

Assessing Impact of Core Components, Coating Formulation and Functional Packaging on Product Quality of Nutraceutical Tablet Dosage Forms

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Introduction

It has been reported that the extracts of Active Nutraceutical Ingredients (ANIs) like Brahmi, Garlic, and Ashwagandha offer health benefits (1–3). However, formulating tablet dosage forms with these ANIs is challenging due to their poor flow and compression properties, as well as their high moisture sensitivity. This study investigates the potential applications of the formulated excipient, Nutracore™, for producing tablets by direct compression (DC) method of these challenging ANIs. Additionally, the study examines the effect of film coating application on resulting tablets and their stability.

Methods

ANI tablets of Brahmi, Garlic, and Ashwagandha were separately compressed via DC method, utilizing Nutracore Filler and Nutracore Lubricant (Refer Table 1: Composition of ANI Tablets). The ANIs were sieved through a #40 mesh screen, followed by blending with filler using a Double Cone Blender (DCM) for 10 minutes at 20 rpm, and then 2 to 3-minute blending with a lubricant in DCM at 20rpm. Nutracore Filler formulations were optimized to achieve disintegration time (DT) of less than 45 minutes for compressed tablets of all three ANIs. Brahmi tablets were compressed using 15.7 x 9.7mm oval, plain, D-type, standard concave tooling with a target weight of 600mg, whereas Garlic and Ashwagandha tablets were produced with a target weight of 450mg using 10mm round, plain, D-type, standard concave tooling. The concentration of Nutracore Filler in Brahmi tablet was higher to achieve the desired disintegration time of the formulation.

Evaluation of Powder Blend and Core Tablets

The physical properties of ANI and respective formulations with Nutracore were assessed. Density and angle of repose of the formulated blend was measured using tap density apparatus (ETD-1020, Electrolab) and powder flow tester (EFT-01, Electrolab), respectively. Percent loss on drying (LOD) and crushing strength of core tablets were measured using Sartorius moisture analyser and Sotax Tablet Tester, respectively. Friability (up to 100 rotations) was evaluated using an Electrolab Friabilator, and tablet disintegration in water was tested with a disintegration tester.

Film Coating of Tablets

All tablet formulations were coated with PVA based Opadry amb II at 3% weight gain with 20% w/w solids in water. The coating of tablets was performed in 10.5-inch fully perforated coating pan (O'HARA Labcoat™ M5), using parameters shown in Table 2.

Stability Testing

Coated tablets were packaged in 50cc HDPE bottles with a desiccant (Desiccant Canisters, Colorcon), sealed and screw-capped and subjected to stability up to 3 months at storage conditions of 30±2°C/65±5% RH and 40±2°C/75±5% RH. Coated tablets were evaluated for physical appearance, LOD, hardness and disintegration time (DT) at predetermined intervals of the stability study.

Results

Improvement in Flow Properties

The initial flow properties of the ANIs for Brahmi, Garlic, and Ashwagandha were suboptimal, with high Carr's Index values ranging from 34.3% to 37.8% and high Angle of Repose values between 44° and 45°. These values indicated poor flow characteristics and difficulty in tablet processing. However, blending with Nutracore led to a significant improvement in these properties. The Carr's Index values for the blended formulations decreased to a range of 25.0% to 27.0%, and the Angle of Repose values improved to a range of 35° to 38° (Table 3). This enhancement in flowability indicates Nutracore blend effectively optimized the flow properties, making the formulations more suitable for the tablet compression process.

Physical Properties of Tablets

The powder blends of Brahmi, Garlic, and Ashwagandha, when prepared with Nutracore, exhibited excellent flow characteristics during compression on the rotary tablet press. This led to the production of core tablets with consistent weight, thickness, desired hardness values (9 -11 kP) and low friability (0.2%), indicating robust mechanical strength.

DT of the tablets is a critical quality attribute, especially for hygroscopic ANIs, which tend to exhibit higher DT due to their moisture-sorbing properties. Despite this challenge, core tablets prepared with Nutracore achieved a DT of less than 45 minutes (Brahmi 27-33 minutes, Garlic 21-23 minutes, and Ashwagandha 29-33 minutes) (Table 3).

Film Coating and Appearance

All core tablets were coated with Opadry amb II at a 3% weight gain. The coated tablets exhibited a smooth and uniform appearance (Figure 1). The physical evaluation showed no significant difference in LOD and DT values between the uncoated and coated tablets (Table 3). This suggests that the coating process did not alter moisture content and other physical properties of the tablets.

Stability Testing

The coated tablets maintained a smooth appearance and stable physical properties during the stability study. The DT values were 30-35 minutes for Brahmi tablets, 22-24 minutes for Garlic tablets, and 31-36 minutes for Ashwagandha tablets (Figure 2-I). There was no significant change in LOD and hardness from the initial measurements to the 3-month time point, indicating good stability during the stability conditions. The hardness values of the coated tablets were 15-16 kP for Brahmi and Garlic tablets and 13-14 kP for Ashwagandha tablets. (Figures 2-II and 2-III).

