

IN FOCUS

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## Enhancing bioavailability and solubility of poorly water-soluble APIs

Combining the advantages of solubilization and solid solutions, Soluplus®, BASF's new excipient innovation, enables new levels of solubility and bioavailability. Read more on how Soluplus and hot melt extrusion processes can make you more successful. **PAGES 2 – 5**

### Dear reader, What value can chemical manufacturers add to the pharmaceutical industry?



At BASF, we believe the answer is: a lot. As The Chemical Company we aim to enable optimal life cycle management of pharmaceuticals, starting from excipients for innovative drug formulation through reliable supply and manufacturing of

active ingredients. This edition of ExAct introduces three new BASF products.

Have you ever faced the problem of formulating a poorly water-soluble drug and increasing its bioavailability? We have discovered that we can solve this challenge, by leveraging our expertise in polymer chemistry. Soluplus® is a new BASF excipient, tailor-made to form solid solutions. It is suitable for innovative processing technologies, such as hot melt extrusion. This new polymer ideally complements our existing excipients solubilizer platform. Why not talk to us about your solubilization needs?

Cutting production costs and reducing complexity are hot topics across the entire pharmaceutical industry. We have used our formulation knowledge

to enable these goals, by introducing new colored coating systems based on Kollicoat® IR, our instant-release coating polymer. The new systems help improve efficiency in production while allowing you the full freedom to reliably create your own colors. Our coating systems professionals around the world will be happy to tell you more.

Our chemical expertise also includes the reliable and fully cGMP-compliant production of active pharmaceutical ingredients at competitive prices. With the launch of Phenylephrine, BASF has enhanced its established API portfolio for the respiratory system. We realized an excellent technology fit at our Minden site, where we look back on over 50 years of API production, for example as a world-leading supplier of Pseudoephedrine. Try out Phenylephrine samples now.

I am certain that we at BASF can make you, our pharma customers, more successful.

Yours sincerely,  
Alexandra Brand  
Director Global Marketing Pharma Ingredients & Services

IN FOCUS

## Soluplus® - The solid solution

D. Djuric, H. Hardung

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**INTRODUCTION** | In recent years it has been observed that the majority of all new chemical entities reveals poor bioavailability due to low solubility in aqueous media. Ways to overcome this solubility hurdle are for instance the use of surfactants, complexation agents, co-solvents and particular drug delivery technologies [1]. One technique which is gaining more and more interest is hot melt extrusion. Even though this technique has been used in the plastics and food industry for decades, it is relatively new in the pharmaceutical industry and only a few products (based on polyethylene glycol or copovidone) are currently available on the market [2, 3]. BASF was the first company in the 1980s who applied the hot melt extrusion process using Kollidon® (povidone) to pharmaceuticals [4]. 30 years later, BASF is now launching Soluplus®, a new excipient particularly developed for solid solutions and hot melt extrusion.

**STRUCTURE AND PROPERTIES** | In contrast to many other excipients used in hot melt extrusion, Soluplus is a polymer with an amphiphilic structure that can be utilized as a matrix excipient in hot melt extrusion and as a solubilizer itself.

It is a graft copolymer comprising polyvinyl caprolactam, polyvinyl acetate and polyethylene glycol moieties. The structure of Soluplus is shown in Figure 1.

Due to its bifunctional character, it is able to act as a matrix polymer for solid solutions on the one hand, and, on the other hand, it is capable of solubilizing poorly-water soluble drugs in aqueous media. Therefore, it combines the advantages of hot melt extrusion/solid solutions and solubilization in one excipient (Figure 2).

Soluplus consists of free flowing white to slightly yellowish granules with a faint characteristic odour and practically no taste. Its glass transition temperature is approximately 70 °C and it has a critical micelle concentration of 7.6 ppm (7.6 mg / L).

This new polymer was tested in comprehensive toxicological studies which document the safety of the product even in relatively high doses.

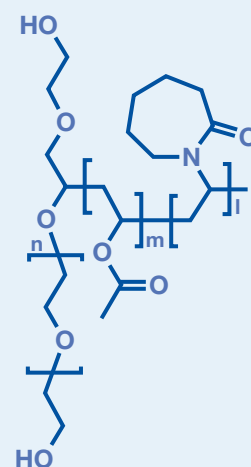


FIGURE 1 Structure of Soluplus®

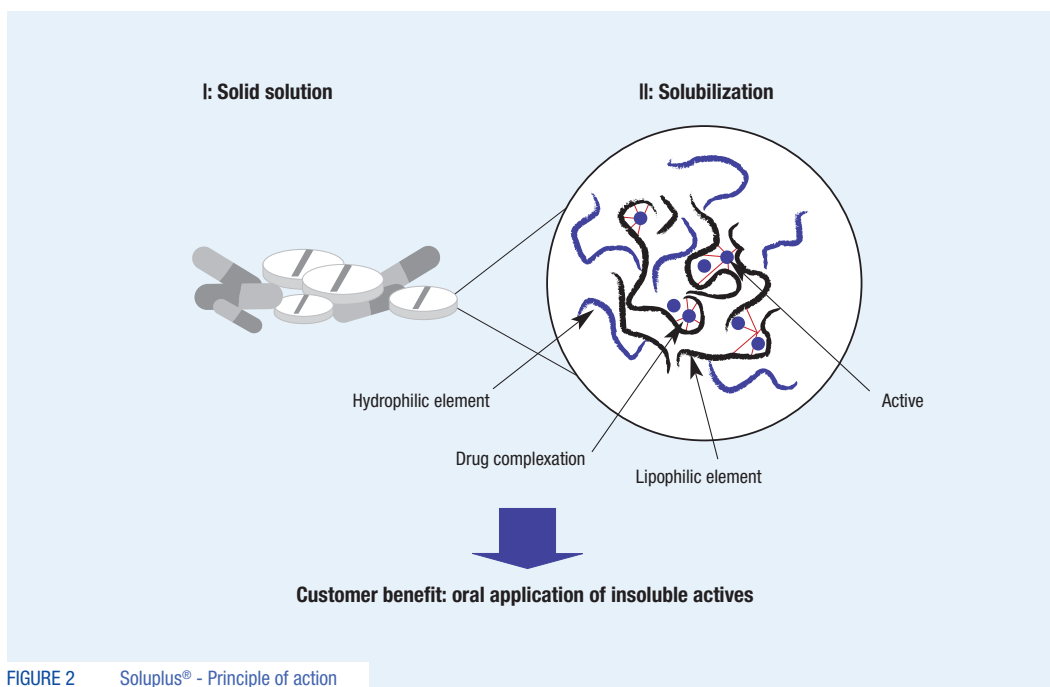


FIGURE 2 Soluplus® - Principle of action

**SOLUBILIZATION** | Due to its amphiphilic structure Soluplus shows a high solubilization capacity for a variety of drugs. This can be tested by determination of the saturation solubility of a poorly water soluble drug in a solution of 10% Soluplus after 72 h of stirring. Phosphate buffer as solvent (pH 7.0) assures comparable conditions when testing ionic drugs so that solubility effects due to pH shifts can be avoided. Figure 3 shows the saturation solubility of the poorly water-soluble drugs estradiol, carbamazepine, fenofibrate and itraconazole in phosphate buffer with 10% Soluplus, Solutol HS® 15 and Cremophor® RH 40, respectively, and the solubility in phosphate buffer without any further excipients.

Compared to the solubility of the mentioned drugs in pure phosphate buffer Soluplus increases the solubility in aqueous media and reveals in most cases a better solubility than the surfactants Solutol HS 15 and Cremophor RH 40.

