluble in water and a vitamin C tablet (B), with water-soluble constituents. To obtain detailed information on their compression properties, the pure dry binders were compressed (C).

Table 1: Formulations

<table>
<thead>
<tr>
<th>Dry Binder</th>
<th>Formulations</th>
<th>A (%)</th>
<th>B (%)</th>
<th>C (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiTab</td>
<td>90, 85, 80</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Acrosolv</td>
<td>90, 85, 80</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Ludipress</td>
<td>5, 10, 15</td>
<td>5, 10, 15</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Dry Binder</td>
<td>4, 5</td>
<td>3, 0</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Kollidon CL</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
<td></td>
</tr>
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</table>

Table 2: Mean Particle Size

<table>
<thead>
<tr>
<th>Dry Binder</th>
<th>Mean Particle Size D (4,3)</th>
<th>Bulk Density</th>
<th>Hausmann Ratio</th>
<th>Angle of Repose</th>
<th>Flow time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kollidon 30</td>
<td>50</td>
<td>0.389</td>
<td>1.24</td>
<td>28</td>
<td>75</td>
</tr>
<tr>
<td>Kollidon VA 64</td>
<td>43</td>
<td>0.241</td>
<td>1.37</td>
<td>35</td>
<td>block</td>
</tr>
<tr>
<td>MC PH 101</td>
<td>65</td>
<td>0.326</td>
<td>1.40</td>
<td>41</td>
<td>block</td>
</tr>
<tr>
<td>HPMC 2910</td>
<td>82</td>
<td>0.367</td>
<td>1.37</td>
<td>42</td>
<td>block</td>
</tr>
<tr>
<td>Maltodextrin DE 18</td>
<td>74</td>
<td>0.522</td>
<td>1.34</td>
<td>44</td>
<td>block</td>
</tr>
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</table>

Results and Discussion
The dry binders tested exhibited considerable differences in their powder properties (Table 2) which are of interest with reference to tabletability.

The particle size determinations clearly show that Kollidon VA 64 is the finest product and should, with its shell-like structure (Figure 2), be able to coat drug and filler particles and bind them together under compression.

The hardness of the tablets (A) made with Kollidon VA 64 places them in a class of their own (Figure 3).

At a compression force of 18 kN and a dry binder content of 50 mg, the hardness of the tablets exceeds that of tablets without a dry binder by 120%. If the same compression force is used in each case and the dry binder content is increased from 25 to 50 to 75 mg, Kollidon VA 64 gives the steepest increase in hardness.

Vitamin C powder (B) was selected as a substance that is very difficult to compress into tablets and in mixtures with excipients, also greatly reduces compressibility. The compression force-hardness curves (Figure 4) are similar in appearance to those for the tablets of formulation A:

without dry binder: low hardness
with HPMC 2910: slight improvements
Kollidon 30 and MC PH 101: exceptional hardness

Because of the polymerized vinyl acetate component, Kollidon VA 64 is a softer and more plastic material than the other dry binders. This is confirmed by the low glass transition temperature (103°C).

The plasticity values of the products (Figure 5) were determined from the force-displacement curves (C). Kollidon VA 64 possesses a high plasticity of over 90% that remains constant from 10 to 18 to 25 kN.

Table 2: Mean Particle Size

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**Conclusions**

- Kollidon VA 64 possesses unique properties as a dry binder, irrespective of the formulation, which far exceed those of all other materials tested.
- Important information can be derived on the effectiveness of dry binders from force displacement curves.
- The dry binding properties of a substance can be attributed to various physical properties like particle shape and plasticity.

**References**

2. V. Bühler, Kollidon – Polyvinylpyrrolidone for the pharmaceutical industry, BASF AG (1996).
One Source

BASF – worldwide ingredient source for the pharma industry.

BASF is one of the world's leading chemical companies. Profound know-how in chemistry including polymer chemistry have yielded in a wide range of high-quality bulk active ingredients, excipients and vitamins. With proven brands like Kollidon BASF has written history in pharmaceutical technology. For 60 years BASF has been a reliable source of pharmaceutical ingredients and a partner for the pharmaceutical industry all over the world.

Pharmaceutical ingredients, like finished pharmaceutical products are subject to strict quality requirements. A variety of chemical and physical parameters determine their quality. BASF products are manufactured to the modern standards of quality management in the pharmaceutical industry, i.e. ISO standards and Good Manufacturing Practice (GMP). Each batch is analyzed and issued with a Certificate of Analysis that confirms its pharmacopoeia quality or specification requirements.

Our production facilities meet the requirements of national and international authorities. Highly motivated staff permanently contributes to the improvement of the quality standards and the reliability of BASF products.

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**New Pharma Actives**

- Doxazosin Mesylate antihypertensive
- Fluoxetine HCl antidepressant
- Omeprazole inhibitor of gastric acid secretion
- Paroxetine HCl antidepressant
- Selegiline HCl and free base antiparkinsonian
- Sertraline HCl antidepressant
- Terazosin HCl antihypertensive

**Excipients**

**Kollicoat® grades**
- enteric film coatings
- Kollicoat® MAE 30 DP
- Kollicoat® MAE 100 P

**Kollidon® grades**
- solubilizers, binders
- Kollidon® 12 PF/17 PF
- Kollidon® 25/30/90 F
- disintegrants, suspension stabilizers
- Kollidon® CL
- Kollidon® CL-M
- (dry) binders, film formers
- Kollidon® VA 64

**Ludipress® grades**
- direct compression agents
- Ludipress®
- Ludipress® LCE

**Breakthrough in sustained release coating!**

**Kollicoat® SR 30 D**

**Enteric film coatings**

**Kollicoat® EMM 30 D**

**Sustained release film coatings**

**Kollicoat® SR 30 D**

**Sustained release excipients**

**Kollidon® SR**
Progress in pharmaceutical forms and the need for efficient manufacturing lead to growing sophistication of active ingredients and excipients. Multi-disciplinary R&D teams continuously develop variations on proven products and completely new products to fulfill the customer demands in the future.

Global Availability
As a transnational company BASF is represented all over the world. To take care for the demands of our customers the BASF companies have highly trained sales teams in place. Various regional distribution centers enable us to deliver the right product to the right place at the right time. Two production sites for Kollidon provides a second-source backup. With high-quality ingredients, a knowledgable technical service and a supply safety we aim to maintain a close partnership with the pharmaceutical industry.
BASF – Expertise in Health and Nutrition

Vitamins

Fat-soluble Vitamins
- Vitamin A (retinol)
- Vitamin B12 (ergocalciferol)
- Vitamin D2 (cholecalciferol)
- Vitamin E (tocopherol)
- Vitamin K1 (phytomenadione)

Carotenoids
- Beta-carotene

Water-soluble Vitamins
- Vitamin B1 (thiamine)
- Vitamin B2 (riboflavin)
- Niacin
- Pantothenic acid
- Vitamin B6 (pyridoxine)
- Vitamin B12 (cobalamin)
- Vitamin H (d-biotin)
- Vitamin C (ascorbic acid)

BASF now provides a whole range of pharma ingredients.

Actives
- Analgesics
- Purines
- Ephedrines
- PVP-Iodine
- Crospovidone
- Tretinoin
- Isotretinoin
- Retinol
- Assorted Pharma Actives
- New Pharma Actives

Excipients
- Kollicoat®
- Kollidon®
- Ludipress®
- Lutrol®
- Cremophor®
- Solvents®
- Solutol® HS 15

Vitamins

BASF now provides a whole range of pharma ingredients.