



Antacid Actives Product Guide

Global Leader in Immediate Relief

Antacid Actives



Solving formulation challenges
using superior functional materials.



About the Company

SPI Pharma provides highly functional excipients, actives and services that solve challenging formulation problems. With a diverse sales force, industry recognized technical teams and sales in over 55 countries, SPI has a global reach with a regional focus.

SPI Pharma has been the global leader in immediate relief antacid actives for over 30 years. We provide excellent service, quality and custom solutions. We specialize in aluminum, magnesium and calcium products as well as preformulated solutions for the production of antacid suspensions and tablets.

All facilities meet cGMP requirements for APIs and Finished Dosage Form (FDFs) where applicable. Our sites are frequently audited by US FDA, ANSM (French Regulatory Authority) and our customers. When the product is compendial, it meets or exceeds the appropriate USP and/or EP pharmacopoeia.

With manufacturing locations in the US and France, SPI Pharma provides security of supply at the highest quality standards through dual sourcing. We work to exceed the expectations for each customer, every time. Your journey to formulation success starts here.

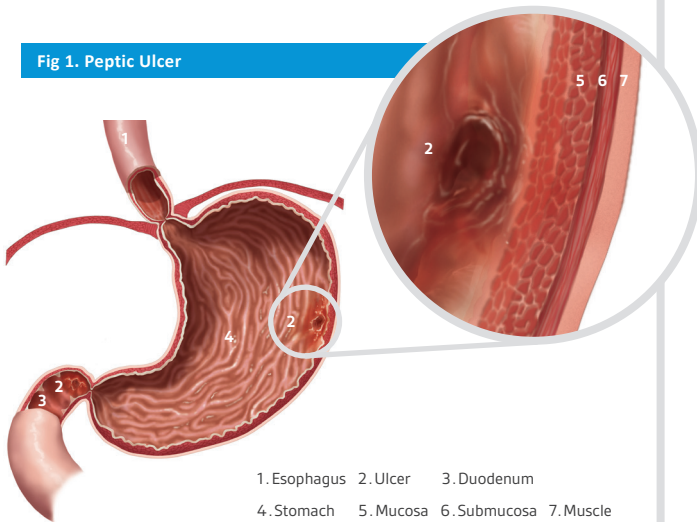


The Need For Antacids

Acid indigestion and heartburn affect a large part of the worldwide population. Each year, people spend billions of dollars globally on antacids in search of relief. Patients are prescribed antacid specialties to relieve the symptoms caused by hyperacidity and/or peptic ulcers (acid indigestion) or Gastroesophageal Reflux Disease (GERD/heartburn).

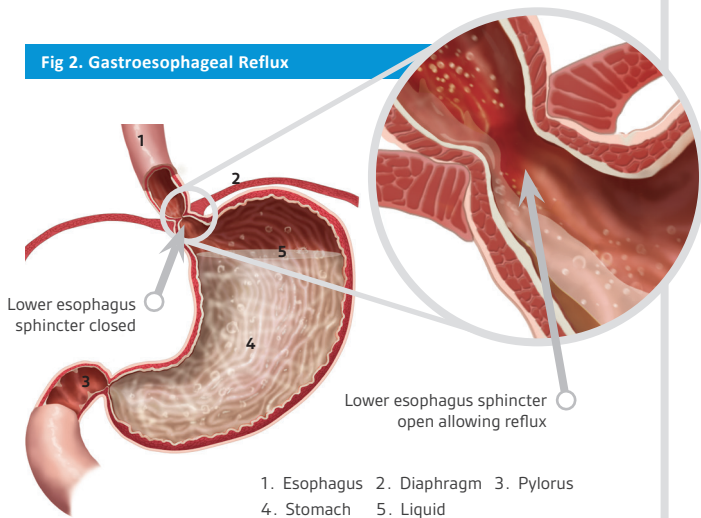
Peptic ulcers are open sores that develop on the inside lining of the stomach, upper small intestine or esophagus. The most common symptoms of a peptic ulcer are heartburn and pain.

Fig 1. Peptic Ulcer



GERD occurs when the lower esophageal sphincter does not close properly and stomach contents leak back, or reflux, into the esophagus. When refluxed stomach acid touches the lining of the esophagus, it causes a burning sensation in the chest or throat called heartburn. The main symptoms are persistent heartburn and acid regurgitation.

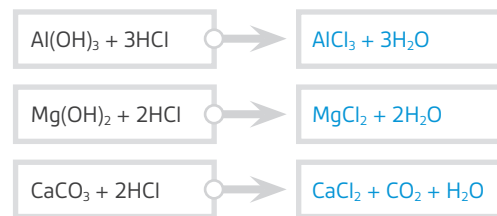
Fig 2. Gastroesophageal Reflux



Antacid Specialty products are well-known for the symptomatic treatment of gastritis & GERD. They have been safely employed for many years to relieve the symptoms caused by these conditions. Antacids are available in both tablet and liquid form, through prescription products or over-the-counter (OTC) products.

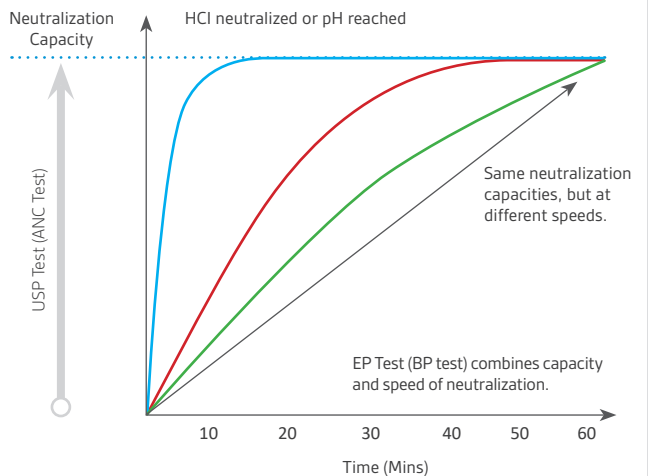
Antacid Active Ingredients work by neutralizing or adsorbing the acids in the stomach (hydrochloric and bile acids) in order to relieve the irritation or burning pain of the gastric or esophageal mucosa.

Fig 3. Neutralization of Hydrochloric Acid



The neutralizing capacity and the speed of neutralization can be measured in vitro at 37°C by various tests including Acid Neutralizing Capacity (ANC) a USP Test, BP Test (Ph Eur Test), Acid Consuming Capacity (ACC), pH Stat or Sjogren Test and Rossett Rice Test. Antacid active ingredients can reach the same neutralization capacity but at different speeds.

Fig 4. Capacity and Speed of Neutralization





You Have Options With SPI Pharma

There are multiple approaches to dealing with acid indigestion and heartburn. SPI Pharma offers single active ingredients or preformulated combination actives of aluminum compounds, magnesium compounds, aluminum/magnesium compounds, carbonated compounds and associations of antacids (antiflatulent and antiregurgitant).



Aluminum Compounds

Aluminum Hydroxide

Aluminum hydroxide is a typical antacid active. It can be used alone or in combination with magnesium hydroxide to obtain the desired acid neutralizing capacity (ANC). Aluminum hydroxide as an antacid is not exactly an aluminum hydroxide, $\text{Al}(\text{OH})_3$. Aluminum hydroxide gels are amorphous in nature and contain carbonate in the gel structure. The presence of carbonate increases the reactivity of the aluminum, allowing for its acid neutralizing capacity, making it a more effective antacid.

Our line of aluminum hydroxide gels provides options to our customers based on various assays and viscosities to meet their suspension formulation needs.

Whether produced by a wet granulation or direct compression process, we offer a portfolio of aluminum powders varying in density and particle size distribution to meet your antacid tablet requirements.

Our line of aluminum hydroxide gels and powders is available worldwide and provides the consistent quality required for pharmaceutical use. The aluminum assay for all products is not less than 76.5% on an $\text{Al}(\text{OH})_3$ basis or not less than 50% on an Al_2O_3 basis.

Aluminum Phosphate

In gel form, aluminum phosphate (AlPO_4) functions by coating the stomach wall. It does not neutralize stomach acids. Aluminum phosphate absorbs gall salts and stomach gas. Since the product does not chelate alimentary phosphate, it does not deplete phosphorus from the stomach.

Boehmite

Boehmite is a crystalline form of aluminum hydroxide. Unlike the amorphous form of aluminum hydroxide gel, Boehmite does not dissolve in hydrochloric acid (HCl). Boehmite protects the stomach wall by absorbing stomach acid and creating a high viscosity gel. It has low aluminum solubility. Boehmite antacid active is considered an aluminum hydroxide, but is not chemically $\text{Al}(\text{OH})_3$. It is an aluminum oxyhydroxide: $\text{AlO}(\text{OH}) \cdot x\text{H}_2\text{O}$. Composed of fibrous primary particles of a few nanometers, Pseudo-Boehmite has adsorption properties and a large surface area.



Magnesium Compounds

Magnesium Hydroxide

Like aluminum hydroxide, magnesium hydroxide is also a typical antacid active; both are often combined, offering a good neutralizing and pH buffering effect and compensating their side effects. It is also used as a laxative active (Milk Of Magnesia).

Our line of magnesium hydroxide gels and pastes is available worldwide and provides the consistent quality required for pharmaceutical use. Magnesium hydroxide is a primary ingredient in antacid suspensions on a global basis. Our magnesium hydroxide pastes and gels vary in assay and viscosity to meet your formulation needs.

SPI Pharma manufactures magnesium hydroxide powders for use as the active component in wet granulated and directly compressible antacid tablets. A wide range of magnesium powders is available. They vary in density and particle size distribution. On dry basis, magnesium hydroxide, dried at 105°C for 2 hours, contains not less than 95.0% and not more than 100.5% of Mg(OH)₂.

Aluminum/Magnesium Compounds

Aluminum Hydroxide Magnesium Carbonate

Aluminum hydroxide magnesium carbonate (AHMC), Al(OH)₃-2x(CO₃)x / MgCO₃, is a co-processed active ingredient combining aluminum hydroxide and magnesium carbonate. Our AHMC 0611 grade is specifically designed for rehydration from the powdered form to a smooth, viscous, non-separating suspension.

You can choose between our two grades, 0600 and 0652, which vary in assay ratio between aluminum hydroxide and magnesium carbonate to meet your needs for antacid tablets. SPI Pharma can customize this ratio and particle size.

