SPI Pharma™
Making a Difference
An ABF Ingredients Company

CoBlend Grades

Pumpable Preformulated Aluminum and Magnesium Hydroxide Gels for Antacid Suspensions

CoBlend is a customized, preformulated, pumpable gel of aluminum hydroxide and magnesium hydroxide combined with sorbitol and preservatives. It is designed to improve taste and mouthfeel, simplify the manufacturing process, and reduce cost in the production of immediate relief antacid suspensions.

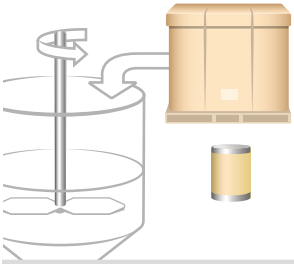
Why Use CoBlend from SPI Pharma?

- Easy to handle preformulated pumpable gel
- Customers have experienced up to 50% cost reduction in productivity improvements, inventory and QC. CoBlend simplifies the manufacturing process by combining two APIs and excipients into one preformulated product
- Excellent assay and ratio consistency formulated to the customers' desired label claim
- Great mouthfeel due to narrow and fine particle size distribution
- Used in a closed processing system which reduces micro contamination risk and product losses

CoBlend Optimized Process

EASY TO PUMP

- 1 Homogeneisation step
- 1 Final control

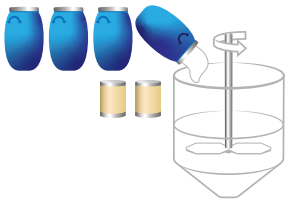


- Reduced inventory
- Short process (low cycle time, high productivity)
- Less risk of microbiological contamination
- Less QC testing (less raw material QC test + less in-process testing)
- Very consistent process

Suspension with Paste

DIFFICULT TO TRANSFER

- 3 (at least) Intermediate homogeneisation steps
- 1 Intermediate control (ratio)
- 1 Final homogeneisation step
- 1 Final control



- Long process
- Risk of microbiological contamination due to handling pastes and excipients
- Irregular process (several homogenization steps)
- More QC testing

CoBlend Grades

Let SPI Pharma's experts help you create cost effective antacid suspensions using CoBlend.

Starting formulas for antacids suspensions using two different grades of preformulated pumpable CoBlend

	Using CoBlend AMS138	Using CoBlend AMS106
	LABEL CLAIM for 10 ml	LABEL CLAIM for 10 ml
Aluminum Hydroxide [1]	**800 mg** *Al. Hyd. Dried Gel USP (Powder form)* equivalent to: **612 mg** $Al(OH)_3$ **400 mg** Al_2O_3	**1046 mg** *Al. Hyd. Dried Gel USP (Powder form)* equivalent to: **800 mg** $Al(OH)_3$ **523 mg** Al_2O_3
Magnesium Hydroxide	**800 mg** $Mg(OH)_2$	**800 mg** $Mg(OH)_2$
Simethicone [2]	**60 mg**	**60 mg**

(1) As per USP Monograph for "*Alumina, Magnesia, and Simethicone Oral Suspension*", or for "Alumina, Magnesia Oral Suspension". "*Oral Suspension may be labeled to state the aluminum hydroxide content in terms of the equivalent amount of dried aluminum hydroxide gel, on the basis that each mg of dried gel is equivalent to 0.765 mg of* $Al(OH)_3$" or equivalent to 0.500 mg of Al_2O_3.

(2) Optional and quantity can be adjusted to desired label claim target

Formulation for 1000 (ml product)	AMS 138	AMS 106
CoBlend	689.00 g	800.00 g
Simethicone Emulsion 30%	20.00 g	20.00 g
Sorbitol Solution 70% [3]	79.00 g	68.00 g
Xanthan Gum *(pre-dispersed in water)* [3]	2.00 g	2.00 g
Sodium Citrate	2.50 g	2.50 g
Sodium Saccharin [3]	2.00 g	2.00 g
Hydrogen Peroxide 35% [3]	0.57 g	0.57 g
Methyl Paraben [3]	1.00 g	1.00 g
Propyl Paraben [3]	0.30 g	0.30 g
Flavor [3]	0.10 g	0.10 g
Purified Water	q.s to 1000 ml	q.s to 1000 ml

(3) Quantities can be adjusted to achieve desired viscosity, sweetness, flavor and preservation levels.