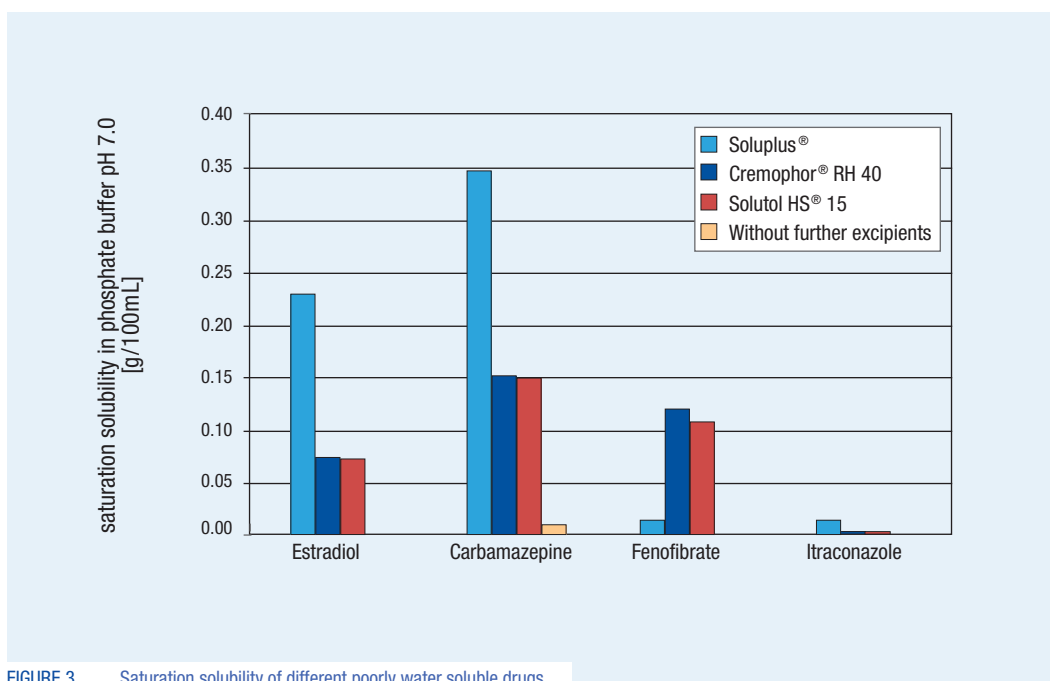


FIGURE 3 Saturation solubility of different poorly water soluble drugs

**SOLID SOLUTION/HOT MELT EXTRUSION PROCESS**

| With its glass transition temperature of around 70 °C Soluplus is very suitable for melt extrusion processes. The pure polymer can be extruded on a 16 mm twin-screw extruder at temperatures starting around 120 °C up to 180 °C depending on the applied screw configuration. The polymer shows no chemical degradation even after extrusion at 180 °C.

Incorporation of active ingredients can reduce the glass transition temperature of the polymer and therefore result in extrusion temperatures lower than 140 °C. In some cases the extrusion temperatures can even be reduced below 100 °C.

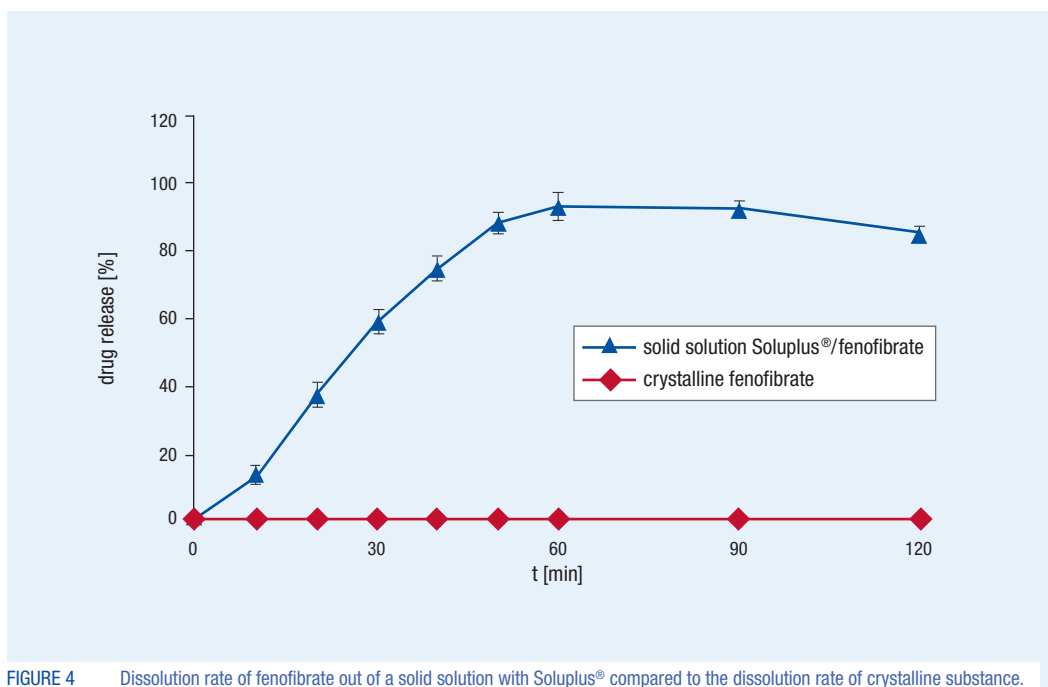


FIGURE 4 Dissolution rate of fenofibrate out of a solid solution with Soluplus® compared to the dissolution rate of crystalline substance.

It is possible to produce a solid solution with fenofibrate (melting point approximately 81 °C) and 20% drug content at 100 °C. Parameters for a 16 mm twin-screw extruder were 200 rpm and 1 kg / h powder feed rate. The resulting transparent and clear extrudates showed no crystalline amounts of drug determined by x-ray diffraction. Drug release was tested according to USP, apparatus II, 50 rpm, 700 mL HCl (0.08 molar) under non-sink conditions. Drug release was determined out of cut extrudates of comparable length (3 mm in length and diameter). The drug amount was 100 mg. To avoid lumping either of crystalline active or solid solution a disintegrant

(5% Kollidon CL) was added to the formulations. During dissolution samples were manually taken through a glass drip and immediately diluted in methanol (ratio 1:9). This procedure avoids a recrystallization of the active when the sample cools down to room temperature.

Figure 4 shows the dissolution rate of fenofibrate out of a solid solution with Soluplus and the dissolution rate of crystalline substance. The dissolution profile of the solid solution exhibits an almost complete release of fenofibrate from the formulation whereas for the crystalline fenofibrate formulation no drug release could be detected.

**BIOAVAILABILITY** | As outlined above, poor water solubility of drugs often leads to poor or almost no bioavailability. Soluplus can increase the bioavailability of such active ingredients after oral application.

A solid solution was prepared with fenofibrate and Soluplus (ratio 20:80) and was administered to beagle dogs. In comparison crystalline substance was administered as well. Each dog received 10 mg drug / kg bodyweight in form of filled hard gelatine capsules. To avoid lumping either of crystalline API or solid solution a disintegrant (5% Kollidon CL) was also added to the formulations.

Figure 5 shows the blood concentration of both formulations of fenofibrate administered to beagle dogs. The solid solution leads to a 5-fold increase in bioavailability, compared to the crystalline formulation.

