

A photograph of the Great Wall of China winding through green hills under a clear blue sky.

Traditional Medicine meets modern excipients

We shape your traditional formulations

Dr. Kathrin Meyer-Boehm and Kevin Wang (BASF China),
two enablers in excipients



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Exceptional excipients for traditional formulations



“I grew up with Traditional Medicine, and I want to make sure it continues to flourish in the 21st century and beyond. But to achieve this, we must embrace the potential of innovative and modern excipients – without sacrificing the values of Traditional Medicine...”

...explains Kevin Wang, a BASF enabler. He knows that to ensure the success of Traditional Medicine products in today's market, manufacturers must enhance the unique benefits of their formulations with cutting-edge excipients. Together with his colleagues at BASF Asia Pacific, Mr. Wang explores how exceptional products such as high-performance solubilizers, innovative taste-masking and protective coatings, and effective disintegrants can revolutionize traditional products and enhance patient compliance – opening up a whole new world of opportunities.

Traditional Medicine: founded on tradition – but with an eye to the future

With a rich history spanning thousands of years, Traditional Chinese Medicine has had a major influence on medical practice around the world – from Kampo in Japan or Jamu in Indonesia to traditional Korean medicine. Recent years have seen renewed interest in traditional formulations from all four corners of the globe, making herbal remedies more popular than ever before.



But if these products are to secure and expand their market position, they must respond to today's challenges – as Professor Ping Qineng, Dean Emeritus of the School of Pharmacy at China Pharmaceutical University and Former Vice Director of Pharmaceutics Discipline for the China Pharmaceutical Association, explains:

“Traditional formulations need special care. The unique properties of traditional herbals are one of the biggest challenges faced by formulators: it is essential to use modern technologies and excipients in order to meet patients' needs.”

Traditional Medicine: overcoming the challenges

In order to perform to their full potential, Traditional Medicine products must surmount a number of obstacles. Because traditional formulations demand high concentrations of natural ingredients, the excipients used must be effective in small doses. Poor solubility and long disintegration times can impede the delivery speed of active ingredients, while high stickiness and viscosity can create problems when processing herbal extracts. Moreover, effective taste masking and color coating are a must in order to ensure patient compliance. But whatever the challenge, BASF has a solution: read on to find out more.



How innovative excipients can revolutionize Traditional Medicine

Traditional herbals: challenging properties

- Poorly soluble
- Moisture sensitive
- Unpleasant taste or odor
- Dark, uneven coloring
- Heat sensitive
- pH sensitive

Traditional Medicine: formulation challenges

- High dosage of natural ingredients
- High viscosity of herbal extracts
- Extreme stickiness of herbal extracts
- Poor disintegration of formulations
- Moisture sensitivity of formulations
- Unpleasant taste or odor of formulations

High-performance excipients for Traditional Medicine

BASF excipients turn traditional formulations into modern solid oral dosage forms (SODFs), offering:

- Tailor-made solutions for reformulating traditional products
- Exceptionally easy-to-process excipients
- More efficient production and lower costs
- Improved biocompatibility

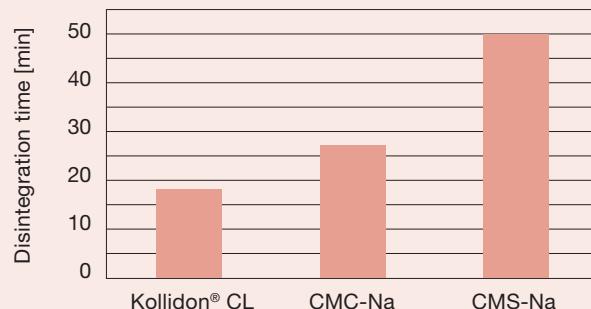
The challenges faced by Traditional Medicine – and BASF's solutions

A

Solutions for rapid disintegration

When it comes to Traditional Medicine tablets, the large volume of herbals required can limit the amount of excipients that can be added. Which means the disintegrant used must be highly effective if the desired disintegration time is to be achieved. Where standard disintegrants often fall short, BASF's **Kollidon® CL** delivers real results. In the test depicted in this graphic, Kollidon® CL produced the highest disintegration speed (18 minutes) – 50 percent faster than croscarmellose sodium (CMC-Na: 27 minutes) and almost three times faster than sodium starch glycolate (CMS-Na: 50 minutes).

Disintegration time of Traditional Medicine tablets featuring various disintegrants (concentration of disintegrant: 15 %)



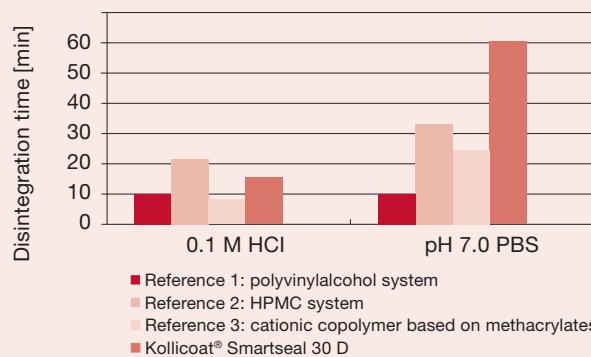
Comparing the efficiency of disintegrants in Traditional Medicine tablets

B

Solutions for reliable taste masking

Delivering effective protection from bitter tastes or unpleasant odors can often present a challenge when formulating Traditional Medicine tablets. **Kollicoat® Smartseal 30 D** offers a solution, ensuring effective taste masking without compromising on the release times of active ingredients once swallowed. In the example given here, when applied to green tea tablets, Kollicoat® Smartseal 30 D provided the greatest protection in the mouth (pH 7) yet rapid disintegration in the stomach (pH 1) – even after 10 days stored under stressed conditions.

