

# Simplified Formulation of Dietary Supplements Using High Functionality Clean Label Excipients

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## Introduction

Formulation development of dietary supplements (DS) into robust solid dosage forms can be complex and time consuming. In the nutraceutical sector, consumers desire clean label products containing natural (all plant-based ingredients), easily recognizable ingredients<sup>1</sup>. To meet this demand, there is need to develop nutraceutical excipients that reduce time and effort for DS product development.

The purpose of this study was to develop clean label, highly functional excipients for manufacturing of acceptable DS tablets.

- The novel nutraceutical excipients include a Nutracore™ filler excipient blend and Nutracore™ lubricant blend (with both lubricant and glidant properties).
- Three model dietary supplement ingredients were used for tablet formulations: ashwagandha powder, ashwagandha granules and garlic powder.

## Objectives:

- To evaluate applicability of clean label Nutracore blends with a range of DS for the powder properties and their tablet performance.
- Competitive evaluation of prepared tablets against two commercially available DS tablets containing either synthetic pharmaceutical excipients or clean label excipients.

## Methods

**Powder Testing:** Properties of blends were evaluated in terms of appearance, bulk density, and particle size distribution (PSD). PSD and flowability were evaluated using Malvern Mastersizer Scirocco 2000 and Flodex™. The three model DS powders were characterized for powder properties and tableability with Nutracore filler and lubricant blends.

Powder blends were formulated as shown in Table 1 and made using 2-step mixing where the DS and the Nutracore filler blend were mixed for 3 minutes in a V-blender, followed by the lubricant blend and mixing for additional 2 minutes. Tablets were directly compressed into 450 mg, 10 mm round, biconvex tablets using a Piccola tablet press operated at 50 rpm turret speed and 25 kN compression force.

**Table 1: Formulation Composition for the Clean Label Tablet Formulations**

| Excipient                  | %w/w in formulation |      |      |
|----------------------------|---------------------|------|------|
| Ashwagandha Powder         | 52.0                | -    | -    |
| Ashwagandha Granules       | -                   | 52.0 | -    |
| Garlic Powder              | -                   | -    | 52.0 |
| Nutracore Filler Blend     | 45.5                | 45.5 | 45.5 |
| Nutracore Lubricant Blend) | 2.5                 | 2.5  | 2.5  |
| Total                      | 100                 | 100  | 100  |

**Tablet Evaluation:** Prepared tablets were evaluated for appearance, tensile strength (USP <1217>) and disintegration time (DT) (USP <701>).

**Evaluation vs. Marketed Product:** The Nutracore tablet properties (tensile strength and disintegration time) of were compared to two marketed dietary supplement (DS) products. The garlic containing product is an enteric coated tablet. For better comparison of disintegration time, garlic tablet prepared using Nutracore blends was enteric coated using Nutrateric® coating at 3% weight gain (WG).

## Results

- Nutracore lubricant blend had a light-brown appearance and free flowing powdery form.
- The filler blend was an off-white, free flowing powder with Flodex values of 7-9 mm and compressibility index of 24.6 %.
- The powder properties of pure clean label blends and the three DS are given in Table 2.

**Table 2: Powder Properties of the Nutracore Excipient Blends and DS**

| Material             | Bulk Density (g/mL) | Particle Size (µm) |       |       |
|----------------------|---------------------|--------------------|-------|-------|
|                      |                     | Dv10               | Dv50  | Dv90  |
| Nutracore Filler     | 0.50                | 31.5               | 97.5  | 202.7 |
| Nutracore Lubricant  | 0.26                | 2.3                | 14.9  | 48.2  |
| Garlic powder        | 0.52                | 7.4                | 35.7  | 123.6 |
| Ashwagandha powder   | 0.53                | 7.5                | 26.1  | 62.0  |
| Ashwagandha granules | 0.37                | 105.8              | 246.0 | 498.3 |