Magaldrate

Magaldrate, Al₅Mg₁₀(OH)₃₁(SO₄)₂·xH₂O, is a basic aluminum and magnesium compound possessing a layer structure connected by water and sulfate bridges. It is crystalline by nature. This unique crystal lattice structure results in the high reactivity for magaldrate. The antacid effectiveness of magaldrate can be used to treat peptic ulcers because it neutralizes gastric acid very quickly while buffering the pH (keeping it between 5-6), even in the presence of proteins and pepsin. Magaldrate can also absorb large quantities of bile acids which prevent these acids from attacking the mucous membranes.

Magaldrate is a highly reactive antacid designed for the formulation of suspensions and tablets. The gel is available as 10 or 20% suspension. We offer a powder form as well.



Carbonated Compounds

Calcium Carbonate

SPI Pharma manufactures directly compressible (DC) calcium carbonate products for swallow and chewable tablets that have high functionality and create a superior mouthfeel.

Calcium carbonate, CaCO₃, is a very reactive antacid active which is often used in combination with magnesium compounds.

Calcium carbonate has a crystalline structure. It can be natural or precipitated and found in different forms (e.g. Aragonite & Calcite). On dry basis, calcium carbonate, dried at 200°C for 4 hours, contains not less than 98.5% and not more than 100.5% of CaCO₃.

Preformulated Combinations

CoDried Powders

DC CoDried powders are preformulated products for a more simple, quick and cost effective manufacturing process of immediate relief antacid tablets. An improved, smooth mouthfeel is created by porous, spherical particles with uniform size distribution. This delivers a uniform and homogenous dosage. The process is very consistent because it utilizes CoDried technology, creating the same composition from one granule to another.

CoBlend Suspensions

CoBlend is a customized preformulated product designed to simplify the manufacturing process, improve taste and reduce cost in the production of immediate relief antacid suspensions. An improved, smooth mouthfeel is created by blending the actives with sorbitol

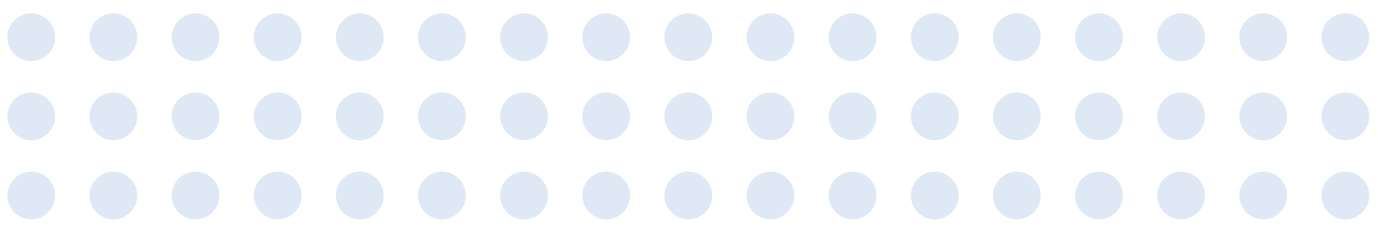


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Introduction to Antacid Specialties Formulations

Formulations can be prepared from different types of actives. Antacid suspensions can be made from viscous pastes, pumpable gels, powders (preferably micronized) or preformulated products. Antacid tablets can be made from powders, directly compressible (DC) ingredients or DC preformulated products.

Your next step will be to determine which products best suit your formulation needs by using the comparison chart and decision guides in the pages that follow. From there, more detailed information about the products you have selected can be found in the corresponding sections. As always, our sales and technical teams are ready to assist you with any questions that arise.

Antacid Comparison Chart

Description

Action

● Neutralizing effect ● Protective effect

Aluminum Hydroxide Gels & Powders

Aluminum hydroxide is an amorphous form of aluminum hydroxide in which there is a partial substitution of carbonate for hydroxide. On dry basis, it contains the equivalent of NLT 76.5% of $\text{Al}(\text{OH})_3$, and it may contain varying quantities of basic aluminum carbonate and bicarbonate.

Aluminum hydroxide is a typical antacid active, very often combined with magnesium hydroxide. Aluminum hydroxide as an antacid is not exactly an aluminum hydroxide ($\text{Al}(\text{OH})_3$), it is an aluminum « hydroxy-carbonate » ($\text{Al}(\text{OH})_{3-2x}(\text{CO}_3)_x$, with x within 0.1 to 0.4 where some hydroxides (OH^-) are substituted by carbonates (CO_3^{2-}). It has an amorphous structure. It is this amorphous structure which allows the acid neutralizing capacity.

Side effects: Constipating. Can chelate dietary phosphate, so can potentially deplete phosphate from the stomach.

Magnesium Hydroxide Gels & Powders

On dry basis magnesium hydroxide, dried at 105°C for 2 hours, contains not less than 95.0% and not more than 100.5% of $\text{Mg}(\text{OH})_2$.

Like aluminum hydroxide, magnesium hydroxide is also a typical antacid active. Both are often combined, offering a good neutralizing and pH buffering effect and compensating their side effects. It is also used as laxative active (Milk of Magnesia). Magnesium hydroxide has a crystalline structure.

Calcium Carbonate Powders

On dry basis calcium carbonate, dried at 200°C for 4 hours, contains not less than 98.5% and not more than 100.5% of CaCO_3 .

Calcium carbonate is a very reactive antacid active which is used alone or in combination with magnesium compounds. It has a crystalline structure and buffering properties.

Magaldrate Gels & Powders

Magaldrate is a chemical combination of aluminum and magnesium hydroxides and sulphate, corresponding to the formula: $\text{Al}_5\text{Mg}_{10}(\text{OH})_{31}(\text{SO}_4)_2 \cdot x\text{H}_2\text{O}$. It contains the equivalent of not less than 90.0% and not more than 105.0% of $\text{Al}_5\text{Mg}_{10}(\text{OH})_{31}(\text{SO}_4)_2$, calculated on the dried basis.

Magaldrate is a basic aluminum and magnesium compound possessing a layer structure connected by water and sulphate bridges and is crystalline by nature. This unique crystal lattice structure results in the high reactivity for magaldrate. The antacid effectiveness of magaldrate can be used to treat peptic ulcers because it neutralizes gastric acid very quickly while buffering the pH even in presence of proteins and pepsin. Magaldrate can also absorb large quantities of bile acids which prevent these acids from attacking the mucous membranes.

Aluminum Phosphate Gel

Aluminum phosphate gel is a suspension of hydrated AlPO_4 . Content: 19.0% to 21.0% of AlPO_4 .

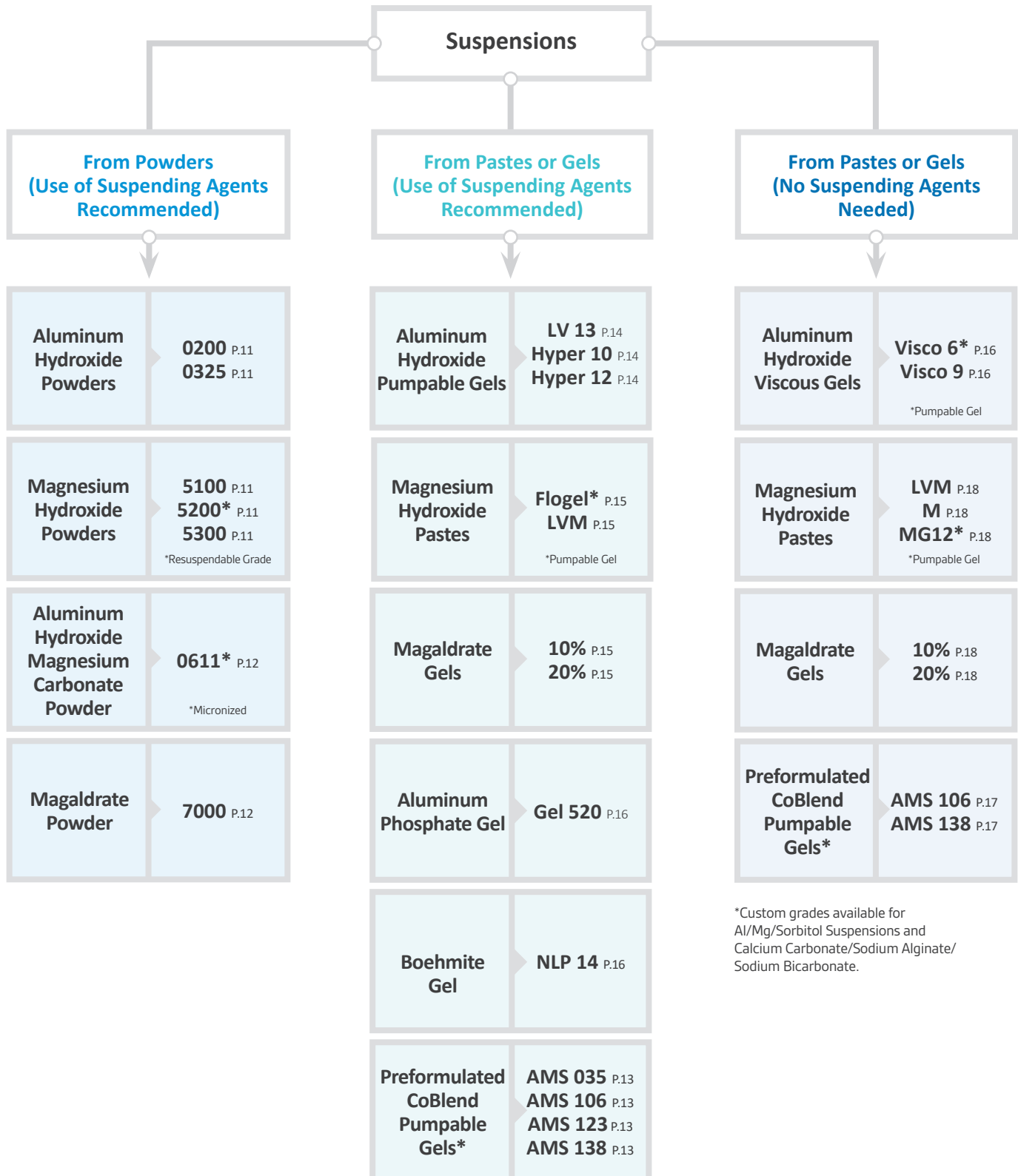
Aluminum phosphate (AlPO_4) functions by coating the stomach wall. It does not neutralize stomach acids. Aluminum phosphate absorbs the bile acids and stomach gas. Since the product does not chelate dietary phosphate, it does not deplete phosphate from the stomach.