*Soluplus® is BASF's new and innovative polymeric solubilizer, specifically developed for melt extrusion processes.*

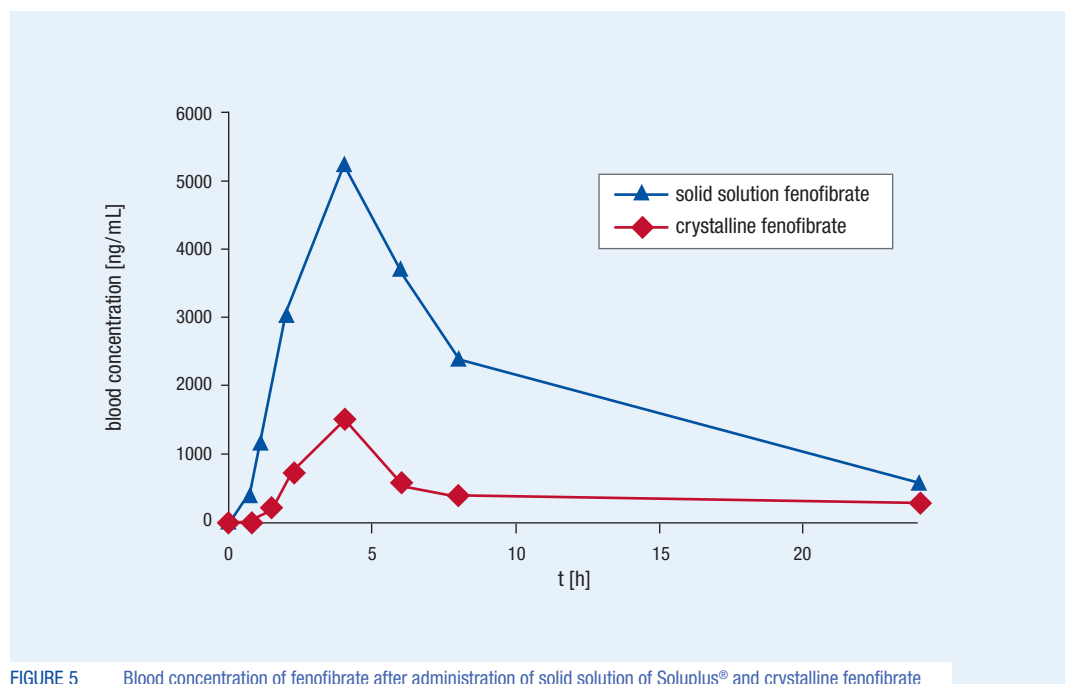


FIGURE 5 Blood concentration of fenofibrate after administration of solid solution of Soluplus® and crystalline fenofibrate

**CONCLUSION** | Soluplus combines the advantages of solubilization and solid solutions. It can be used as a matrix excipient for solid solutions. Due to the high flowability and excellent extrudability it shows superior performance in hot melt extrusion processes.

The safety of the new polymer is documented by comprehensive studies.

Even though Soluplus was developed for solid solutions it can as well be used for other applications. Beside drug layering and spray drying, it can also be applied as a binder in wet granulation or a dry binder in direct compression. Such multiple applications open the door to benefit from the solubilization capabilities of Soluplus while using it in standard processes. ■■

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FILM COATINGS

## Kollicoat® IR Coating Systems

T. Schmeller

### Kollicoat® IR

➤ Kollicoat IR is a water-soluble film former for instant release coating of pharmaceutical dosage forms. It consists of a polyvinyl alcohol polymer grafted onto polyethylene glycol (PEG-g-PVA Polymer (Figure 1) in a ratio of approximately 75 : 25. Kollicoat IR has the following major advantages:

- Water soluble polymer with low viscosity even in concentrated solutions
- Excellent mechanical properties in terms of tensile strength and elongation at break
- High elasticity to reduce the incidence of film cracking on the edges of tablets
- A PEG backbone and therefore does not require an external plasticizer
- Low tackiness
- Polymer with excellent film adherence properties to all kinds of tablet cores
- Shortened coating time due to high solids content in spray suspension
- High pigment loading capacity

Several registrations of pharmaceutical products exist, e.g. in the US, Europe, Japan and many other countries all over the world, although the product was launched only in 2003.

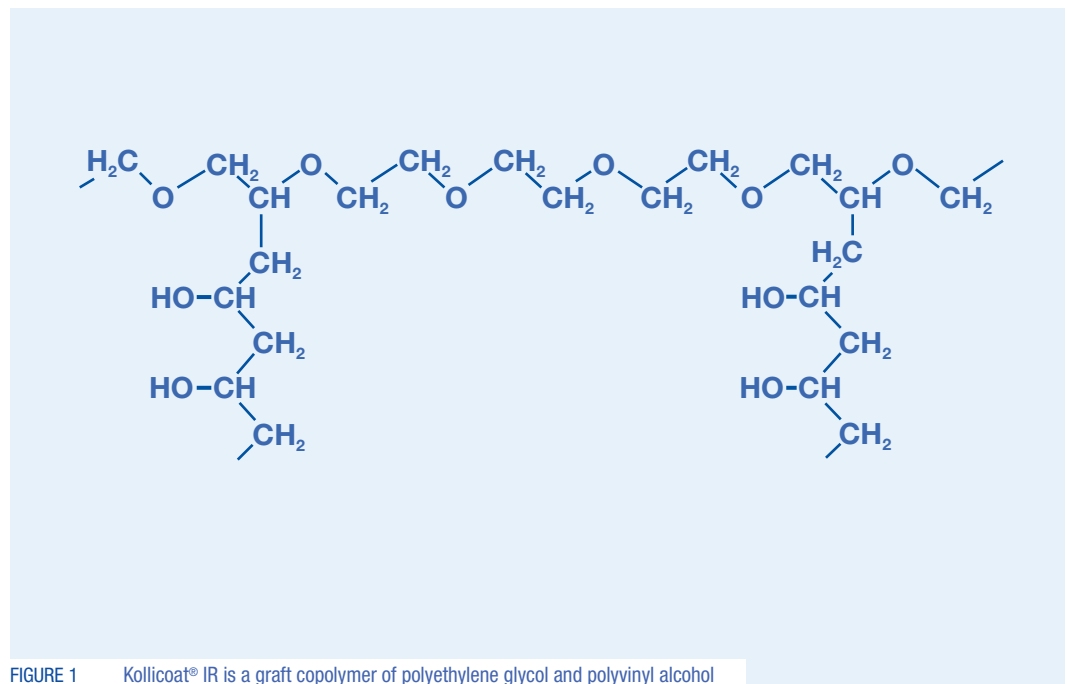


FIGURE 1 Kollicoat® IR is a graft copolymer of polyethylene glycol and polyvinyl alcohol

*Kollicoat® IR is already approved in several finished products around the globe.*

