

**CASE STUDY | ORAL DOSAGE****Immediate release film coating system for heat sensitive oral dosage forms****SITUATION**

Immediate release coating of oral dosage serves a multitude of purposes. Coating masks unpleasant taste or odor of tablet contents, which increases patient compliance and facilitates swallowing. It also increases stability, improves appearance, and creates a unique look for identification. At present, polymer-based systems are widely used by the pharmaceutical industry for film-coating of oral dosage forms. To achieve proper film formation and acceptable processing time, the coating suspension should be supplied at high solid content.

For this reason, commercially available polymer-based coating systems, for example containing HydroxyPropyl Methyl Cellulose (HPMC) or Poly Vinyl Acetate (PVA), are prepared with an organic co-solvent or by heating (bed temperature above 34 °C). Organic solvents are not favored due to add-on product cost, induced by compliance with environmental and OSHA regulations. Furthermore, tablets containing heat sensitive excipients cannot withstand heating conditions without undergoing chemical or physical degradation.

**CHALLENGE**

Water-soluble formulations allowing film coating at low bed temperature is in great need for oral dosage forms containing heat sensitive actives or excipients, as well as ingredients that melt or which solubility drastically increases with temperature.

**SOLUTION**

Fully formulated ready-to-use system: ReadilyCOAT® is a homogeneous blend of plant-derived LYCOAT® RS (modified pregelatinized pea starch polymer), plasticizer, and other additives.

ReadilyCOAT® is a breakthrough in film-coating for heat-sensitive products, offering a practical solution for tablet film-coating at low bed temperature.

**ReadilyCOAT® ready-to-use system key benefits:**

- Superior aqueous film coating at low bed temperature: ReadilyCOAT® foam and lump-free aqueous suspension can be prepared in minutes at high solid content, due to low viscosity; no heating or organic co-solvent required. ReadilyCOAT® creates high quality tablet coating even at low tablet bed temperature and reduced coating time, using standard equipment.
- Patient and regulatory compliance: Compared to synthetic or highly modified polymers, LYCOAT® RS, modified pregelatinized pea starch polymer has a pleasant neutral odor and taste LYCOAT® RS is hypoallergenic (non-animal origin; made from non-GMO gluten-free pea), inert, biocompatible and biodegradable. ReadilyCOAT® compositions meet regulatory requirements of major markets for pharmaceutical and dietary applications.

## RESULTS

### 1. Film-coating of tablets containing heat-sensitive ingredients at room temperature by ReadilyCOAT®, ready-to-use system resulted in stable product:

- **Chemical Stability:**  
Heat-sensitive active (unstable at temperature higher than 30°C) was chemically unchanged for the low-temperature coated tablets, while it was out of specification for tablets coated at elevated temperature of 35°C.
- **Physical Stability:**  
Shape of tablets containing lipid excipient was unaffected at a low-temperature coating, while those coated in standard conditions lost their shape due to excipient melting at 35°C. Logos on tablets containing highly soluble excipient sorbitol disappeared partially (figure) upon coating at 35°C (sorbitol solubility drastically increases at elevated temperatures). Sorbitol-based tablets coated at ambient (room) temperature kept imprinted logos unchanged.



Tablets containing sorbitol coated at 18°C (left) and 35°C (right).

### 2. Appealing tablet film coating was achieved at a tablet bed temperature below 22°C within acceptable production time of 1-1.5 hours (spray time) for a batch size up to 35 kg:

Standard equipment with fully perforated coating pan was used. Water as a lone solvent was applied throughout the process, improving manufacturing safety and decreasing environmental impact, as well as easing equipment clean up, and consequently cost of production.

Batch size	0.9 kg	2.5 kg	35 kg
Product Bed Temperature	17°C	19-22°C	20°C
Final Coating	3%	4%	4%
Spray Time	65 min	63.3 min	89.5 min
Equipment Used	Labcoat M, O'Hare	LDCS, freund Vector	VHC-5811, Freund-Vector

Select coating parameters listed for film-coating with ReadilyCOAT® at 20% dry substance

### 3. Excellent visual appearance and physical traits of the ReadilyCOAT®, ready-to-use system, film-coated tablets were achieved at low bed temperature (below 22°C):

- No visual defects detected (tablet shape retained, logos unaffected),
- Tablets were glossy strong coating achieved (no edge chipping, measured by friability testing with 0% weight loss),
- Ideal coating solution for immediate release dosage forms (disintegration time of coated tablets was only slightly above uncoated, variation in time < 80 sec between coated and uncoated tablets).

## CONCLUSION

Heat can be a factor or a catalyzer of degradation of many ingredients. LYCOAT®, modified pregelatinized pea starch polymer and ReadilyCOAT®, ready-to-use system, are coating solutions that ensure the stability of a heat sensitive formulation. LYCOAT® and ReadilyCOAT® can prevent the use of organic solvents while providing an uncompromised quality coating achieved with a cost efficient coating process.

## REFERENCES

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2. Smith TJ., Crawford R., Popescu C., Le Bihan G., Croquet S., Parissaux X., Lefevre P., Eye on excipients. *Tablets & Capsules*. 2017:41-44
3. LYCOAT® and ReadilyCOAT® specs: <https://www.roquette.com/pharma/selected-solutions/pharma-lycoat/>