Boehmite Gel

Boehmite gel is a white or almost white, translucent, viscous, colloidal gel of aluminum oxide hydroxide: $[\text{AlO}(\text{OH})]_n \cdot n\text{H}_2\text{O}$.

Boehmite is a crystalline form of aluminum hydroxide. Unlike the amorphous form of aluminum hydroxide gel, boehmite does not dissolve in hydrochloric acid (HCl). Boehmite protects the stomach wall by absorbing stomach acid and creating a "high viscosity gel." It is chosen primarily because of its lower aluminum solubility. The product, by design, has lower acid neutralizing capacity (ANC) compared to standard aluminum hydroxide gel.

Antacid Suspensions Product Selection Guide



From Powders with Suspending Agents

Aluminum Hydroxide Powders

Grade: 0200, 0325

SPI Pharma manufactures aluminum hydroxide powders as the active component in antacid suspensions. The aluminum hydroxide powders can be used alone or in combination with other ingredients for this purpose.

A wide range of aluminum powders is available. They vary in apparent density and particle size distribution. The aluminum assay for all products is not less than 76.5% on an $\text{Al}(\text{OH})_3$ basis or not less than 50% on an Al_2O_3 basis.

Grade 0200

Fine powder, USP, EP	Tapped Density (g/mL) 0.16-0.25
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Grade 0325

Denser powder, USP, EP	Tapped Density (g/mL) 0.30-0.40
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Magnesium Hydroxide Powders

Grade: 5100, 5200, 5300

Magnesium hydroxide as aluminum hydroxide is a typical antacid active; both are often combined, offering a good neutralizing and pH buffering effect and compensating their side effects.

Grade 5100

Dense powder, USP, EP, Low lead	Tapped Density (g/mL) 0.68-0.84
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5100 is free flowing and blends very well with other ingredients. It is low lead (<125 ppb).

Grade 5200

Resuspendible powder, USP, EP	Tapped Density (g/mL) 0.60-0.75
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5200 is a medium density product specifically designed for rehydration from the powdered form to produce a smooth, viscous, nonseparating suspension. It is cost effective for shipment anywhere in the world since it eliminates the cost of shipping water.

Grade 5300

Dense powder, USP, EP	Tapped Density (g/mL) 0.60-0.90
--------------------------	------------------------------------

5300 is a dense powder that conforms to both USP and EP standards.



Aluminum Hydroxide and Magnesium Carbonate Powder

Grade: 0611 (Micronized)

AHMC is codried, powder of aluminum hydroxide and magnesium carbonate. SPI can customize the ratio and particle size.

Grade **0611**

% Aluminum as Al ₂ O ₃	Apparent Density (g/mL)
39.0-44.0	NMT 0.20

% Magnesium as MgO
6.0-9.0

AHMC 0611 is specifically designed for rehydration from the powdered form to a smooth, viscous, non-separating suspension.



Magaldrate Powder

Grade: 7000

Magaldrate is a highly reactive antacid designed for formulation of suspensions and tablets. The high reactivity of the product is a result of its unique crystal structure.

Grade **7000**

% Magaldrate Assay	Tapped Density (g/mL)
90.0-105.0	0.60-0.90

Magaldrate Powder conforms to both USP and EP standards.

Antacid Suspensions

From Pastes or Gels with Suspending Agents

Preformulated CoBlend Pumpable Gels

Grade: Custom

CoBlend is a customized preformulated product designed to simplify the manufacturing process, improve taste and reduce cost in the production of immediate relief antacid suspensions. An improved, smooth mouthfeel is created by blending the actives with sorbitol.

Standard grades of CoBlend are listed below.

Grade **AMS 035**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	0.35

Final Formulation Label Claim/5mL
405 mg Dried Al(OH)₃ USP/100 mg Mg(OH)₂

Grade **AMS 106**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	1.06

Final Formulation Label Claim/5mL
200 mg Al(OH)₃/200 mg Mg(OH)₂

Grade **AMS 123**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	1.23

Final Formulation Label Claim/5mL
225 mg Dried Al(OH)₃ USP/200 mg Mg(OH)₂

Grade **AMS 138**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	1.38

Final Formulation Label Claim/5mL
200 mg Dried Al(OH)₃ USP/200 mg Mg(OH)₂

These custom formulated antacid suspensions are designed to simplify the manufacturing process, improve taste and reduce cost.

- + Easy to handle, pumpable formulation
- + Improved mouthfeel and reactivity
- + Excellent consistency
- + Low lead versions (<70 ppb) available
- + Manufactured under cGMP standards
- + Simpler manufacturing process that results in lower cost (see page 15).

Fig 1. Particle Size Distribution

CoBlend

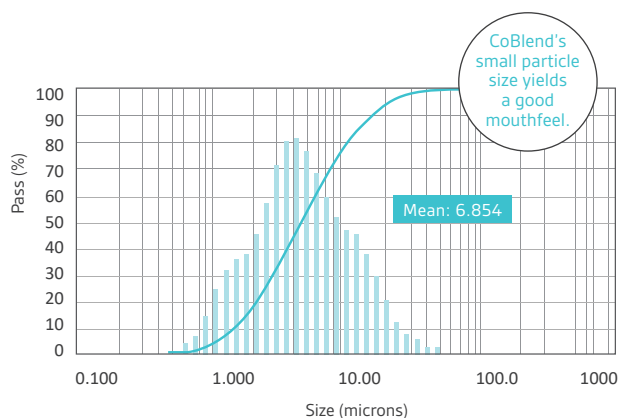
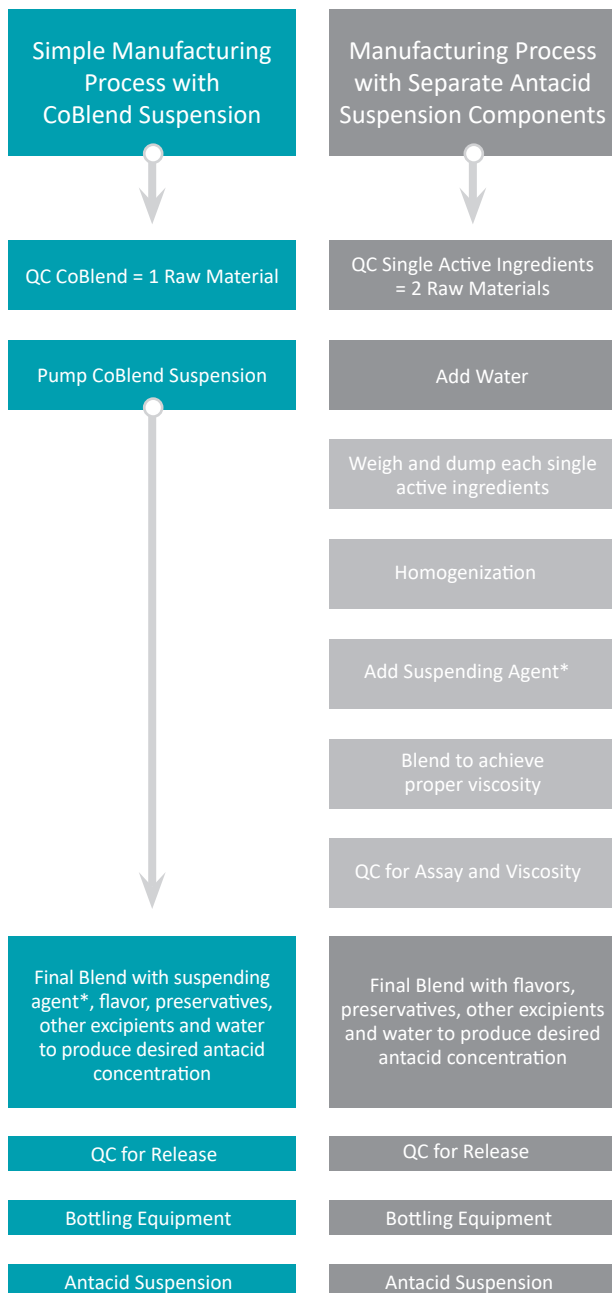


Fig 2. A simpler, better and less expensive way to make an antacid suspension CoBlend



*Addition of suspending agent depends on customer viscosity requirement for their antacid suspension

For information on customization, contact our sales team at salesinfo@spipharma.com.

Aluminum Hydroxide Pumpable Gels Grade: LV13, Hyper 10, Hyper 12

These low viscosity gels are pumpable with standard equipment and can be shipped in drums, totes and bulk container trucks. Because of the lower viscosity upon dilution to final formulation, the use of suspending agents and thickeners are recommended to achieve appropriate thickness for an antacid suspension.

Grade **LV 13**

% Assay as Al(OH) ₃	% Assay as Al ₂ O ₃
19.1-21.4	12.5-14.0

Viscosity
400-2000 cps as-is, Brookfield Viscometer

Grade **Hyper 10**

% Assay as Al(OH) ₃	% Assay as Al ₂ O ₃
13.0-15.3	8.5-10.0

Viscosity
250-500 cps as-is, Brookfield Viscometer

Grade **Hyper 12**

% Assay as Al(OH) ₃	% Assay as Al ₂ O ₃
NLT 18.3	NLT 12

Viscosity
2000-8000 cps as-is Brookfield Viscometer

Antacid Suspensions

From Pastes or Gels with Suspending Agents

Magnesium Hydroxide Pastes

Grade: Flogel, LVM

Magnesium hydroxide, $Mg(OH)_2$, as aluminum hydroxide is a typical active in pharmaceutical antacid formulations; often, they are combined. Selecting the right grade of magnesium paste allows the formulator to make a high quality antacid at a competitive price.

Grade **Flogel**

% $Mg(OH)_2$ Assay	Viscosity @ 7.75% cps
29.0-33.0	NMT 500

Flogel is a pumpable magnesium hydroxide suspension. Because of its very low viscosity, Flogel requires the use of suspending agents.

Grade **LVM**

% $Mg(OH)_2$ Assay	Viscosity @ 7.75% cps
29.0-33.0	800-1800

LVM Magnesium Paste is recommended for regular and extra strength products. A suspending agent may be required.

Magaldrate Gels

Grade: 10%, 20%

Magaldrate is a highly reactive antacid designed for the formulation of suspensions and tablets. The high reactivity of the product is a result of the unique crystal structure of the magaldrate. The gel is available as 10 or 20% suspension. The need for a suspending agent depends on the desired viscosity, it may not be required with our magaldrate suspensions.