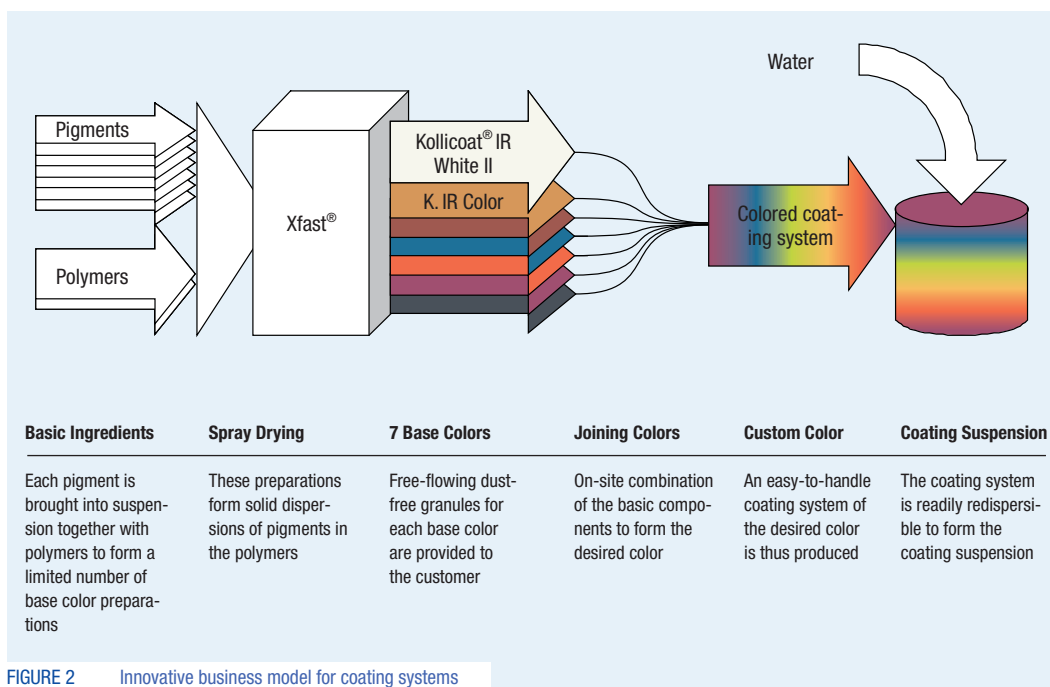


FIGURE 2 Innovative business model for coating systems

**BASF coating systems at a glance**

BASF has developed colored coating systems for instant release film-coating based on Kollicoat IR. They are free flowing, nearly dust-free and easy to re-disperse granules manufactured using BASF's Xfast® technology. The low viscosity of Kollicoat IR results in a solids content of 20 to 30% in the coating solution, which is significantly higher than with any other coating polymer.

BASF offers seven base colors, which can be combined to achieve a wide variety of different color shades (Figure 2). To support the formulation, development software was programmed, which predicts recipes of the base colors to achieve a desired color shade.

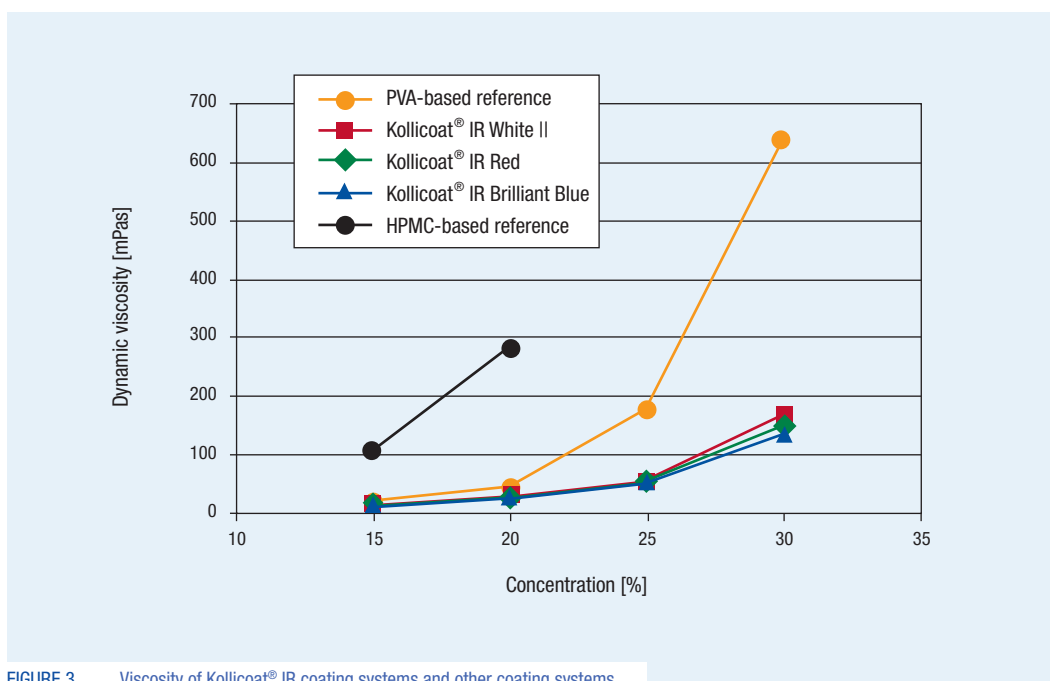


FIGURE 3 Viscosity of Kollicoat® IR coating systems and other coating systems

*Kollicoat® IR has a low viscosity at high solids contents and shortens the coating time.*

**The new line of products offers many benefits**

- Due to the low viscosity, solids contents of up to 30% can be sprayed (Figure 3), which results in significant cost savings and environmental protection. Production scale trials showed a reduction of coating time by 30 to 40%, which leads to significant savings in electrical energy. Based on the current energy mix, 1 kWh of electricity causes the emission of roughly 540 g of CO<sub>2</sub><sup>[1]</sup>. Taking a standard batch size of 300 kg into account, which is very common in the pharmaceutical industry, the CO<sub>2</sub> savings are roughly 26 kg per lot. Considering a finished product of 350 mg per tablet and two billion tablets per year, the annual savings add up to about 60 metric tons of CO<sub>2</sub><sup>[2]</sup>.
- Because of the limited number of base colors, the complexity in the supply chain is reduced, compared to individualized coating systems. Hundreds of colors can be derived from only seven base colors (Figure 4). This also enables production to respond quickly to changes in the production schedule, because no individual color shade needs to be available, but only a maximum of seven base colors.
- Due to the Xfast manufacturing process applied, products are granular, forming solid dispersions of pigments embedded in the polymer matrix.
- The granular structure results in nearly no dust (Figure 5) and excellent flow properties (average angle of repose 32°), whereas regular coating systems are very dusty.



FIGURE 4 Selection of colors derived from the seven base colors

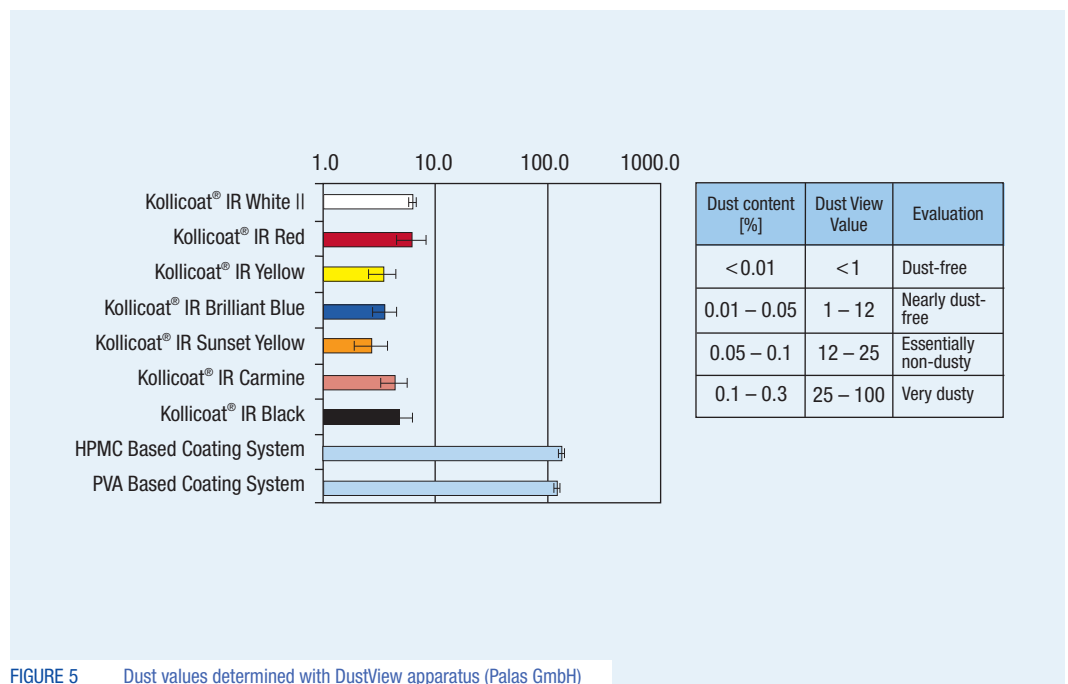


FIGURE 5 Dust values determined with DustView apparatus (Palas GmbH)

