

Magaldrate Fluid Gel 20%

Pumpable Gel for Antacid Suspensions



Magaldrate 20% pumpable gel is easy to handle as you make cost effective antacid suspensions with a pleasant mouthfeel. With its high concentration a wider range of finished product dosages can be produced.

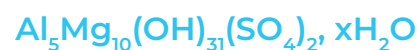
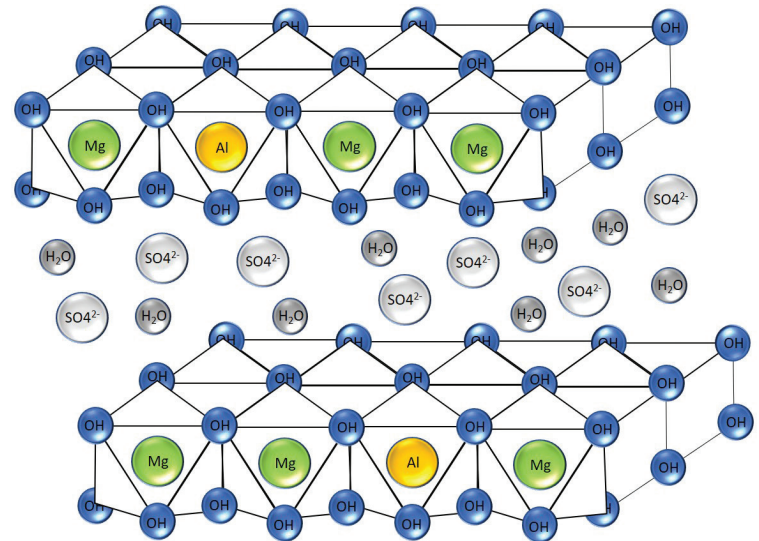
Why Use Magaldrate Fluid Gel 20% for Antacid Suspensions?

The unique crystal lattice structure of Magaldrate provides the following properties:

- High Acid Neutralizing Capacity (ANC)
- Buffering Effect at a pH range between 5 and 6
- Adsorption of bile acids and proteins

Magaldrate's unique chemical properties are used for:

- Traditional antacid neutralization action
- Relief of peptic ulcer
- Prevention of damage to gastric mucosa



Magaldrate is a basic Aluminum and Magnesium compound possessing a layer structure connected by water and sulfate bridges.

Magaldrate is crystalline by nature which makes it very stable.

Magaldrate Fluid Gel 20%

SPI Pharma's expertise will help you to create antacid suspensions with cost effective, Magaldrate 20% pumpable gel.

Starting formula for antacids suspensions using Magaldrate gel 20%

LABEL CLAIM for 10 ml	
Magaldrate	800 mg
FORMULATION	Quantities for 1,000 ml
Magaldrate Gel at 20% Magaldrate	400.00 g
Xanthan Gum (<i>pre-dispersed in water</i>) ⁽¹⁾	2.00 g
Anhydrous Citric Acid ⁽¹⁾	2.00 g
Sorbitol Solution 70% ⁽¹⁾	71.42 g
Sodium Saccharin ⁽¹⁾	2.00 g
Hydrogen Peroxide 35% ⁽¹⁾	0.57 g
Methyl Paraben ⁽¹⁾	1.00 g
Propyl Paraben ⁽¹⁾	0.30 g
Flavor ⁽¹⁾	0.10 g
Purified Water	q.s to 1000 ml

(1) 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 Magaldrate Gel 20%, Anhydrous Citric Acid, sodium saccharin, sorbitol, and parabens into water (100 – 200 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 1,000 ml



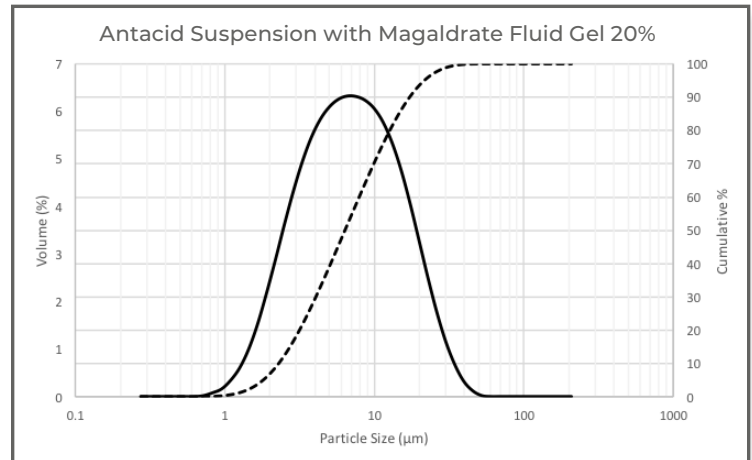
Physical Characteristics of the suspension produced from Starting Formula

Appearance: Thin creamy thixotropic white to off-white suspension, easy to re-suspend with a gentle shake.

Specific Gravity: 1.00 – 1.10

Note: Magaldrate Fluid Gel 10% is also available

Figure 1 : Narrow and fine Particle Size Distribution centered on about 7 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†

Magaldrate Fluid Gel 20%

- ✓ Technical File
- ✓ ASMF
- ✓ Non-GMO
- ✓ Gluten Free
- ✓ Aflatoxin Free
- ✓ cGMP*
- ✓ Nanomaterial Free
- ✓ Origin
- ✓ Latex Free
- ✓ Absence of Residual Solvents
- ✓ Absence of Phthalates
- ✓ Tested for Elemental Impurities
- ✓ TSE/BSE
- ✓ Absence of Allergens
- ✓ Melamine Free

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



Excipients for Swallow Tablets



Taste Masked Actives



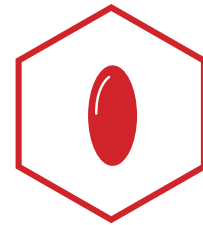
ODTs/ODPs



Effervescent Tablets



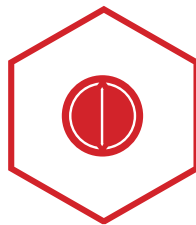
Vaccine Adjuvants



Soft Gel Capsules



Antacid & Laxative Ingredients



Chewable Tablets & Lozenges



Nutraceutical Applications

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