Grade **10%**

% Magaldrate Assay	% $Al(OH)_3$ @100%
9.8-10.5	32.1-45.9

% $Mg(OH)_2$ @ 100%	Viscosity, as-is, Haake mPas
49.2-66.6	NLT 50

Grade **20%**

% Magaldrate Assay	% $Al(OH)_3$ @100%
20.0-23.0	32.1-45.9

% $Mg(OH)_2$ @ 100%	Viscosity, as-is, Haake mPas
49.2-66.6	NLT 50

Other Aluminum-Based Products

Grade: Aluminum Phosphate, Boehmite

Aluminum Phosphate

This product contains 20% aluminum phosphate (AlPO_4) and functions by coating the stomach wall. It does not neutralize stomach acids. Aluminum phosphate absorbs gall salts and stomach gas. Since the product does not chelate dietary phosphate, it does not deplete phosphate from the stomach.

Grade **Gel 520**

Characteristics	% Aluminum as AlPO_4
Pumpable Suspension	19.0-21.0

Boehmite Gel

Boehmite is a crystalline form of aluminum hydroxide. Unlike the amorphous form of aluminum hydroxide gel, Boehmite does not dissolve in Hydrochloric Acid (HCl). Boehmite protects the stomach wall by absorbing stomach acid and creating a high viscosity gel.

Grade **NLP 14**

Characteristics	% Al_2O_3 Content
Pumpable Suspension	14.0-16.0

Antacid Suspensions

From Pastes or Gels without Suspending Agents

Aluminum Hydroxide Viscous Gels

Grade: Visco 6, Visco 9

Viscous aluminum hydroxide products are typically used in regular strength antacid suspensions. The products provide the appropriate thickness without requiring the use of gums or suspending agents. These gels can be dumped from drums with suitable equipment or pumped from the drum with specially designed pumps. Visco 6 has the same advantages as Visco 9 but is easier to transfer because it is pumpable. It can be delivered in drums, totes and even bulk container trucks.

Grade **Visco 6**

% Assay as $\text{Al}(\text{OH})_3$	% Assay as Al_2O_3
8.4-9.9	5.5-6.5

Viscosity
1500-3000 cps, Brookfield Viscometer*

Grade **Visco 9**

% Assay as $\text{Al}(\text{OH})_3$	% Assay as Al_2O_3
NLT 13.6	NLT 8.9

Viscosity
NLT 1500 cps, Brookfield Viscometer*

*test is run on aqueous suspension containing 6.12% $\text{Al}(\text{OH})_3$ (4% Al_2O_3), Brookfield Viscometer, LV, Spindle 2, speed 12 rpm.

Antacid Suspensions

From Pastes or Gels without Suspending Agents

Preformulated CoBlend Pumpable Gel

Grade: Custom

CoBlend is a customized preformulated product designed to simplify the manufacturing process, improve taste and reduce cost in the production of immediate relief antacid suspensions. An improved, smooth mouthfeel is created by blending the actives with sorbitol. Standard grades of CoBlend are listed below.

Grade **AMS 106**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	1.06

Final Formulation Label Claim/5mL
200 mg Al(OH)₃/200 mg Mg(OH)₂

Grade **AMS 138**

Ingredients	Ratio of MgO to Al ₂ O ₃
Al/Mg/Sorbitol	1.38

Final Formulation Label Claim/5mL
200 mg Dried Al(OH)₃ USP/200 mg Mg(OH)₂

These custom formulated antacid suspensions are designed to simplify the manufacturing process, improve taste and reduce cost.

- + Easy to handle, pumpable formulation
- + Improved mouthfeel and reactivity
- + Excellent consistency
- + Low lead versions (<70 ppb) available
- + Manufactured under cGMP standards
- + Simpler manufacturing process that results in lower cost (p.17)

Fig 1. Particle Size Distribution CoBlend

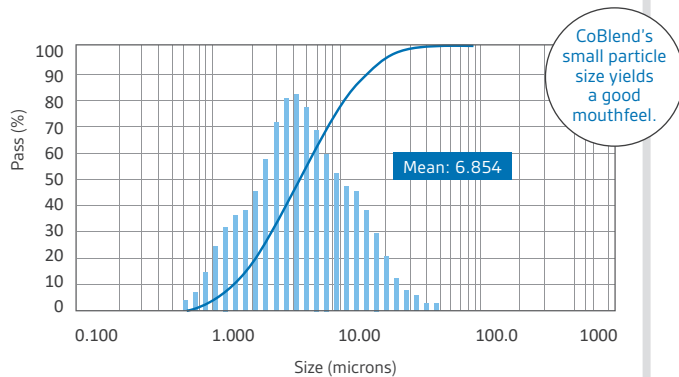
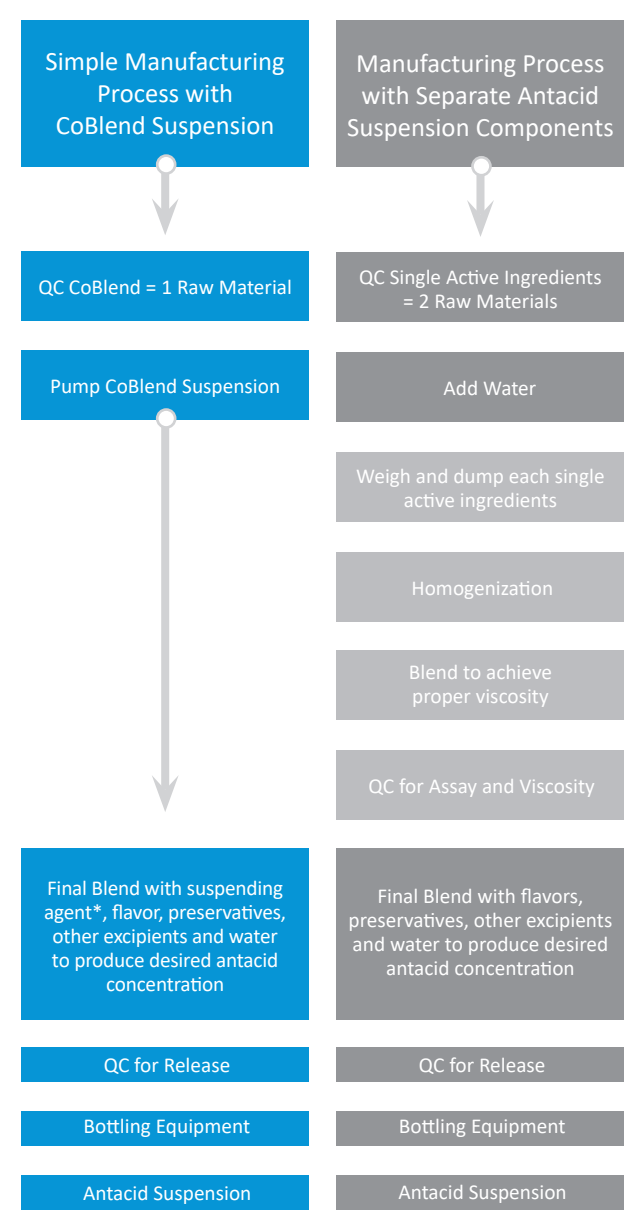


Fig 2. A simpler, better and less expensive way to make an antacid suspension CoBlend



*Addition of suspending agent depends on customer viscosity requirement for their antacid suspension

For information on customization, contact our sales team at salesinfo@spipharma.com.

Magnesium Hydroxide Pastes

Grade: LVM, M, MG12

We provide a wide range of magnesium hydroxide gels and pastes varying in assay and viscosity to meet your formulation needs. Selecting the right grade of magnesium gel or paste allows the formulator to make a high quality antacid at a competitive price.

Grade **LVM**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
29.0-33.0	800-1800

LVM magnesium paste is recommended for regular and extra strength products.

Grade **M**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
29.0-33.0	1400-3000

M magnesium paste is ideally suited for regular strength antacid suspensions or Milk of Magnesia (MoM) laxatives. Because the M grade has high viscosity and it yields a creamy product, suspending agents are not necessary.

Grade **MG12**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
10.0-14.0	1900-3000

MG12 magnesium paste is ideally suited for regular strength antacid suspensions or Milk of Magnesia (MoM) laxatives. MG12 has the same advantages as M but is easier to transfer because it is pumpable. It can be delivered in drums, totes and even bulk container trucks.

Magaldrate Gel

Grade: 10%, 20%

Magaldrate is a highly reactive antacid designed for the formulation of suspensions and tablets. The high reactivity of the product is a result of its unique crystal structure. The gel is available as 10 or 20% suspension.

Grade **10%**

% Magaldrate Assay	% Al(OH) ₃ @100%
9.8-10.5	32.1-45.9

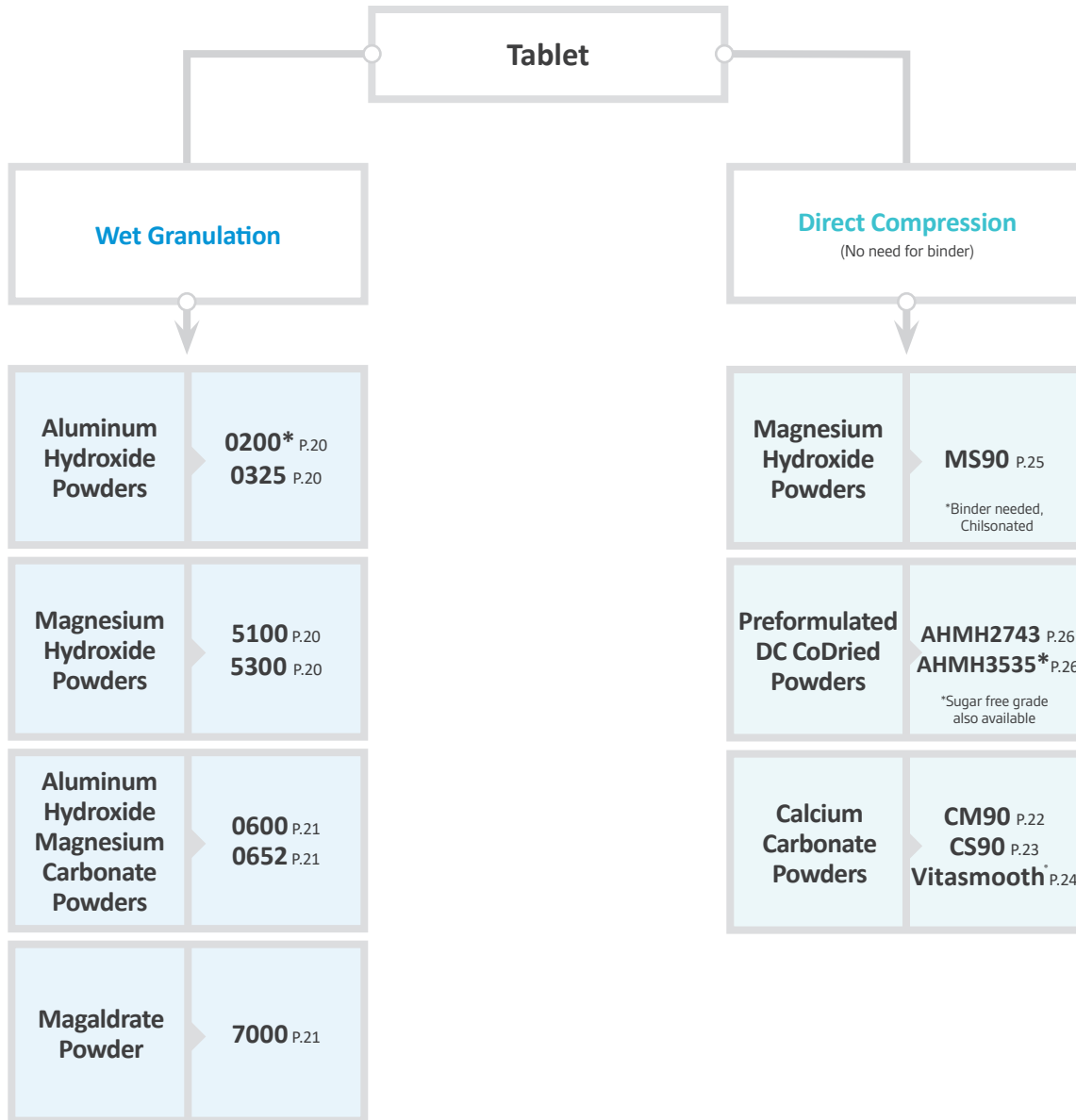
%Mg(OH) ₂ @ 100%	Viscosity, as-is, Haake mPas
49.2-66.6	NLT 50