- Kollicoat IR coating systems do not require wetting and can be re-dispersed at production scale with low shear mixers within 20 minutes. They even re-disperse without stirring (Figure 6).
- Due to the large parameter room, the production process is robust and easy to scale up. Even at temperatures below 20 °C an excellent film is formed, which is of particular relevance for thermo-sensitive active ingredients. The process parameter chart<sup>[3]</sup> for Kollicoat IR White II shows these processing advantages at a glance (Figure 7):

*Handling of Kollicoat® IR coating systems is very robust, which makes scale-up easy.*

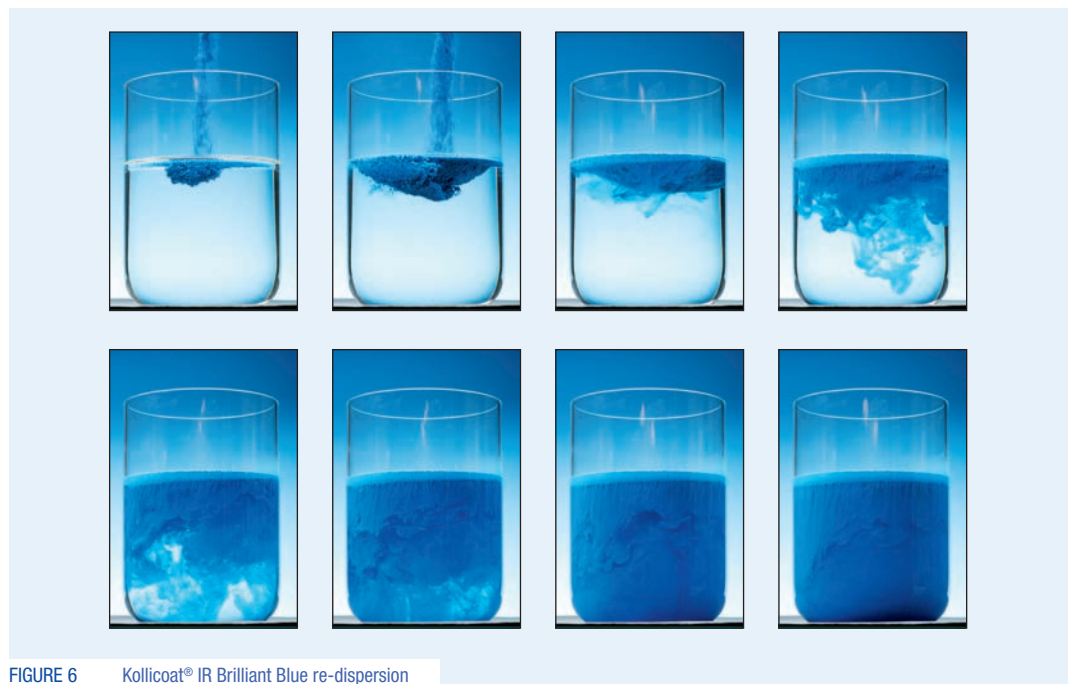


FIGURE 6 Kollicoat® IR Brilliant Blue re-dispersion

### Regulatory status

#### Kollicoat IR

Kollicoat IR was approved as coating agent in medicinal products in the U.S., the EU, and in Japan. The polymer is also approved and used as coating agent in finished products in several other countries all over the world.

A new monograph entitled “Macrogol Poly (vinylalcohol) Grafted Copolymer” has just been published in Supplement 6.7 of the European Pharmacopeia. A draft USP/NF monograph entitled “Ethylene Glycol and Vinyl Alcohol Graft Copolymer” was published in Pharmacopeial Forum 35(2).

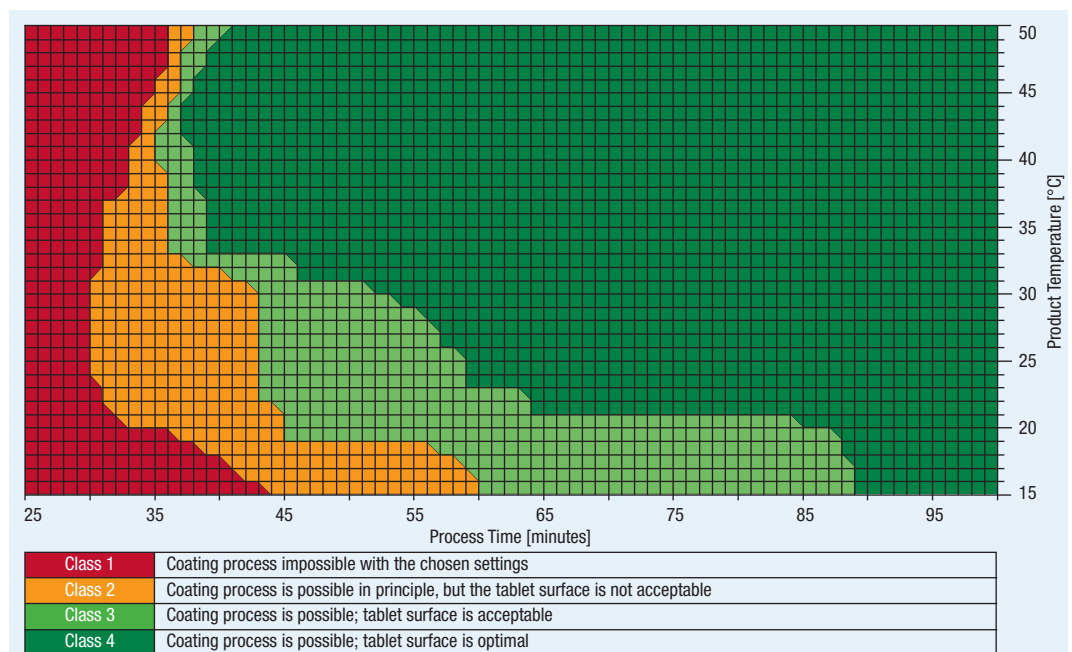


FIGURE 7 Process parameter chart for Kollicoat® IR White II

Pigment	Sunset Yellow	Carmin	Brilliant Blue	Titanium dioxide	Iron oxides
<b>E-Nos.</b>	E 110	E 120	E 133	E 171	E 172
<b>CAS-Nos.</b>	2783-94-0	1390-65-4	3844-45-9	13463-67-7	Yellow: 51274-00-1, 20344-49-4; Red: 1309-37-1; Black: 1317-61-9 12227-89-3
<b>Pharmacopoeial monographs</b>	-	JPE	-	Ph. Eur., USP, JP	USP (Ferric oxide), JPE
<b>Limits</b>					
Medicinal products (EU)	q.s.	q.s.	q.s.	q.s.	q.s.
Medicinal products (U.S.)	q.s.	q.s.	q.s.	q.s.	5 mg/d <sup>3</sup>
Medicinal products (Japan)	• 0.1% [w/w] <sup>1</sup>	• 1.8 mg/d <sup>2</sup>	• 0.1% [w/w] <sup>1</sup>	• 384 mg/d <sup>2</sup>	Red: • 95.4 mg/d <sup>2</sup> Yellow: • 5.67 mg/d <sup>2</sup> Black: • 1.539 mg/d <sup>2</sup>

<sup>1</sup> Not more than 0.1% by weight of color (lake or dye) can be used in a dosage form (MHLW's BIRYO limit on trace amounts).

<sup>2</sup> Limit acc. to the dictionary of Pharmaceutical Excipients (Japan)

<sup>3</sup> May be safely used to color ingested or topically applied drugs. Generally subject to the restriction that if the color additive is used in drugs ingested by humans, the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron per day (Code of Federal Regulations Title 21 Food and Drugs).

