



PURPOSE

Talc has been traditionally used as an anti-tack agent in various immediate release and enteric coating formulations. However, it is subject to sedimentation and may cause system instability. Sedimentation of talc can lead to process concerns such as gun clogging which may lead to frequent process interruptions. The objective of this study was to determine the feasibility of formulating a ready mixed immediate release coating system containing polymer, plasticizer, and a non-talc anti-adherent agent. The experiments mentioned in the article demonstrate the possibility of using capric glycerides as the non-talc anti-tack agent.

OBJECTIVE

To determine the feasibility of formulating a ready mixed immediate release coating system containing polymer, plasticizer, and a non-talc anti-adherent agent. The experiments mentioned in the article demonstrate the possibility of using capric glycerides as the non-talc anti tack agent.

METHODS

3.1 Coating formulation preparation

PVA based coating formulations were formulated with either talc or capric glycerides as anti-tack agents. Laboratory scale mixers were used to prepare the coating formulations. The ingredients were added and blended together in the mixer until uniform powder blends were obtained.

3.2 Coating suspension preparation and tablet coating

Suspensions of both coating formulations were prepared using a laboratory scale stirrer. These were found to be smooth and sprayable. Plain placebo tablets were coated using these suspensions in a 6 inch conventional coating pan with pre-determined coating parameters.

3.3 Evaluation of coated tablets and stability studies

Coated tablets were evaluated for appearance, disintegration time and coating defects.

The appearance and disintegration characteristics of the coated tablets from both the formulations were comparable. Coated tablets of the talc based formulations were slightly better in terms of gloss than the capric glyceride based formulations. No coating process related issues were observed with either system during the coating process.

Table No. 1. Coating Process Parameters

Parameters	Values
Inlet Air Temp. (°C)	65-70
Product Bed Temp. (°C)	42-45
Atomizing air pressure (bar)	1.2
Pan speed (rpm)	40-50
Peristaltic pump speed (rpm)	0-1
Nozzle Bore (mm)	1
Baffles (No.)	3
Spray Gun	Binks
Spray rate (gm/min.)	2-4
Weight gain (%)	2.5-3

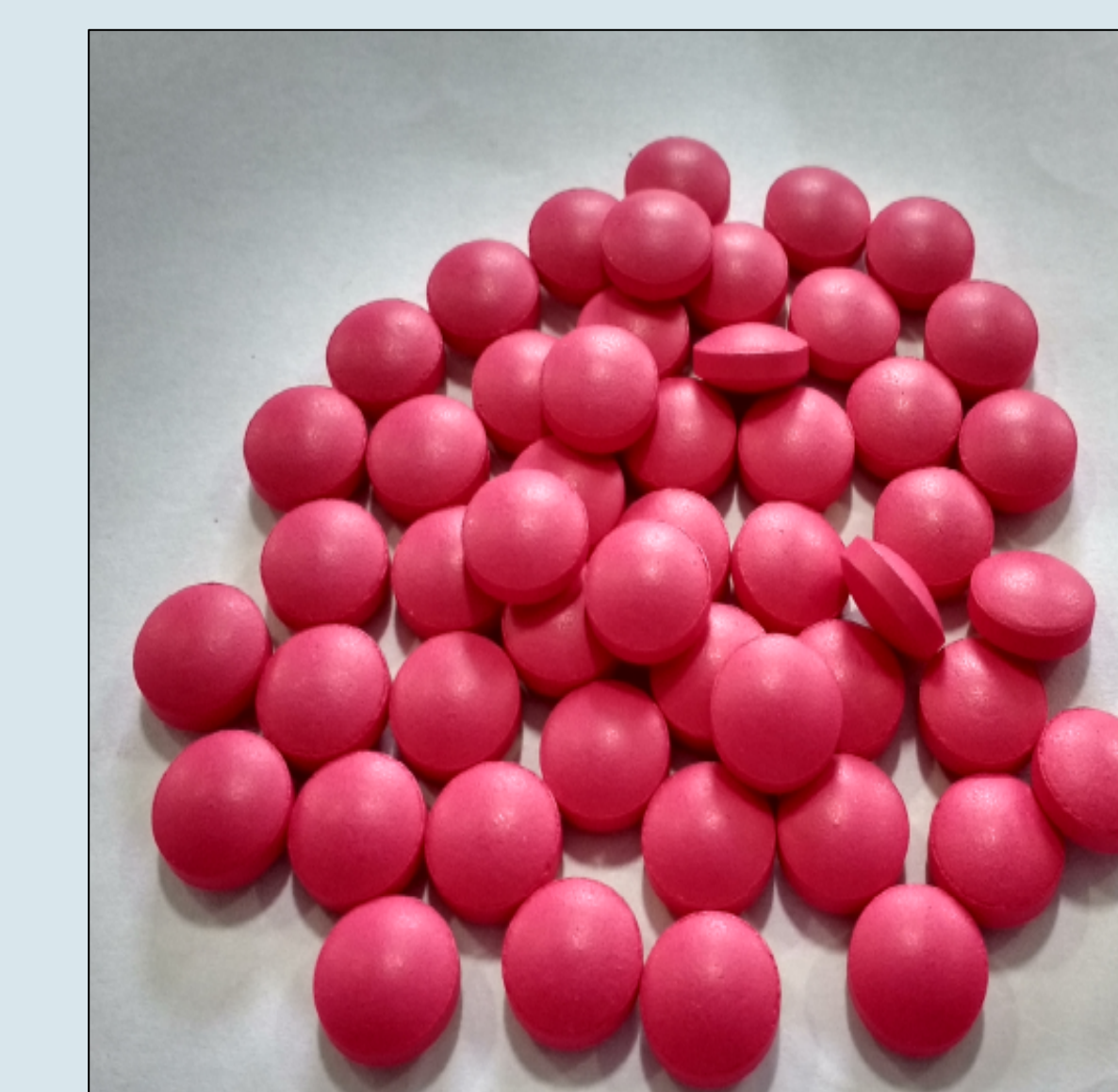


Fig.No.1 Coated tablet with Talc Formulation Fig.No.2 Coated tablet with Capric Glycerides Formulation)

RESULTS

Coating suspensions that had been reconstituted at 20 % w/w were found to be smooth and possess good sprayability. No coating issues were observed during the coating process. In all trials, coated tablet surfaces were found to be good. The appearance and disintegration characteristics of the coated tablets from both the formulations were comparable. Tablets coated with the talc based formulation were slightly better in terms of gloss than the capric glyceride based formulation.

Table No. 2. Coating Process Parameters

Sr. No.	Parameters	Observations	
		Talc Formulation	Capric Glycerides Formulation
A) Coated Suspension Characteristics			
1	Appearance	Agglomerate free coating suspension.	
2	Color	Pink	Pink
B) Process Feasibility			
1	Ease of Operation	No gun blocking observed during the coating process.	
2	Sprayability	Easily sprayable coating suspension	
C) Coated Tablet Characteristics*			
1	Appearance*	Smooth and glossy surface	Smooth Surface
2	Coating Defects	Nil	
3	Disintegration Test (Min.)*	4 Min.	3 Min 40 Sec.

*100 tablets were observed for Appearance, Logo Clarity and Coating Defects.

CONCLUSIONS

Based on these studies it can be concluded that capric glycerides may be used as anti-tack agents to replace talc in ready mix coating formulations. Compared with talc, capric glycerides can be used at lower concentrations (5%w/w) thus avoiding the sedimentation and gun clogging issues often seen where talc based formulations (15%w/w) have been used.

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