Grade **20%**

% Magaldrate Assay	% Al(OH) ₃ @100%
20.0-23.0	32.1-45.9

%Mg(OH) ₂ @ 100%	Viscosity, as-is, Haake mPas
49.2-66.6	NLT 50

Antacid Tablet Product Selection Guide



Antacid Tablets

Wet Granulation

Aluminum Hydroxide Powders

Grade: 0200, 0325

SPI Pharma uses aluminum hydroxide powders as the active component in wet granulated and directly compressible antacid tablets. The aluminum hydroxide powders can be used alone or in combination with other ingredients for this purpose.

A wide range of aluminum powders is available. They vary in apparent density and particle size distribution. The aluminum concentration is constant. The aluminum assay for all products is not less than 76.5% on an $\text{Al}(\text{OH})_3$ basis or not less than 50% on an Al_2O_3 basis.

Grade **0200**

Fine powder, Tapped Density (g/mL)
USP, EP 0.16-0.25

Grade **0325**

Denser powder, Tapped Density (g/mL)
USP, EP 0.30-0.40

Magnesium Hydroxide Powders

Grade: 5100, 5300

Magnesium hydroxide as aluminum hydroxide is a typical Antacid Active; both are often combined, offering a good neutralizing and pH buffering effect and compensating their side effects.

Grade **5100**

Dense powder, Tapped Density (g/mL)
USP, EP, Low lead 0.68-0.84

5100 is free flowing and blends very well with other ingredients. It is low lead (<125 ppb).

Grade **5300**

Dense powder, Tapped Density (g/mL)
USP, EP 0.60-0.90

5300 is a dense powder that conforms to both USP and EP standards.

Antacid Tablets

Wet Granulation

Aluminum Hydroxide and Magnesium Carbonate Powders Grade: AHMC 0600, AHMC 0652

AHMC is codried powder available in various ratios and particle sizes.

Grade **0600**

% Aluminum as Al ₂ O ₃	Apparent Density (g/mL)
38.0-45.0	0.30-0.40

% Magnesium as MgO
6.0-10.0

Grade **0652**

% Aluminum as Al ₂ O ₃	Apparent Density (g/mL)
34.0-38.0	0.30-0.40

% Magnesium as MgO
11.0-15.0

Magaldrate Powder Grade: 7000

Magaldrate is a highly reactive antacid designed for formulation of suspensions and tablets. The high reactivity of the product is a result of the unique crystal structure of the magaldrate.

Grade **7000**

% Magaldrate Assay	Tapped Density (g/mL)
90.0-105.0	0.60-0.90

Magaldrate powder conforms to both USP and EP standards.

Antacid Tablets

Direct Compression (no need for binder)

DC Calcium Carbonate

Grade: CM90, CS90, Vitasmooth

CM90 calcium granulation is ideal for supplements requiring a creamy mouth feel, high calcium carbonate assay, and high density. Due to its high density and high assay, CM90 is ideal for targeting lower tablet weights and lower tablet volumes, while still providing the required calcium content. CM90 can be used in both wet granulation and direct compression systems.

Grade CM90

Ingredients

Calcium Carbonate

Maltodextrin

PSD – 200 mesh

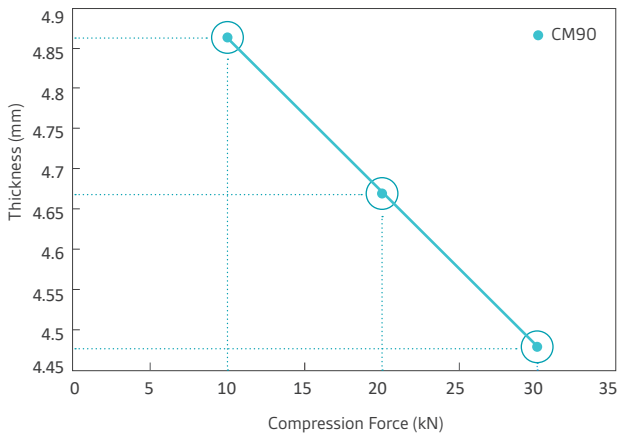
Tapped density (g/mL)

NMT 25.0% through

1.462

Fig 1. Compression

CM90



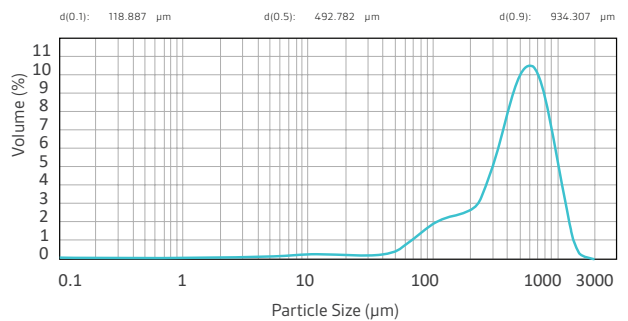
Due to the high product density indicated by the compression graph, CM90 provides for the manufacture of relatively thin tablets for a given weight, leading to an overall reduction in tablet volume. Additionally, the high calcium assay CM90 exhibits is ideal for the manufacture of high dose calcium supplements or antacids, creating the ability to produce a relatively small tablet for a given calcium carbonate dose.

CM90 generates a minimal amount of friction upon ejection from the tablet die. This reduces the wear and tear on the tableting press and ensures that tablet ejection will not decrease tablet robustness.

Fig 2. Particle Size Distribution

CM90

Typical particle size for CM90 is centered around 500 microns.



Antacid Tablets

Direct Compression (no need for binder)

DC Calcium Carbonate

Grade: CM90, CS90, Vitasmooth

A highly compactable, porous calcium carbonate with smooth organoleptics, CS90 is ideal for Antacid formulations and Nutritional Supplements, especially where tablet weight is a concern. CS90 has a high surface area, unique formulation and processing. It is readily compacted by direct compression methodology, omitting the need for wet granulation processes. This allows decreased overall tablet weights.

Grade **CS90***

*Low lead available

Ingredients

Calcium Carbonate

Starch

PSD – 230 mesh

Tapped density (g/mL)

NMT 25.0% through

0.75-0.95

Fig 1. Compaction

CS90

No need for wet granulation. Readily compacted by direct compression. Maintains high assay.

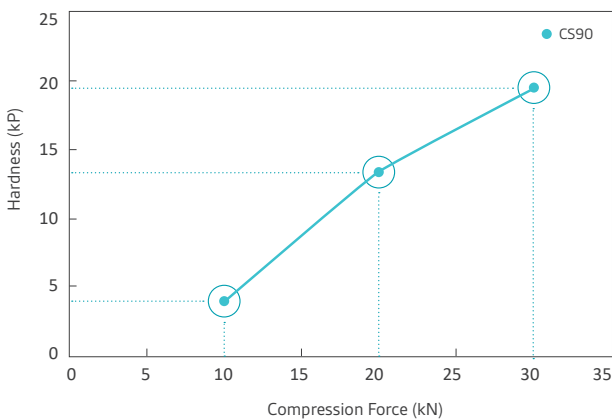


Fig 2. Particle Size Distribution

CS90

CS90 consistently maintains a uniform particle size.

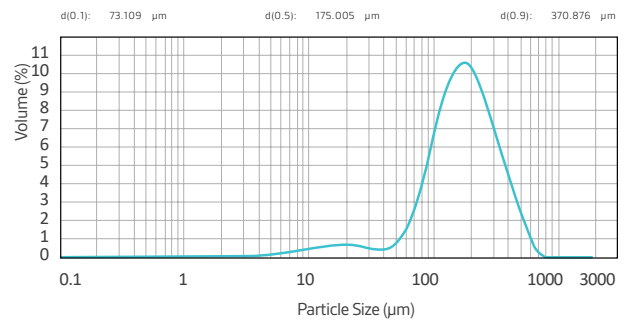
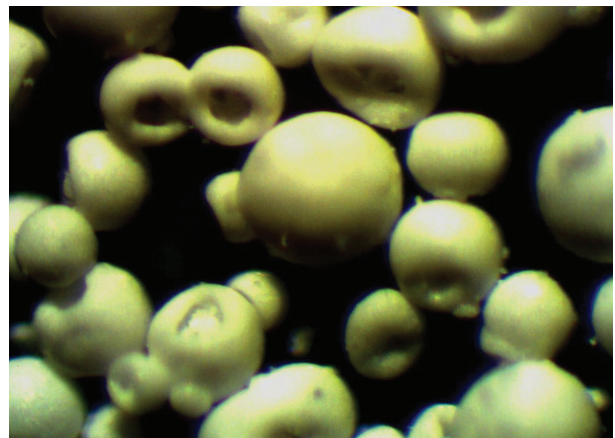


Fig 3. SEM image of CS90

CS90

Uniform particle size, highly compactable, porous calcium carbonate creates smooth organoleptics.