TABLE 1 Regulatory status of pigments used in Kollicoat® IR coating systems

## Pigments

Globally approved pigments are used in Kollicoat IR coating systems (Table 1).

## Conclusion

An innovative toolbox approach to coating systems, which provides cost savings in production, reduces supply chain complexity and offers flexibility and speed in color development. Due to these properties, the new product line helps to reduce CO<sub>2</sub> emissions and thus supports sustainability initiatives.

- Empowering formulators to create their own colors
- Immediate availability of color samples
- Confidential color matching with software support
- Very easy re-dispersion and robust handling of the products
- Significant cost savings due to production efficiency and reduced complexity
- More eco-efficient alternative compared to other products on the market ■■

## LITERATURE

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ACTIVE INGREDIENTS

## Phenylephrine from BASF: Your reliable partner for APIs for respiratory system

T. Aechtner

Further extending its API portfolio, BASF has launched Phenylephrine, an effective decongestant to treat allergic and cold indications, at CPhI worldwide. Produced under cGMP regulations BASF puts a special focus on a reliable consistent product quality in line with the highest international quality standards. With the addition of Phenylephrine, BASF complements the established portfolio for the respiratory system, e.g. Aminophylline, Benzonatate, Pseudoephedrine and Theophylline, as well as the analgesic Ibuprofen and the stimulant Caffeine.

Despite of its already long-lasting existence, the effective profile of Phenylephrine in the cough and cold medicine market makes this product an attractive choice. Although Phenylephrine has been around for a long time, its efficacy in the cough and cold medicine market makes this product an attractive choice.

Phenylephrine Hydrochloride [CAS-No: 61-76-7, (-)-(1R)-(3-Hydroxyphenyl)-2-(methylamino) ethanol Hydrochlorid, is the most utilized salt for the preparation of Phenylephrine-based pharmaceuticals.

*As technology leader with more than 50 years of experience in the production of sympathomimetic amines BASF will be a reliable new source for Phenylephrine.*



Samples of Phenylephrine from BASF

Common formulations are topical applications like eye-drops and nasal-sprays, as well as oral preparations like tablets, capsules and syrups. Typical dosage of Phenylephrine Hydrochloride for oral application is 10 mg per tablet while the daily recommended dose varies between 40 mg and 60 mg.

BASF manufactures enantiomeric pure Phenylephrine Hydrochloride in Minden, Germany. The excellent technology fit at the Minden site enables BASF to provide to customers even more product variety at competitive prices. The pharmaceutical site meets current GMP and FDA requirements and has an excellent inspection track record. The generally high standards of the Minden site combined with more than 50 years of experience as world leading producer of Pseudo-

ephedrine, another popular decongestant in our portfolio, guarantee a product of high quality.

Commercial quantities are available in 25 kg and 5 kg fiber drums with two PE-liners as inner packaging. 100 g samples are available free of charge in glass bottles.

Phenylephrine Hydrochloride will be available around the world utilizing via BASF's global distribution structure.

Regulatory documentation available from BASF are US and European Drug Master Files (DMFs), as well as a CEP (Certificate of European Pharmacopoeia, Certificate of Suitability). A Japanese DMF can be submitted on customer request. ■■

Troubleshooting – Tableting

## How to perform the loss-on-drying test reliably

T. Agnese, T. Cech, F. Wildschek

➤ In the last issues, we addressed problems related to the film coating process. This time we would like to focus on a standard testing method that is used for both powders (e.g. excipient or blends) and tablets – loss-on-drying (LOD).

This test is not only used for the quality control of incoming raw materials, but also for the characterization of powder blends during developmental work and manufacturing processes, where residual water contents of granules after wet granulation processes, for example play a decisive roll for the further processability of the product.

The LOD test is intended to determine the content of volatile matter of any kind in any solid or semi-solid material – whether it is a raw material or a blend composed of several constituents. For pharmaceutical ingredients, moisture especially in the form of freely absorbed water is the most important volatile component. Moisture content must be controlled, as it could influence the main characteristics of the material - in matters of pharmaceutical application namely the flow and compression behaviour, where certain moisture content is required for obtaining good results.

For many years, a detailed description of the LOD test was to be found in the different Pharmacopoeias. Only if a substance needed to be tested differently to that general method, this parameter was part of the individual monograph. Usually, many companies prefer to use specially designed in-house SOPs based on the method originally described in the Pharmacopoeia. As for a number of active ingredients and excipients (e.g. lactose-monohydrate) special test parameters are required, in these cases a loss of information was very likely. To guard against this mistake, the method was recently transformed into a general information by including the exact description on how to perform the test for a certain substance into its monograph. However, very often companies and laboratories did not adapt their SOPs and test programs to these changes.

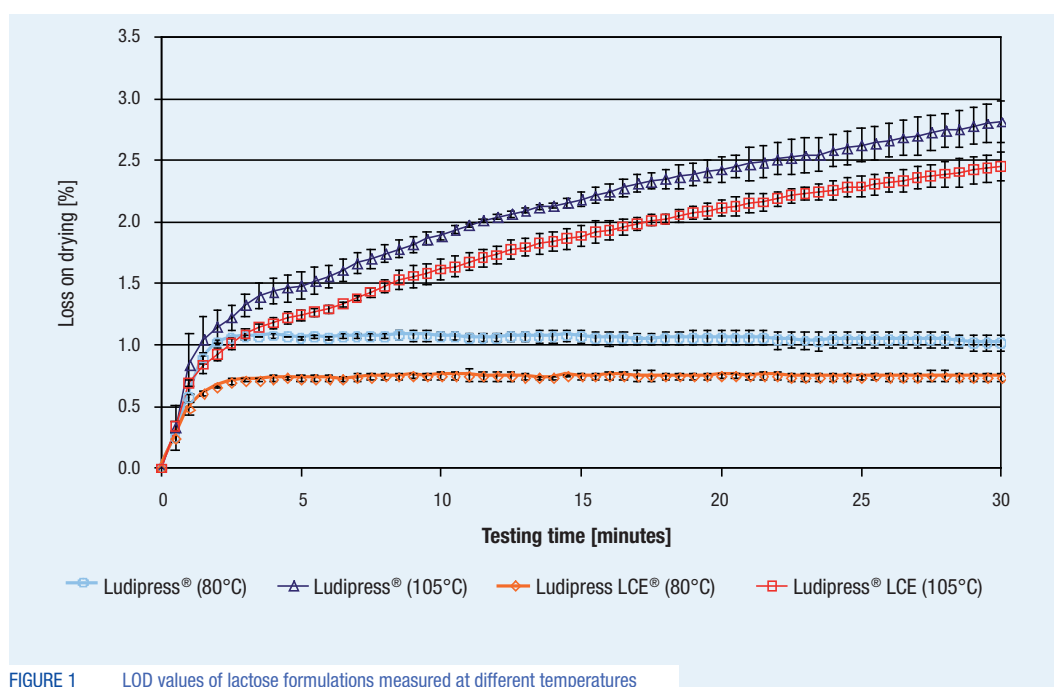


FIGURE 1 LOD values of lactose formulations measured at different temperatures

**PROBLEM | 1. Influence of the material characteristics** As already explained, LOD is the standard method for measuring volatile matter in solid or semi-solid materials. If the main volatile component of the material to be tested is known to be water, the LOD is a quick method for determining the moisture content of raw materials or powder blends, as well as granules, pellets etc. In many in-house methods for LOD, the set temperature is 105°C. Apart from absorbed water either water of crystallization or other volatile components but water, could constitute the volatile matter of the specimen under test. These non-aqueous components would most likely be evaporated at even lower temperatures (e.g. flavors, extracts). Also, if the material under test does not contain non-aqueous volatile ingredients, several problems could occur. Reasons are different levels of

energy needed to evaporate different types of moisture: Absorbed water could normally be eliminated at lower temperatures than the chemically bound water of crystallization. Ludipress® for example, is a direct compression vehicle composed of lactose-monohydrate as filler, Kollidon® 30 as binder and Kollidon CL as disintegrant. Ludipress LCE is an analog ready-to-use excipient only based on lactose-monohydrate and Kollidon 30, intended to be used for the following applications: Lozenges, chewable tablets and effervescent tablets. Figure 1 shows the results of an LOD test performed at two different temperatures. The data suggests that there are obviously different kinds of volatile matter in these specimens. At a temperature of 80°C, only the absorbed water was evaporated. Due to its hygroscopicity, PVP strongly contributes to the uptake of moisture.