Table 1: Composition of ANI Tablets

Ingredients	Supplier	Brahmi	Garlic	Ashwagandha
		%w/w		
Brahmi Extract	Natural Remedies	39.16	--	--
Garlic Extract	Amsar	--	52.23	--
Ashwagandha Extract		--	--	52.23
Nutraceutical Filler - A	Colorcon	--	46.77	--
Nutraceutical Filler - B		--	--	46.77
Nutraceutical Filler - C		59.84	--	--
Nutraceutical Lubricant		1.00	1.00	1.00
Total	--	100	100	100
Tablet weight	--	600 mg	450 mg	450 mg

Table 2: Coating Process Parameters

Process Parameters	Opadry amb II Brown
Coating machine	Ohara LCM-5 (8.5" coating pan)
Pan load	300gm
Inlet Temperature (°C)	60-62
Spray rate (g/min)	2-3
Exhaust Temperature (°C)	45-46
Product Temperature (°C)	44-45
Atomizing Air Pressure (Bar)	1.1-1.2
Pattern Air Pressure (Bar)	1.1-1.2
Air Flow (CFM)	111-115
Pan Speed (rpm)	10-11

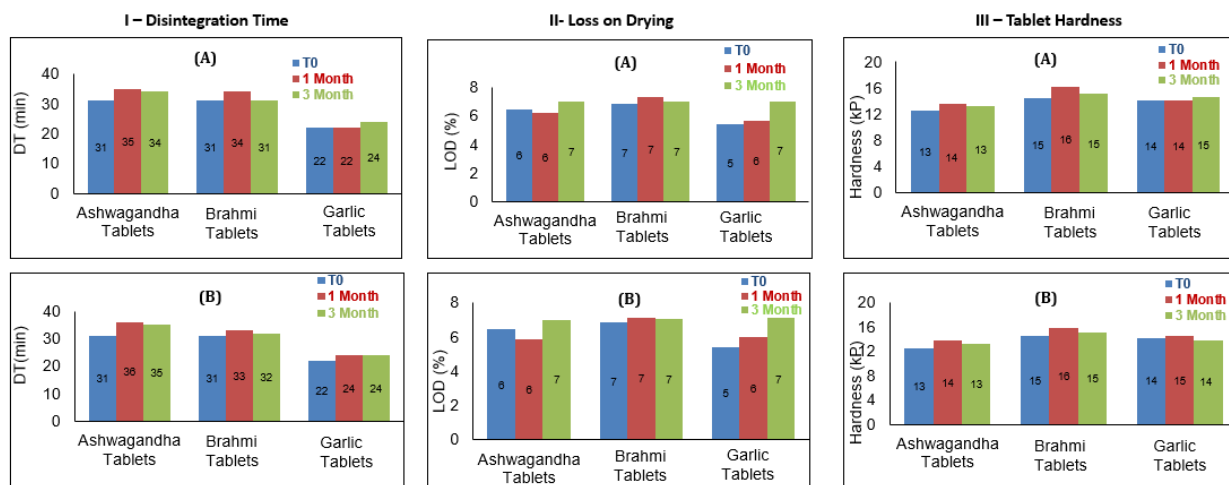
Table 3. Physical Properties of Powders and Compressed Tablets

Physical Properties of Powder	Brahmi		Garlic		Ashwagandha	
	ANI	Blend	ANI	Blend	ANI	Blend
Bulk Density (gm/mL)	0.714	0.625	0.531	0.714	0.675	0.675
Tapped Density (gm/mL)	1.086	0.833	0.833	0.961	1.086	0.925
Carr's Index (%)	34.3	25.0	36.2	25.7	37.8	27.0
Hausner ratio	1.5	1.3	1.6	1.3	1.6	1.4
Angles of Repose	44°	36°	45°	35°	45°	38°
Physical Properties of Tablets	Brahmi		Garlic		Ashwagandha	
	Core	Coated	Core	Coated	Core	Coated
Hardness (kP)	9-10	14-15	9-10	14-15	10-11	12-13
Friability (%)	0.2	0.0	0.2	0.0	0.1	0.0
LOD (%)	7.36	6.84	6.01	5.42	7.08	6.44
DT (min)	27-28	32-35	21-23	23-26	29-33	36-39

Figure 1. Photographs of Ashwagandha (1), Garlic (2) and Brahmi (3) Tablets coated with Opadry amb II



Figure 2: Physical Parameters of Ashwagandha, Brahmi, and Garlic Tablets over 1- and 3-Months Stability Study (A) 40°C/75% RH and (B) 30°C/65% RH



Conclusions

Three ANIs with poor flow and compressibility formulated with Nutracore resulted in robust tablets with desired hardness and disintegration time along with elegant appearance.

In addition, all formulations remained stable at accelerated stability conditions.

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