Antacid Tablets

Direct Compression (no need for binder)

DC Calcium Carbonate

Grade: CM90, CS90, Vitasmooth

Vitasmooth is a highly compactable and organoleptically pleasing formulation of calcium carbonate specifically designed for direct compression.

Grade Vitasmooth

Ingredients

Calcium Carbonate

Dextrose

Sucrose

MCC

Maltodextrin

PSD – 60 mesh

Tapped density (g/mL)

NLT 25.0% retained

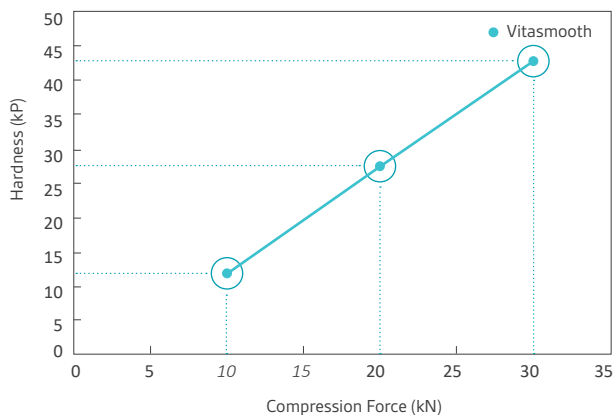
0.80

PSD – 200 mesh

NMT 10.0% retained

Fig 1. Compaction

Vitasmooth

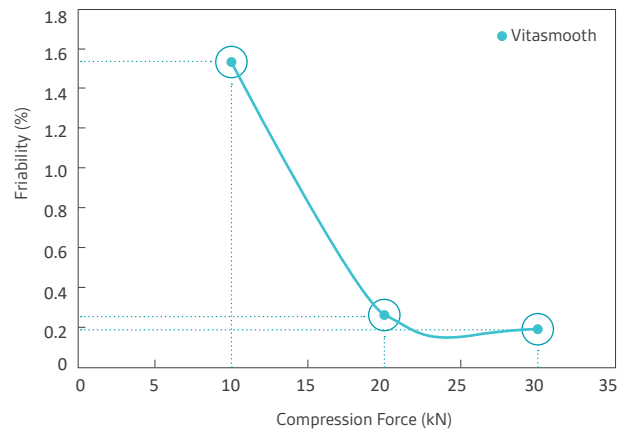


Vitasmooth is readily compactable and can be used in DC tableting without adding binders.

Fig 2. Friability

Vitasmooth

Vitasmooth is low friable, making it the ideal choice for direct compression.



Magnesium Hydroxide Powders

Grade: MS90

MS90 is a spray dried magnesium hydroxide with starch. It is directly compressible for use in antacid and laxative tablets or as a buffering agent in pharmaceutical formulations. Though other magnesium hydroxide manufacturers describe their product as DC, our MS90 is directly compressible on its own without the need for additional binders. The unique spray dried particle provides the product with excellent flow, high compressibility, and smooth mouthfeel. Consisting of a minimum of 90% magnesium hydroxide and manufactured under cGMP conditions, it has the consistent quality for pharmaceutical or nutraceutical use. MS90 magnesium hydroxide allows the formulator to make tablets by direct compression so that the cumbersome and costly wet granulation process can be avoided.

Grade MS90

Ingredients

90-95% Magnesium Hydroxide
5% Starch

Tapped Density	% Moisture @ 105°C
0.65-0.85 g/mL	NMT 3

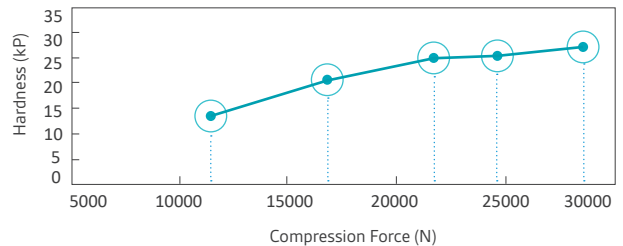
Particle Size Distribution

NLT 500 μ 5% max
NMT 250 μ 60% min
NMT 65 μ 30% max

The spray dried particle makes MS90 highly compressible which allows the formulator to reduce the amount of other binders in the formula; making room for additional actives and/or simply making a smaller tablet. This high compressibility also makes MS90 suitable for both chewable and conventional swallow tablets.

Fig 1. Compaction

MS90



Applications

Pharmaceutical

Direct Compression for Swallow or Chewable Tablets

- + Low ejection forces to save wear on tooling and tablet press
- + Low friability
- + High compressibility – makes thinner swallow tablets

Buffering Agent

- + pH of 10 makes an ideal buffer to be used with APIs in a tablet or capsule formulation to prevent active from acid degradation
- + May be used in antacid formulations

MS90 provides a high magnesium load for antacid activity (acid neutralization). Customized products are available upon request.

Antacid Tablets

Direct Compression (no need for binder)

Preformulated DC CoDried Powder Grade: AHMH2743, AHMH3535

DC CoDried Powders are preformulated products for a more simple, quick and cost effective manufacturing process of immediate relief antacid tablets. An improved, smooth mouthfeel is created by porous, spherical particles with uniform size distribution. This delivers a uniform and homogenous dosage. The process is very consistent because it utilizes CoDried Technology, creating the same composition from one granule to another. Antacid active ingredients are pre-formulated with excipients into DC CoDried Powders to facilitate the manufacturing of antacid tablets.

Grade **AHMH2743**

Aluminum Assay

27% Al Hydrox DG

Magnesium Assay

43% Mg Hydrox

Tablet Type

250mg Al Hydrox Dried Gel
400mg Magnesium Hydroxide

Grade **AHMH3535**

Aluminum Assay

35% Al Hydrox DG

Magnesium Assay

35% Mg Hydrox

Tablet Type

400mg Al Hydrox Dried Gel
400mg Magnesium Hydroxide

Fig 1. SEM image of AHMH3535

AHMH3535

Porous, spherical particles with uniform size distribution create a smooth mouthfeel.

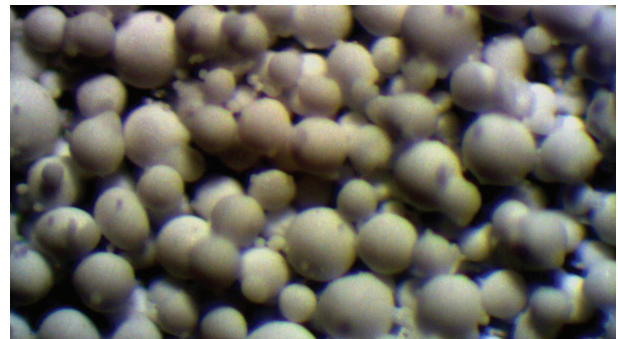


Fig 2. Particle Size Distribution

AHMH3535

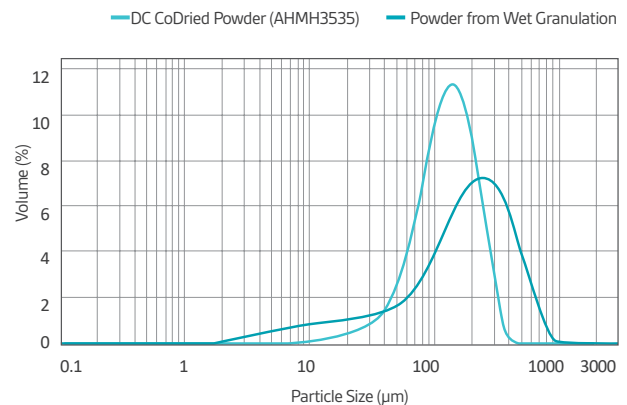
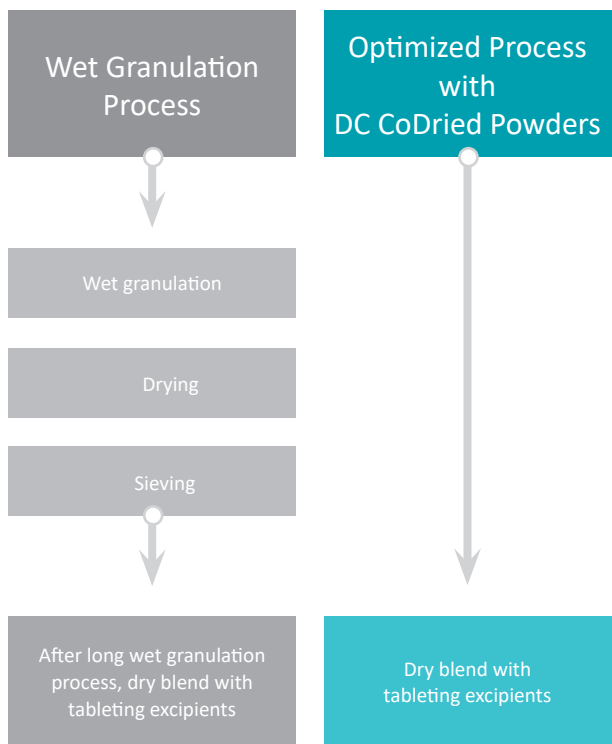


Fig 3. Advantages of DC CoDried Powders DC CoDried



DC CoDried Powders offer many advantages including reduced inventory requiring less QC testing; a short process that maintains a low cycle time and uses less equipment; provides 100% yield; eliminates the risk of batch failure for higher security; and creates a consistent product.

For information on customization, contact our sales team at salesinfo@spipharma.com.