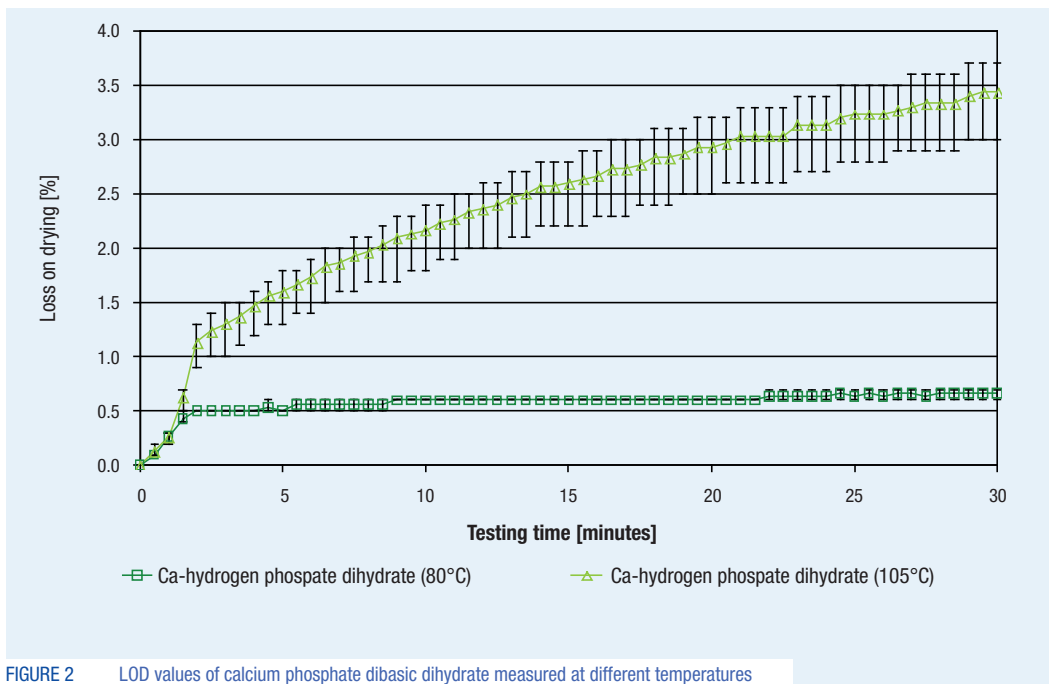


FIGURE 2 LOD values of calcium phosphate dibasic dihydrate measured at different temperatures

This is reflected by the measured LOD values of 0.5% for Ludipress LCE and 1.5% for Ludipress, which not only contains Kollidon 30, but also Kollidon CL. At a temperature of 105°C, the LOD values are on a considerably higher level for both specimens – the reason is the water of crystallization of lactose-monohydrate, which started evaporating under these conditions. However, lactose is not the only pharmaceutical excipient showing this phenomenon. Another example for the temperature dependency of the LOD test is calcium phosphate dibasic dihydrate. As this excipient contains even more water of crystallization, the effect is much more pronounced (Figure 2).

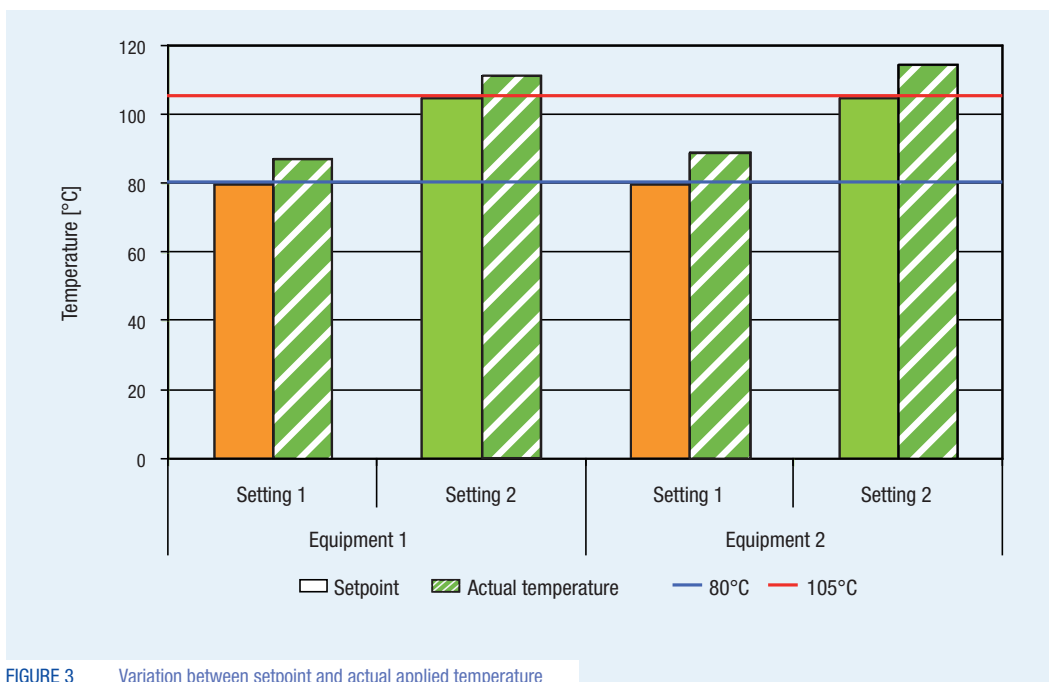


FIGURE 3 Variation between setpoint and actual applied temperature

**2. Influence of the testing equipment** Dependent on the construction of the tester, the actual temperature of the sample always differs from the setpoint. Additionally, comparing different LOD testers, a variation in the positioning of the temperature probe can be found. This leads to variations in the actual sample temperature during the test (Figure 3).

A dependency of the LOD value on the test procedure could also be found. For drying the product, the amount of applied energy is of particular importance. If a constant testing time is used (e.g. five minutes), the delivered energy could differ among the consecutive tests (Figure 4).

During the first test, energy is needed to heat up the equipment itself. Therefore, less energy is available to evaporate volatile components.