Impact of various coating excipients on disintegration of green tea tablets (coating level 4.5mg/cm², 10 days, stressed conditions)



Disintegration of green tea tablets in HCl and phosphate buffer system pH 7

C

Solutions for robust protection

When exposed to moisture, tablet cores can swell and coatings can crack. The outstanding film flexibility offered by **Kollicoat® Protect** delivers exceptional moisture protection and prevents tablet damage.

The pictures shown here compare a HPMC instant-release coating with Kollicoat® Protect: the HPMC coating has buckled under the pressure of 14 days' storage, whereas Kollicoat® Protect remains perfectly intact.



Instant-release reference



Kollicoat® Protect

After 14 days' storage at 40°C/75 % humidity

D

Solutions for biocompatible reformulation

Adverse reactions to Traditional Chinese Medicine injections have prompted the Chinese State Food and Drug Administration (SFDA) to call for a re-evaluation of formulations and production processes as a prerequisite for market approval. BASF can help you re-formulate your traditional injections, using solubilizers such as **Kolliphor® HS 15**. "When used in asarone injections, the solubilization capacity of Kolliphor® HS 15 is comparable with polysorbate 80. Yet the histamine release profile of Kolliphor® HS 15 is similar to saline, leading to the conclusion that Kolliphor® HS 15 is more biocompatible," states Prof. Gong Tao, West China School of Pharmacy at Sichuan University.

Test material	Histamine release level [ug/l]
Marketed product containing polysorbate 80	15-16
Egg white as positive reference	15-16
Injection formulation containing Kolliphor® HS 15	11-12
Saline	11-12

Source: Prof. Gong Tao, West China School of Pharmacy, Sichuan University, Chengdu, China

Whatever the challenge, BASF has the perfect solution for Traditional Medicine formulations

Disintegration

Achieve your target disintegration times – with **Kollidon® CL grades**.

Kollidon® CL is the industry's widest portfolio of superdisintegrants and disintegration enhancers. These highly functional cross-linked PVP polymers ensure that active ingredients are released from any solid dosage form at exceptionally high speed.

Color coatings

Create your own colors to cover dark herbs – with **Kollicoat® IR Coating Systems**.

Distinctive coloring, robust, and rapidly soluble: Kollicoat® IR Coating Systems allow you to create tablet coatings in countless shades, using only seven base colors. The high-quality, flexible and efficient coatings are based on Kollicoat® IR, a polyvinyl alcohol-polyethylene glycol graft copolymer.



Taste masking

Cover the bitter taste of herbal formulations – with **Kollicoat® Smartseal 30 D**.

Kollicoat® Smartseal 30 D effectively protects bitter and moisture-sensitive ingredients: it remains stable in saliva yet ensures rapid release of active ingredients in the acidic environment of the stomach.

Solubilization

Overcome the poor solubility of Traditional Medicine – with **Soluplus®** and **Kolliwax®**, **Kolliphor®**, **Kollisolv®**, and **Kolicream®** grades.

Our extensive portfolio of solubilizers and cosolvents is designed for all common dosage forms, including solids, liquids and semi-solids. It delivers effective solutions for formulating Traditional Medicine injections, creams, tablets, extrudates and more.



Granulation

Granulate herbal powders before direct tablet compression – with binders such as **Kollidon® grades**, **Kollicoat® IR** and **Kollicoat® IR Coating Systems**.

Kollidon® grades can be used as a dry binder for direct compression tableting and as a soluble binder for granulation. Their exceptional binding properties make them an attractive and cost-effective alternative to natural binders.

Clear and flexible coatings

Achieve a clear and flexible coating without requiring an additional plasticizer – with **Kollicoat® IR** and **Kollicoat® Protect**.

Kollicoat® IR and Kollicoat® Protect are water-soluble film-forming agents ideal for manufacturing instant-release coatings for solid dosage forms. Robust yet flexible, they can be sprayed quickly and easily thanks to their high pigment-binding capacity.

Moisture protection

Protect sensitive natural ingredients from moisture and ensure performance in solid oral dosage forms – with **Kollicoat® Protect** and **Kollicoat® Smartseal 30 D**.

Kollicoat® Protect is a highly flexible, easy-to-handle water-soluble film former that requires no plasticizer. When used with pigments, it acts as an effective moisture barrier – providing robust, reliable protection for active ingredients. Kollicoat® Smartseal 30 D, a film former that is soluble in gastric fluid, is a further option for creating a highly impermeable water barrier.

Sustained release

Create custom sustained-release profiles for your herbal formulations – with **Kollicoat® SR 30 D**, and combinations of **Kollicoat® SR 30 D** and **Kollicoat® IR**.

No matter what the dosage form, Kollicoat® SR 30 D enables pH-independent release of active ingredients, with precisely the delay required. Combining the water-insoluble Kollicoat® SR 30 D with the water-soluble polymer Kollicoat® IR gives you even greater flexibility when it comes to creating custom dissolution profiles.

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Taking tradition into the future. Tap into the benefits of BASF excipients for your traditional formulations:

- Tailor-made solutions for reformulating traditional products
- Exceptionally easy-to-process excipients
- More efficient production and lower costs
- Improved biocompatibility

BASF would like to thank our partners for their valuable contributions:



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