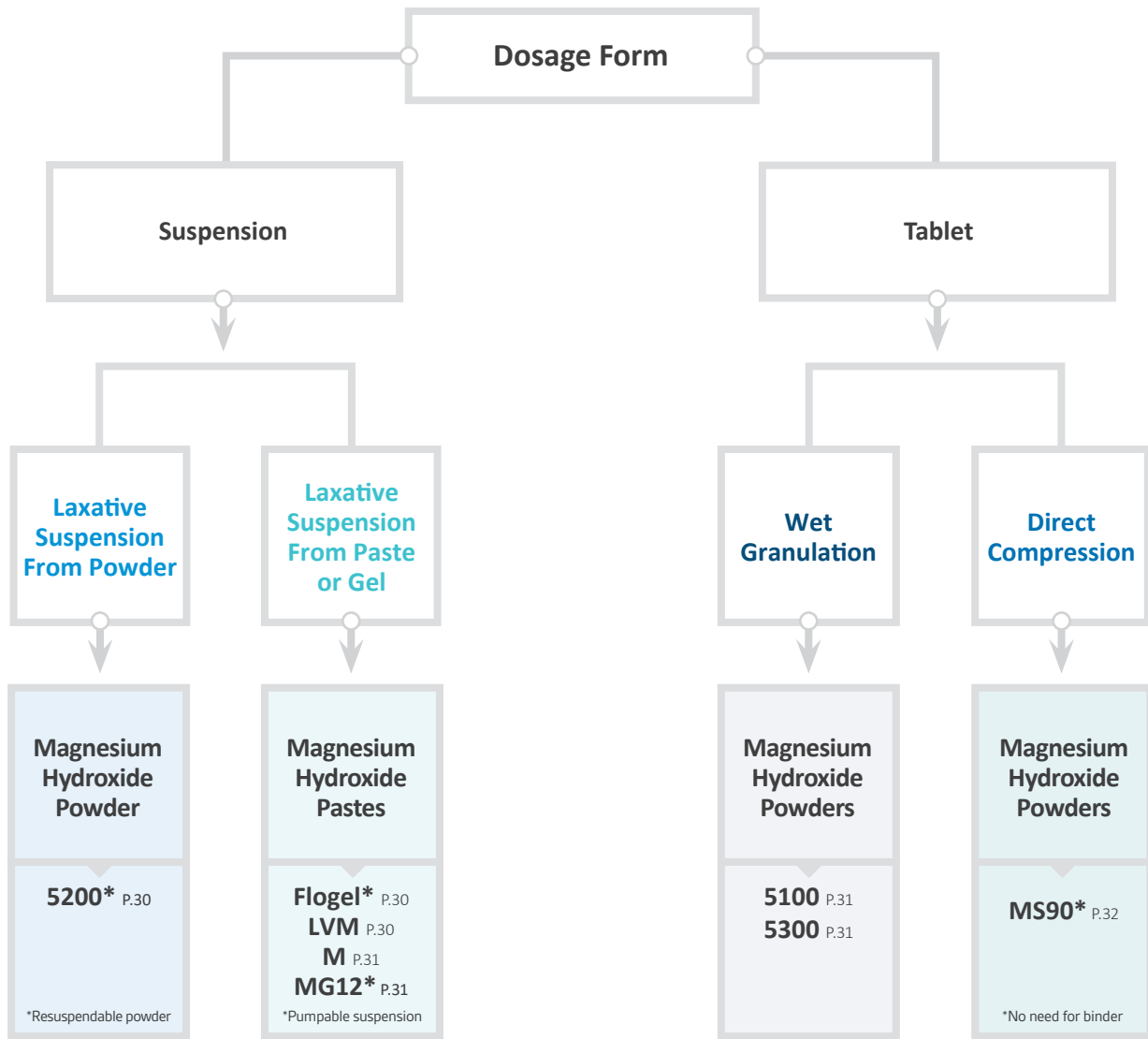


Introduction to Magnesium Hydroxide Based Laxatives

The laxative effect of magnesium appears to come through two different mechanisms. Magnesium relaxes the muscles in the intestines which help to establish a smoother rhythm. Magnesium also attracts water; this increased amount of water in the colon serves to soften the stool, helping to make stools easier to pass.

The term milk of magnesia (MoM) was first used for a white-colored, aqueous, mildly alkaline suspension of magnesium hydroxide formulated by Charles Henry Phillips in 1872 and sold under the brand name Phillips' Milk of Magnesia for medicinal usage. SPI Pharma has several types of magnesium to fit your manufacturing process and formation. Our technical staff can assist in the selection of the product that will run the most effectively for you.

Magnesium Hydroxide Based Laxative Product Selection Guide



Laxative Suspension

From Powder

Magnesium Hydroxide Powders

Grade: 5200

Custom-developed magnesium hydroxide powder from SPI Pharma that can be resuspended to produce a consistently homogenous pourable suspension.

Grade **5200**

Resuspendible powder, USP, EP	% Assay Mg(OH) ₂ 95.0-100.0
----------------------------------	---

Viscosity @ 7.75% Mg(OH)₂
1200-2200 cps Brookfield Viscometer

5200 is a medium density product specifically designed for rehydration from the powdered form to produce a smooth, viscous, nonseparating suspension. This is required for milk of magnesia (MoM) laxative systems. It is cost effective for shipment anywhere in the world since it eliminates the cost of shipping water.

Laxative Suspension

From Paste or Gel

Magnesium Hydroxide Pastes

Grade: Flogel, LVM, MG12, M

Our line of magnesium hydroxide pastes are available worldwide and provide the consistent quality required for pharmaceutical use. These magnesium hydroxide pastes are used for laxative suspensions requiring a suspending agent.

Grade **Flogel**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
29.0-33.0	NMT 500

Flogel is a pumpable magnesium hydroxide suspension. Because of its very low viscosity, Flogel requires the use of suspending agents.

Grade **LVM**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
29.0-33.0	800-1800

LVM magnesium paste yields a medium viscosity upon dilution and may require the use of suspending agent to achieve the desired final viscosity.



Laxative Tablet

Wet Granulation

Magnesium Hydroxide Powders Grade: 5100, 5300

Our line of magnesium hydroxide powders are available worldwide and provide the consistent quality required for pharmaceutical use. These magnesium hydroxide powders are used in a wet granulation process to produce laxative tablets.

Grade **MG12**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
10.0-14.0	1900-3000

MG12 magnesium paste is ideally suited for milk of magnesia (MoM) laxatives. MG12 has same advantages as our M product, but is easier to transfer. It can be delivered in drums, totes and even bulk container trucks.

Grade **M**

% Mg(OH) ₂ Assay	Viscosity @ 7.75% cps
29.0-33.0	1900-3000

M magnesium paste is ideally suited for milk of magnesia (MoM) laxatives. Because the M grade has high viscosity and it yields a creamy product, suspending agents are not necessary.

Grade **5100**

Dense powder, USP, EP	Tapped Density (g/mL)
	0.68-0.84

5100 is free flowing and blends very well with other ingredients. It is low lead (<125 ppb).

Grade **5300**

Dense powder, USP, EP	Tapped Density (g/mL)
	0.60-0.90

5300 is a dense powder that conforms to both USP and EP standards.

Laxative Tablet

Direct Compression

Magnesium Hydroxide Powders

Grade: MS90

MS90 is a spray dried magnesium hydroxide with starch. It is directly compressible for use in laxative tablets. Though other magnesium hydroxide manufacturers describe their product as DC, our MS90 is directly compressible on its own without the need for additional binders. The unique spray dried particle provides the product with excellent flow, high compressibility, and smooth mouthfeel. Consisting of a minimum of 90% magnesium hydroxide and manufactured under cGMP conditions, it has the consistent quality required for pharmaceutical use. MS90 magnesium hydroxide allows the formulator to make tablets by direct compression so that the cumbersome and costly wet granulation process can be avoided.

Grade **MS90**

Ingredients

90-95% Magnesium Hydroxide

5% Starch

Tapped Density

0.65-0.85 g/mL

% Moisture @ 105°C

NMT 3

Particle Size Distribution

NLT 500 μ 5% max

NMT 250 μ 60% min

NMT 65 μ 30% max

The spray dried particle makes MS90 highly compressible which allows the formulator to reduce the amount of other binders in the formula; making room for additional actives and/or simply making a smaller tablet. This high compressibility also makes MS90 suitable for both chewable and conventional swallow tablets.

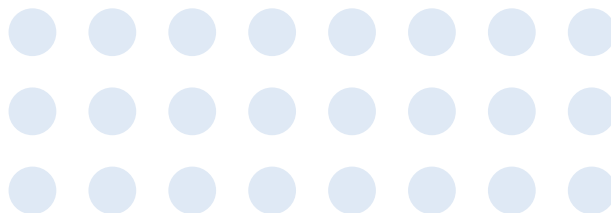
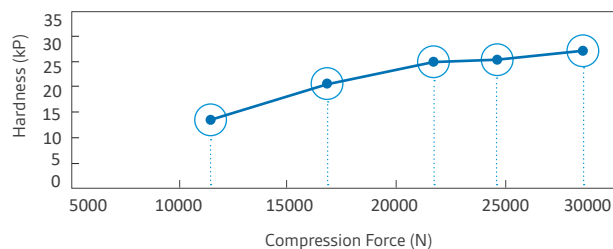


Fig 1. Compactibility

MS90



Direct Compression for Swallow or Chewable Tablets

- + Low ejection forces to save wear on tooling and tablet press
- + Low friability
- + High compressibility – makes thinner swallow tablets



Typical Product Properties

SPI Pharma provides typical properties for our products, including characteristics, physical, chemical and microbial ranges.

The information in the following section is meant to serve as a guideline for your product selection process.

Aluminum Hydroxide Gels

Antacid Actives Typical Product Properties

Aluminum Compounds

Aluminum Hydroxide	Al Hyd Gel Visco 6	Al Hyd Gel Visco 9 USP
Characteristics		
Description	White, viscous suspension which may release small amounts of water on standing	White, viscous suspension which may release small amounts of water on standing
Physical		
⁽²⁾⁽³⁾ Viscosity (Brookfield)	1500 – 3000 cps	NLT 1500 cps
Chemical		
Aluminum Assay Al(OH) ₃		NLT 13.7%
Aluminum Assay Al ₂ O ₃	8.4 – 9.9%	NLT 9.0%
⁽²⁾ pH	5.5 – 6.5	5.5 – 8.0
⁽¹⁾ Chlorides (based on the Al(OH) ₃ content)	NMT 4.7%	NMT 4.7%
⁽¹⁾ Sulfate (based on the Al(OH) ₃ content)	NMT 0.8%	NMT 0.8%
⁽¹⁾ Arsenic (based on the Al(OH) ₃ content)	NMT 10 ppm	NMT 10 ppm
⁽¹⁾ Heavy Metals (based on the Al(OH) ₃ content)	NMT 83 ppm	NMT 83 ppm
% Expected ANC	NLT 65.0% of Expected	NLT 65.0% of Expected
Microbial		
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)
<i>E. Coli</i>	Absence	Absence

Other Notes

(1) These tests are on reduced testing status.

(2) These tests are measured on a 4.0% Al₂O₃ or 6.12% Al(OH)₃ suspension.

(3) These tests are measured at the time of release and are not indicative of stability.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.