**Figure 1: Appearance of Clean Label Tablets vs. Marketed Products**



## Marketed Product Evaluation:

### Ashwagandha Dietary Supplement Case Study

- The composition and tablet performance of the Nutracore tablets and the marketed products of ashwagandha are summarized in Table 3.
- The Nutracore formulation prepared with minimal ingredients was compared with the marketed tablets. The prepared Nutracore tablets had shiny, uniform-colored surfaces, without any visual defects (Figure 1).
- The Nutracore tablets (uncoated) prepared with either powder or granular ashwagandha as a DS were significantly superior in terms of tensile strength and DT compared to the marketed products as detailed in Table 3.
- The tensile strength of tablets prepared using Nutracore excipients with powdered ashwagandha was >1.6 MPa and DT of <25 minutes which was slightly higher compared to tablets prepared with granular ashwagandha.

**Table 3: Composition of Ashwagandha Tablets and Performance: Evaluation vs Marketed Product**

| Parameters             | Clean Label Ashwagandha Powder Tablets             | Clean Label Ashwagandha Granules Tablets              | Marketed Ashwagandha Tablets  |
|------------------------|--|---|---|
| Composition            | Ashwagandha powder, Nutracore Filler and Lubricant | Ashwagandha granules, Nutracore Filler, and Lubricant | KSM-66 Ashwagandha® organic extract, organic dextrose, organic guar gum, organic rice extract, organic rice hulls, organic gum arabic, organic sunflower oil, organic clear coating |
| Tablet properties      | 450 mg, round biconvex uncoated tablets            | 450 mg, round biconvex uncoated tablets               | 850 mg, round biconvex coated tablets   |
| Performance            |  |   |   |
| Tensile strength (MPa) | 2.62 ± 0.18  | 1.94 ± 0.15   | 0.65 ± 0.09   |
| DT (min)               | 23.7   | 16.1  | 58.1  |

**Garlic Dietary Supplement Case Study**

- The composition and the tablet performance of the Nutracore tablets and the marketed products of garlic is summarized in Table 4.
- Despite the garlic tablets with Nutracore ingredients being uncoated, they had higher tensile strength compared to the marketed tablets containing synthetic excipients as shown in Table 4.
- The disintegration time for both marketed tablets and tablets prepared with Nutracore excipients (coated with Nutrateric a nutritional enteric coating) was comparable.

**Table 4: Composition of Garlic Tablets and Performance: Evaluation vs. Marketed Product**

| Parameters             | Clean Label Garlic Tablets                                     | Marketed Garlic Tablets   |
|------------------------|--|---|
| Composition            | Garlic powder, Nutracore Filler, Nutracore Lubricant           | Garlic, Dicalcium phosphate, Vegetable cellulose, Calcium carbonate, Ethyl cellulose, Calcium silicate, Vegetable magnesium stearate, Titanium dioxide (color), Natural palm leaf glaze, Enteric coating (sodium alginate and stearic acid) |
| Tablet properties      | 450 mg, round biconvex enteric coated with Nutrateric at 3% WG | ~740 mg, enteric coated, round biconvex   |
| Performance            |  |   |
| Tensile strength (MPa) | 2.61 ± 0.10 (Uncoated)   | 1.75 ± 0.12   |
| DT (min)               | 46.4   | 52  |

## Conclusions

Nutracore filler and lubricant blends provided simpler, clean label formulations that resulted in robust tablets for ashwagandha and garlic dietary supplements.

Tablet formulations containing label friendly excipients performed significantly better in terms of mechanical strength and disintegration time compared to existing marketed products.

Nutracore filler and lubricant blends are beneficial for nutraceutical applications by reducing time and cost for development.

## References

1. Sarah S. Aboeela, Robert Theisen, Manish Ghimire, Ali Rajabi-Siahboomi. The Effect of a Clean-label, Plant-based Natural Glidant on the Flow Properties of Multiple Model Powders compared to a Synthetic Glidant, AAPS 2022.

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