SPI Pharma™ Making a Difference
An ABF Ingredients Company

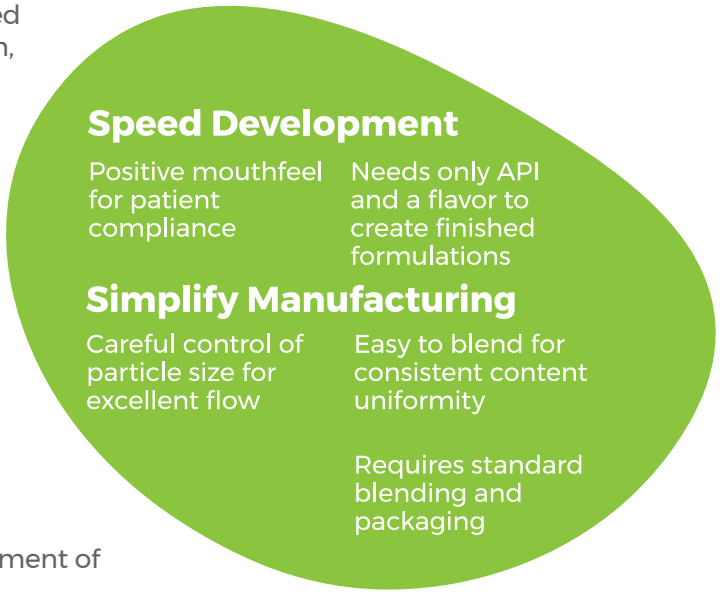
Pharmasperse® ODP Platform

Improved Organoleptics and Content Uniformity of Orally Dispersible Powders

Introduction

Regulators worldwide have put an emphasis on the need to effectively dose sensitive populations such as children, the elderly and the chronically ill in the Pharmaceutical and Nutraceutical markets.

Orally dispersible powders (ODPs) are an increasingly popular method to address this need. ODP formulations have the potential to offer unique products that are suitable for many types of patients including children and geriatrics, require no water to dose, are capable of delivering a high dose, and are highly portable. ODPs in stickpack format can create the opportunity for multiple doses and extensions of current products.



SPI Pharma, an expert in the development of patient friendly dosage forms and excipients, has developed Pharmasperse 416 ODP platform to help speed development of ODP stickpacks.

The Pharmasperse platform has been specifically designed for fast development of stickpacks. It has optimized organoleptics for a patient friendly dose. This optimization yields excellent processing and content uniformity to help reduce manufacturing costs.

Effective Formulation of APAP Stickpack

ODP stickpacks must be paired with the right combination of excipients that meet the requirements of OPD stickpacks must be paired with the right combination of excipients that meet the requirements of both optimal patient experience and technical functionality. Good organoleptics and content uniformity are key factors. To achieve content uniformity, uniform particle size and minimal fines are required.

These considerations can make development increasingly complex and time consuming. The Pharmasperse 416 platform is designed with mouthfeel requirements and content uniformity in mind, eliminating trial and error.

Materials and Methods

Two ODP formulations were developed and optimized using the Pharmasperse platform. It was found to provide a robust formulation by simple addition of a taste masked API and flavor/sweetening components (doses of 250 and 500mg APAP).

Figure 1: Optimized Formula for APAP ODP

Sr. No.	Ingredients	Diluent: Drug Ratio-2:1		Diluent:Drug Ratio- 1:1	
		mg/sachet	%/sachet	mg/sachet	%/sachet
01	Actimask® Acetaminophen	264*	35.2	528**	48.00
02	Pharmasperse® 416	471	62.8	544.5	49.50
03	Sucralose	5.60	0.75	11.00	1.00
04	Citric Acid Anhydrous	3.75	0.5	8.25	0.75
05	Strawberry Flavor	5.60	0.75	8.25	0.75
Total		750	100	1100	100

Results and Discussion

The impact of particle size distribution should be a primary technical consideration. In this specific case, the taste masked API had a PSD of 99% particles in range 350-600 µm. This large particle component is expected to result in grittiness in the formulation. Pharmasperse 416 ODP formulation exhibited creamy mouthfeel, demonstrating an ability to eliminate the grittiness of the large API particles, even at high dose levels.

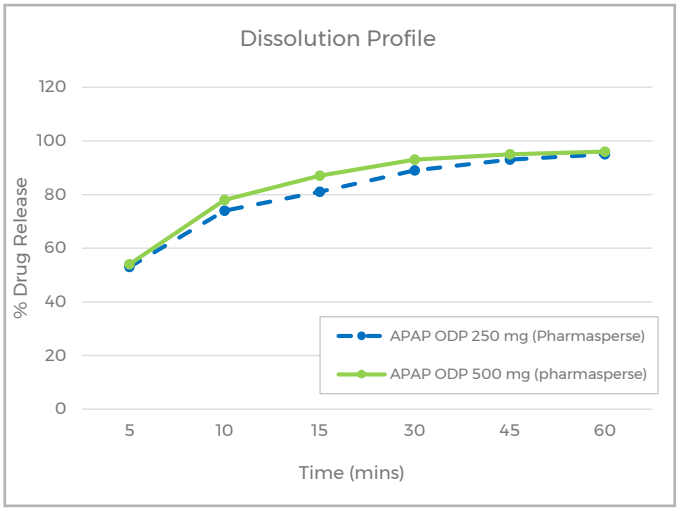
Content uniformity and weight variation are another critical consideration for effective ODP formulations. Each formulation was packed into stickpacks to a target fill weight. Limits for content uniformity are <6.0% for blend uniformity and < 15.0% for the content uniformity of the filled stickpacks respectively. Pharmasperse 416 platform results in effective and efficient filling on standard equipment. Each optimized formulation was tested for drug release using 900 mL pH 5.8 phosphate buffer as the dissolution media in a USP II apparatus with paddle at 50 RPM.

Figure 2: Filling Assessment and Content Uniformity for Two Optimized ODP Formulations

		250 MG(1:2) 195/E003	500 MG (1:1) 195/E004
Stickpack Fill Weight Variable	Target (mg)	750	1100
	Min (mg)	742.5	1092.2
	Max (mg)	765.5	1021.2
	% RSD	1.1	0.8
Blend Uniformity	% RSD	3.0	2.4
Content Uniformity	AV	5.5	5.4
Assay	%	99.8	101.8

Sifted through a #40ASTM sieve and blended in a V-blender rotating at 12 RPM for at least 15 minutes.

Figure 3



Conclusion

Development of a robust patient friendly ODP formulation requires careful consideration of the excipient properties relative to the API taste. ODP carrier choice is critical both in terms of achieving the necessary technical robustness and also in terms of the mouthfeel of the final product. Key issues influencing formulation robustness include API particle size, PSD of the carrier material, and drug loading level. Choice of carrier greatly improves the patient experience and reduces time to market. Pharmasperse in engineered with this in mind.

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