Methodology and Results of Taste Masking Study of Aqueous Shellac Coatings Using Design of Experiments

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PURPOSE

To demonstrate taste masking properties of clear aqueous shellac coating systems.

METHODS

A user defined, quadratic model of 40 experiments was designed with the use of Design-Expert 7 (Stat-Ease). The model is a mixture consisting of 4 formulation variables and one categorical variable: (1) hypromellose 6 cps (HPMC), (2) aqueous shellac (Marcoat 125), (3) talc, and (4) plasticizer type: polyethylene glycol (PEG) 400, triacetin, or glycerin. The HPMC to shellac ranged from 3:1 to 1.3:1. A control formulation was prepared with HPMC and PEG 400 only.

Film Component	DOE (%w/w)	Control (%w/w)
Hydroxypropyl Methylcellulose, 6cps	43-72	89.3
Aqueous Shellac (Marcoat 125)	20-40	—
Talc	0-12	—
Plasticizer (Polyethylene Glycol 400, Triacetin, Glycerin)	4-14	10.7 (PEG 400)
TOTAL	100	100

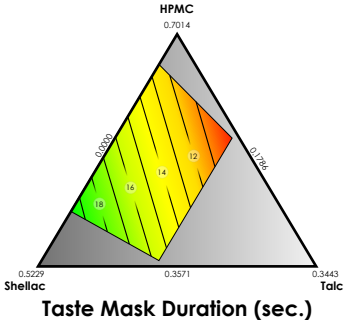
Analysis of Variation (ANOVA) For Taste Mask Duration

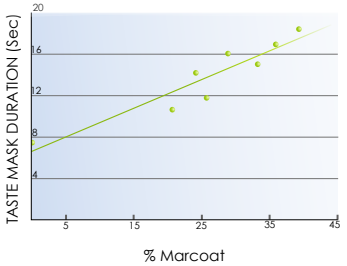
	Sum of Squares	df	Mean Square	F Value	p-value > (Prob F)	
Model (Linear Mixture)	155.82	3	51.94	9.88	<0.0001	significant
Lack of Fit	163.80	31	5.28	1.04	0.5431	not significant

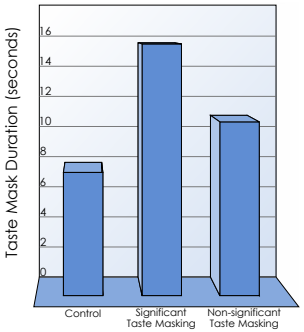
All formulations were prepared to 1.5% weight gain on Ranitidine HCl 150 mg tablets. Formulations were randomly tasted by ten (10) panelists with responses given in seconds until unpleasant taste was detected. Panelists were provided water and unsalted crackers between each test, and only permitted to taste six samples per day. Statistical outliers were removed from the data sets and a two-tailed t-tests were performed to determine if the formulation had statistically significant ($p<0.05$) taste masking properties.

RESULTS

The control formulation delayed an average of 7.7 seconds until unpleasant taste was detected. The Design of Experiments analysis confirmed a strong correlation between shellac level and duration of taste mask. Levels of HPMC, talc, and plasticizer as well as plasticizer type had minimal or slightly negative impact on duration of taste mask. Based on the t-test, formulations with statistical significance had an average taste mask duration of 15.6 seconds; non-significant formulations had an average taste mask duration of 10.8 seconds. The maximum duration of taste mask was 21.2 seconds.







CONCLUSIONS

Aqueous shellac coating systems can create effective taste masking.

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