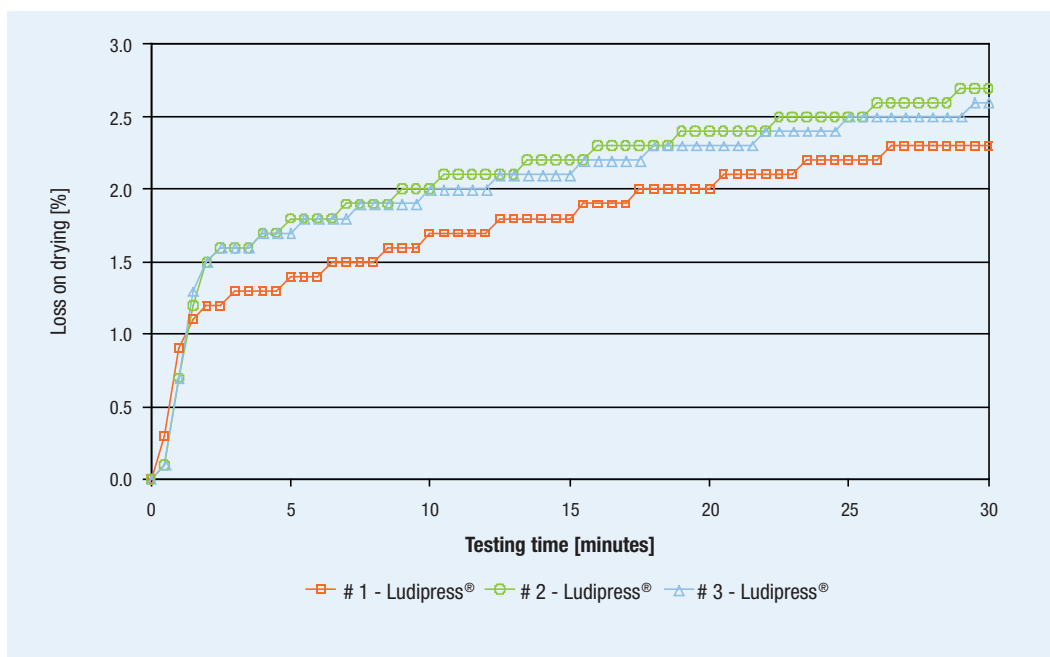


FIGURE 4 Three measurements of a Ludipress® sample, showing the dependency of result on the pre-heating of the testing equipment

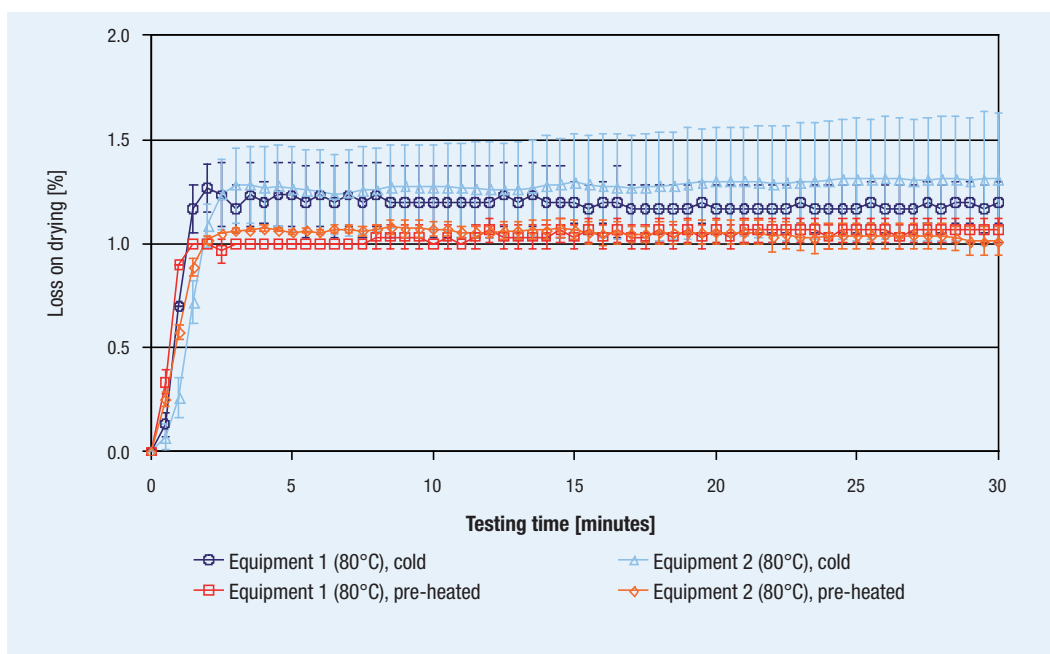


FIGURE 5 Difference in result and standard deviation comparing measurements with and without pre-heating

This leads to a lower LOD value in the first test, whereas in trials two and three – when the equipment runs at the set temperature – the measured values were comparable.

The fact, that the pre-heating is clearly influencing the obtained result of the LOD test is illustrated by Figure 5. As it is difficult to supply the same amount of energy to the sample while the equipment is heating up, the error bars are larger when the test is started without pre-heating.

**SOLUTION** | For the determination of volatile matter of any material containing water of crystallization, the LOD test should be performed at temperatures below 105°C, to avoid the evaporation of chemically bound water. This is especially recommended for powder blends to be transferred to the tableting process, as the content of free water is important for appraising the tableting characteristics for the matter under test.

*Careful selection of the drying temperature and tempering of the equipment can improve the accuracy of loss-on-drying test results.*

If tests are to be conducted in different labs or different sites, the type of equipment has to be considered as well. As LOD testers vary in their construction, diverse results can be obtained even when the same temperature settings are used. To gain comparable results, it might be worth considering different temperature settings at different testers to adjust same amounts of energy applied to the sample.

To assure reliable results, the testing equipment should always be pre-heated before performing tests. Most testers allow setting a standby temperature in the range of 40 to 100°C. ■■

## UPDATE REGULATORY AFFAIRS

Substance-/monograph name: BASF-product name (If different from substance name)

- Ph.Eur. monograph Kollicoat® IR "Macrogol Poly(Vinyl Alcohol) Grafted Copolymer, Ph.Eur. 6.7
- USP/NF draft monograph Kollicoat® MAE 100 P "Partially Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer" will be published in Pharmacopeial Forum 35 (5)
- Amylmetacresol monograph published in Pharmeuropa 21.1
- New US DMF Ludipress®, DMF # 22948
- New CEP Oxymetazoline hydrochloride R0-CEP 2008-064
- NEW CEP for Kollidon® 12 PF and Kollidon® 17 PF: Povidone 'nominal K-value 12' & Povidone 'nominal K-value 17' R0-CEP 2007-077
- Phenylephrine Hydrochloride  
The Applicant's Part of the E-DMF is available on request.  
A Certificate of Suitability of the European Pharmacopoeia (CEP) has been applied for.  
A US-DMF has been filed with the FDA.

 **CALENDAR**

**November 8-12, 2009\***  
AAPS Annual Meeting and Exposition  
Los Angeles, CA, USA

**November 10-15, 2009**  
2nd International Congress  
on Biohydrogel  
Viareggio, Italy

**March 8-11, 2010**  
7th World Meeting on Pharmaceutics,  
Biopharmaceutics  
and Pharmaceutical Technology  
Valetta, Malta

**July 10-14, 2010\***  
The 37th Annual Meeting and Exposition of  
the Controlled Release Society  
Portland, Oregon, USA

**November 14-18, 2010\***  
AAPS Annual Meeting and Exposition  
New Orleans, Louisiana, USA

**July 30-August 3, 2011\***  
The 38th Annual Meeting and Exposition of  
the Controlled Release Society  
National Harbor, Maryland, USA

\* BASF participation

 **PREVIEW**

## Formulation opportunities in hot melt extrusion

Hot melt extrusion was presented in issue 22 of ExAct. While that article dealt mainly with the principle of hot melt extrusion and the suitability of various polymers for this process, the one in our next issue of ExAct will cover more specific topics: combinations of polymers with certain plasticizers or other polymers and the impact of active ingredients. The basic questions to be answered are: How are formulation properties changed by certain additives, and what can be used in order to achieve particular characteristics either during processing or in the final formulation? These findings should enable drug developers to design suitable and robust formulations, optimize them and speed up the development process.

 **CONTACT**

### What opportunities can we open up for you?

Would you like to discuss a particular challenge or product in more detail? Or do you have any questions? Simply call or e-mail us. We would be glad to help.

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