Manufacturing Guidance for 1000 ml

Easy manufacturing steps, no special mixer device needed

1. Blending: Blend CoBlend, sodium citrate, sodium saccharin, sorbitol, simethicone (optional), hydrogen peroxide and parabens into water (0 – 100 ml)
2. Dispersion: add a suspension of Xanthan Gum at 0.5% to 1.0% and flavor
3. Homogenization: q.s with purified water to 1000 ml

SPI Pharma™
Making a Difference
An ABF Ingredients Company

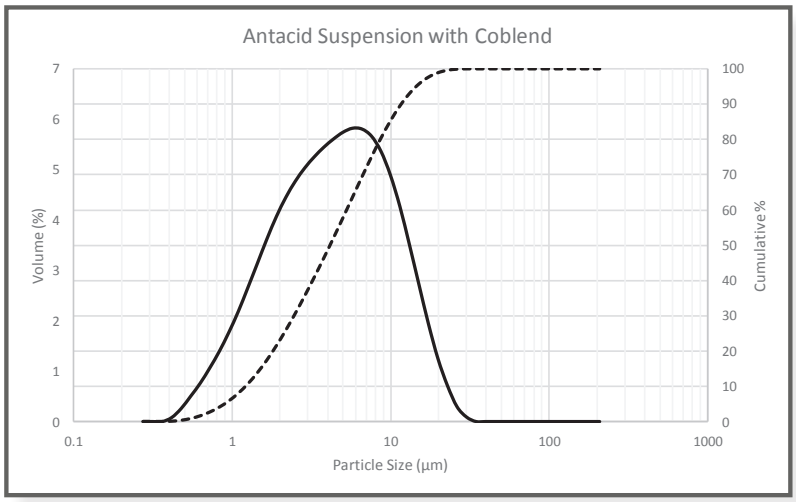
Physical Characteristics of the suspension produced from Starting Formula

Appearance: Creamy thixotropic white to off-white suspension, easy to re-suspend

pH: 7.0 – 8.6 (USP Monograph for Alumina, Magnesia, and Simethicone Oral Suspension)

Specific Gravity: 1.10 – 1.15

Figure 1 : Narrow and fine Particle Size Distribution centered on about 5 µm for a pleasant mouthfeel



Elemental Impurities

Operating in a highly regulated industry, we understand the importance of minimal elemental impurities for our customers. We perform a thorough risk assessment on all of our products to ensure regulatory compliance. SPI Pharma has invested approximately $1M of testing technology, resources and external testing to ensure our customers the peace of mind that our products are below the threshold and only require annual confirmation testing. Customers can depend on our certification and can alleviate their burden of testing.

Regulatory Compliance†

Aluminum and Magnesium Hydroxide gel - CoBlend	
✓	Non-GMO
✓	Technical File
✓	Gluten Free
✓	cGMP*
✓	Tested for Elemental Impurities
✓	Vegan
✓	Absence of Residual Solvents
✓	Absence of Phthalates
✓	GRAS
✓	Prop 65
✓	USP
✓	BSE/TSE
✓	Absence of Allergens

* Redacted EIR issued by USFDA is available and is equivalent to cGMP certificate.
† Documents available upon request

SPI Pharma™
Making a Difference
An ABF Ingredients Company

Naturally Sourced Minerals

Over the last 50 years, SPI Pharma has established a breadth of experience and knowledge to produce high quality magnesium products for pharmaceutical and healthcare products.

In the United States many of our Magnesium Hydroxide based products originate from the Delaware Bay. This location was chosen due to the excellent quality and salinity of the seawater.

What happens once the extraction process is complete?

After extraction, we test the seawater to guarantee quality and return it back to the bay to support the natural ecosystem.

SPI Pharma
salesinfo@spipharma.com
@spipharma_real
@spipharma
www.spipharma.com
SPI Pharma

ABFI
AB Enzymes
ABITEC
Ohly
PGP International
SPI Pharma™
An ABF Ingredients Company

October 2019