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Introduction:

Semisolid preparations in the form of creams, ointments, and gels make up a large portion of compounded prescriptions. As time saving measures, various mixing mechanisms have been developed to aid the compounder in creating homogenous and elegant preparations in the shortest possible amount of time. Though time saving is a key goal of these technologies, homogeneity is necessary to ensure the patient gets an accurate and repeatable dose with each applicaton of the resultant semisolid preparaton.

The FagronLab™ PM140 is a new planetary mixing device from FagronLab. It mixes through a combination of spinning and rotation in an enclosed environment. Unlike other technologies, such as Unguator or EMP devices, the FagronLab™ PM140 mixing mechanism results in dearration of the contained preparation. This dearration is especially beneficial for preparations that have a tendency to take on air during high shear mixing proceses.

Evaluation of creams, gels, ointments, and even viscous suspensions mixed on the FagronLab™ PM140 have yielded smooth, dearrated and apparently homogenous preparations in the lab at a variety of mixing times. In order to demonstrate the suitability of the FagronLab™ PM140 mixing mechanism, we set out to validate a mixing time for hormone containing preparations in the FagronLab™ PM140.

Selecting a preparation:

In order to validate a mixing method, we first wanted to select an active pharmaceutical ingredient (API) that is commonly used across a wide range of concentrations. We also wanted to test a worst-case scenario of a powder being added directly to a cream base with no wetting agent to facilitate easier mixing of the product into the cream base.

For this reason progesterone was selected as the API of choice in our HRT Heavy cream base. The concentrations chosen for our high and low mixing study evaluation are as below:

Progesterone 1mg/g Cream (HRT Heavy)
Progesterone 200mg/g Cream (HRT Heavy)

Procedure:

Hormone creams were prepared in FagronLab™ PM140 jars using the sandwich method (approximately half of total cream on the bottom of the jar to cover the bottom, API in the middle, and remaining cream on top). Two samples were prepared using this method for each concentration for a total of 4 samples. One preparation at each concentration was mixed on the FagronLab™ PM140, one for 3 minutes and one for 5 mintues. The samples were then submitted to an FDA registered, cGMP compliant independent laboratory for testing.

Testing was performed by pulling three samples from different sections of each preparation and using a stability indicating HPLC method to test for potency. Uniformity of dosage forms and homogeneity is generally calculated as relative standard deviation (RSD), which serves to inform us how different the values in a particular data set are relative to the mean. In order to demonstrate homogeneity, the goal was to achieve an RSD of 3% or less.

Results:

Progesterone 1mg/g – 3 Minute Mix

Sample Number	Concentration (mg/g)	% Label Claim
1	1.013	101.3
2	1.022	102.2
3	1.012	101.2
RSD	0.54%	

Progesterone 1mg/g – 5 Minute Mix

Sample Number	Concentration (mg/g)	% Label Claim
1	1.067	106.7
2	1.047	104.7
3	1.061	106.1
RSD	0.97%	

Progesterone 200mg/g – 3 Minute Mix

Sample Number	Concentration (mg/g)	% Label Claim
1	209.7	104.9
2	205.3	102.7
3	204.6	102.3
RSD	1.34%	

Progesterone 200mg/g – 5 Minute Mix

Sample Number	Concentration (mg/g)	% Label Claim
1	205.4	102.7
2	202.8	101.4
3	202.9	101.5
RSD	0.72%	

Discussion:

Both the 3 minute and 5 minute mixing times were sufficient to mix progesterone 1mg/g and progesterone 200mg/g to attain an RSD of less than our target maximum value of 3%. Furthermore, all concentrations and mixing parameters resulted in RSD of less than 2% and the 5 minute mix resulted in an RSD less than 1% for both concentrations. These findings support the utility of the FagronLab™ PM140 as a mixing device across a wide range of concentrations even in the worst-case scenario of absence of solvent and suggest that either a 3 minute or 5 minute mixing procedure is valid for low and high concentration hormone preparations.

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!