

# Aqueous Shellac Coatings with Effective Taste Masking and Stable Release Properties

**Dana Moseson**

tdmoseson@emersonresources.com

Ryan Mulcrone

Stephen Levine

Nicolas Kirkland

Terry Smith

## PURPOSE

To demonstrate effective taste masking and stable release properties of clear aqueous shellac coatings. Historically, bleached shellac and shellac applied from solvents are known to slow release profiles due to cross-linking and esterification.

## METHODS

Ranitidine HCl 150mg tablets were coated to 1.5% weight gain with formulations consisting of hypromellose 6 cps and aqueous shellac (Marcoat 125) at a ratio of 3 to 1, talc at 9% of the combined polymer, and either polyethylene glycol (PEG) 400 or triacetin (TA) at 12% of the combined polymer. Two HPMC-only control formulations were prepared with PEG 400 at 12% of the polymer and talc at 0% and 9% of the polymer. Taste masking was assessed for test and control formulations by 10 panelists with responses given in seconds until unpleasant taste was detected. Formulations were stored in induction sealed bottles without desiccant at controlled room temperature 25°C/60% RH and accelerated 40°C/75% RH storage conditions and evaluated for dissolution and disintegration according to USP <711> and USP <701>. The USP monograph for Ranitidine tablets requires NLT 80% dissolution in 45 minutes.

Formulation Component	Coatings with Shellac/PEG	Coatings with Shellac/TA	Control 1 (No Shellac)	Control 2 (No Shellac)
Hydroxypropyl Methylcellulose, 6cps	61.9%	61.9%	89.3%	82.7%
Aqueous Shellac (Marcoat 125)	20.6%	20.6%	20	20
Talc	7.6%	7.6%	—	7.4%
Polyethylene glycol 400	9.9%	—	10.7%	9.9%
Triacetin	—	7.4%	—	—

## RESULTS

When assessed for taste masking, the control formulations delayed an average of 7.4 seconds until unpleasant taste was detected. The shellac formulations with triacetin and PEG 400 delayed detection of unpleasant taste by 40%. The control formulations were at 90% dissolution in 45 minutes, meeting the USP dissolution criteria upon initial testing. The shellac formulation with triacetin stored in accelerated conditions was at 90%, 86%, 85% and 90% dissolution at 0, 1, 3 and 6 months. The shellac formulation with PEG 400 stored in accelerated conditions was at 87%, 98%, 91% and 89% dissolution at 0, 1, 3 and 6 months. The control formulations with or without talc are completely disintegrated in 10.2 and 10.5 minutes upon initial testing. After 0, 3, and 6 months in controlled room temperature conditions, the shellac formulation with triacetin completes disintegration in 10.0, 11.1, and 11.4 minutes; the shellac formulation with PEG 400 completes disintegration in 12.8, 10.7, and 13.0 minutes.

## CONCLUSIONS

Aqueous shellac coatings can be prepared with stable release and effective taste masking properties.