Al Hyd Gel LV13 USP	Al Hyd Gel Hyper 10	Al Hyd Gel Hyper 12 USP
White, viscous suspension which may release small amounts of water on standing	White, viscous suspension which may release small amounts of water on standing	White, viscous suspension which may release small amounts of water on standing
	250 – 500 cps “as is”	< 600 mPs “as is”*
19.1– 21.4%	13.0 – 15.3%	NLT 18.3%
12.5 – 14.0%	8.5 – 10.0%	NLT 12.0%
5.5 – 8.0	5.5 – 8.0	5.5 – 8.0
NMT 4.7%	NMT 4.7%	NMT 4.7%
NMT 0.8%		NMT 0.8%
NMT 10 ppm	NMT 10 ppm	NMT 10 ppm
NMT 83 ppm	NMT 83 ppm	NMT 83 ppm
NLT 65.0% of Expected		NLT 65.0% of Expected
NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)
Absence	Absence	Absence

Other Notes

(1) These tests are on reduced testing status.

(2) These tests are measured on a 4.0 % Al₂O₃ or 6.12% Al(OH)₃ suspension.

(3) These tests are measured at the time of release and are not indicative of stability.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

*Viscosity is tested using Haake versus Brookfield.

Aluminum Hydroxide Powders

Antacid Actives Typical Product Properties

Aluminum Compounds

Aluminum Hydroxide	0200 Dried Al Hyd Gel USP	0200 Dried Al Hyd Gel Ph. Eur
Characteristics		
Description	White, odorless, tasteless, amorphous powder	White or almost white, amorphous powder
Physical		
Tapped Density (Info only)	0.16 – 0.25 g/mL	0.16 – 0.25 g/mL
Apparent Density (Info only)		
Particle Size – 400 Micron		
Chemical		
Aluminum Assay Al(OH) ₃	NLT 76.5% Al(OH) ₃	47.0% – 60.0% as Al ₂ O ₃
⁽²⁾ pH	NMT 10.0	
⁽¹⁾ Chlorides	NMT 0.85%	NMT 1.0%
⁽¹⁾ Sulfate	NMT 0.6%	NMT 1.0%
⁽¹⁾ Arsenic	NMT 8 ppm	NMT 4 ppm
⁽¹⁾ Heavy Metals	NMT 0.006%	NMT 60 ppm
Acid Neutralizing Capacity	NLT 25.0 mEq/g	
Acid Consuming Capacity		NLT 250 mL 0.1N HCl/g
Neutralizing Capacity		NMT 35.0 mL

Other Notes

(1) These tests are on reduced testing status.

(2) These tests are measured on a 4.0 % Al₂O₃ or 6.12% Al(OH)₃ suspension.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.



0325 Dried Al Hyd Gel USP	0325 Dried Al Hyd Gel Ph. Eur
White, odorless, tasteless, amorphous powder	White or almost white, amorphous powder
0.29 – 0.58 g/mL	0.29 – 0.58 g/mL
NLT 76.5% Al(OH) ₃	47.0 – 60.0%
NMT 10.0	
NMT 0.85%	NMT 1.0%
NMT 0.6%	NMT 1.0%
NMT 8 ppm	NMT 4 ppm
NMT 0.006%	NMT 60 ppm
NLT 25.0 mEq/g	NMT 35.0 mL
	NLT 250 mL 0.1N HCl/g
	NMT 35.0 mL

Other Notes

(1) These tests are on reduced testing status.

(2) These tests are measured on a 4.0 % Al₂O₃ or 6.12% Al(OH)₃ suspension.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

Aluminum Phosphate Gel

Boehmite Gel

Antacid Actives Typical Product Properties

Aluminum Compounds

Aluminum Phosphate/ Boehmite	Al Phosphate Gel, 520 Ph. Eur	Al Boehmite Gel, NLP14
Characteristics		
Description	White pumpable suspension, from which small amounts of clear liquid may separate on standing	White to off-white odorless gel
Physical		
⁽²⁾⁽³⁾ Viscosity (Haake)		< 600 mPs
Chemical		
Aluminum Assay $AlPO_4$	19.0 – 21.0%	
Aluminum Assay Al_2O_3		14.0 – 16.0%
Residue on ignition	19.0% – 23.0%	
Soluble aluminum	NMT 50 ppm	NMT 50 ppm
Soluble phosphate	NMT 0.5% as PO_4	
⁽²⁾ pH	6.0 – 8.0	7.5 – 9.5
Peroxides	NMT 150 ppm as H_2O_2	
⁽¹⁾⁽²⁾ Chlorides	NMT 500 ppm	NMT 0.25%
⁽¹⁾⁽²⁾ Sulfate	NMT 0.2%	NMT 0.25%
⁽¹⁾⁽²⁾ Arsenic	NMT 1 ppm	NMT 0.6 ppm
⁽¹⁾⁽²⁾ Heavy Metals	NMT 10 ppm	NMT 5 ppm
Acid Neutralizing Capacity	pH @ 15 min is 2.0 – 2.5	
Microbial		
Microbial Total Aerobic Count	NMT 100 cfu/g	NMT 100 cfu/g
<i>E. Coli</i>	Absence	Absence

Other Notes

(1) These tests are on reduced testing status.

(2) These tests are measured on a 4.0% Al_2O_3 or 6.12% $Al(OH)_3$ suspension.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

(3) These tests are measured at the time of release and are not indicative of stability.

Magnesium Hydroxide Pastes

Antacid Actives Typical Product Properties

Magnesium Compounds

Magnesium Hydroxide	Mg Hyd Paste USP LVM	Mg Hyd Paste USP Type M	Flogel USP	Mg Hyd MG12
Characteristics				
Description	White to off-white paste	White to off-white paste	White to off-white gel	White wet gel suspension
Physical				
* ⁽³⁾ Viscosity (Brookfield)	800 – 1800 cps	1400 – 3000 cps	NMT 8000 cps @ 28% Mg(OH) ₂	1900 – 3000 cps
Chemical				
Assay Mg(OH) ₂	29.0 – 33.0%	29.0 – 33.0%	29.0 – 33.0%	10.0 – 14.0%
⁽²⁾ Calcium @ 100%	NMT 1.5%	NMT 1.5%	NMT 1.5%	NMT 1.5%
⁽²⁾ Lead (by ICP-MS)	NMT 1.5 ppm	NMT 1.5 ppm	NMT 1.5 ppm	
*Soluble Alkalies	NMT 1.0 mL	NMT 1.0 mL	NMT 1.0 mL	NMT 1.0 mL
*Soluble Salts	NMT 12 mg	NMT 12 mg	NMT 12 mg	
* ⁽¹⁾ Heavy Metals	NMT 5 ppm	NMT 5 ppm	NMT 5 ppm	NMT 5 ppm
Microbial				
Microbial Total Aerobic Count	NMT 400 (cfu/g)	NMT 400 (cfu/g)	NMT 400 (cfu/g)	NMT 400 (cfu/g)
<i>E. Coli</i>	Absence	Absence	Absence	Absence

Other Notes

(1) These tests are on reduced testing status.

(*) These tests are performed on a 7.75% w/w Mg(OH)₂ test suspension prepared from a Composite sample.

(2) These tests are calculated to a dry basis.

(3) These tests are measured at the time of release and are not indicative of stability.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

Antacid Actives Typical Product Properties

Magnesium Compounds

Magnesium Hydroxide	5100 CG Mg Hyd Powder USP	DC Magnesium Hyd MS90
Characteristics		
Description	Bulky white powder	White to off-white granular powder
Physical		
Tapped Density (Info only)	0.68 – 0.84 g/mL	0.65 – 0.85 g/mL
Chemical		
Assay (dried @ 105 deg C for 2 hrs)	95.0 – 100.5% Mg(OH) ₂	90.0 – 96.0% Mg(OH) ₂
Loss on Drying	NMT 2.0%	NMT 3.0%
Loss on Ignition (LOI)	30.0 – 33.0%	
Soluble Salts and Alkalies	NMT 2.0 mL of acid and NMT 10 mg residue	
⁽²⁾⁽³⁾ Lead (by ICP-MS)	NMT 1.5 ppm	
⁽²⁾ Calcium @ 100%	NMT 1.5%	
⁽¹⁾ Heavy Metals	NMT 20 ppm	
Soluble Substances		
Subs. insoluble in Acetic Acid		
Chloride		
Sulfate		
Iron		
Arsenic		
Microbial		
<i>E. Coli</i>	Absence	Absence

Other Notes

(1) These tests are on a reduced testing status.

(2) These tests are calculated to a dry basis.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

(3) Available with lead specification of NMT 100 ppb.



5200 Mg Hyd Powder USP Resusp	5200 Mg Hyd Pdr Ph. Eur Resusp	5300 Mg Hyd USP	5300 Mg Hyd Ph. Eur
White or almost white, fine, amorphous powder	Bulky white powder	Bulky white powder	White or almost white, fine, amorphous powder
0.60 – 0.75 g/mL	0.60 – 0.75 g/mL	0.60 – 0.90 g/mL	0.60 – 0.90 g/mL
95.0 – 100.5% Mg(OH) ₃	95.0 – 100.5% Mg(OH) ₃	95.0 – 100.5% Mg(OH) ₂	95.0 – 100.5% Mg(OH) ₃
NMT 2.0%		NMT 2.0%	
30.0 – 33.0%	29.0 – 32.5%	30.0 – 33.0%	29.0 – 32.5%
NMT 2.0 mL of acid and NMT 10 mg residue		NMT 2.0 mL of acid and NMT 10 mg residue	
NMT 1.5 ppm		NMT 1.5 ppm	
NMT 1.5%	NMT 1.5%	NMT 1.5%	NMT 1.5%
NMT 20 ppm	NMT 30 ppm	NMT 20 ppm	NMT 30 ppm
	NMT 2.0%		NMT 2.0%
	NMT 0.1%		NMT 0.1%
	NMT 0.1%		NMT 0.1%
	NMT 1.0%		NMT 1.0%
	NMT 0.07%		NMT 0.07%
	NMT 4 ppm		NMT 4 ppm
Absence	Absence	Absence	Absence

Other Notes

(1) These tests are on a reduced testing status.

(2) These tests are calculated to a dry basis.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

(4) These tests are measured at the time of release and are not indicative of stability.

Aluminum Hydroxide Magnesium Carbonate

Antacid Actives Typical Product Properties

Aluminum Magnesium Compounds

Aluminum Hydroxide/ Magnesium Carbonate	0600 Al Hyd/ Mg Carb	0611 Al Hyd/ Mg Carb	0652 Al Hyd/ Mg Carb
Characteristics			
Description	White, amorphous odorless powder	White, amorphous odorless powder	White, amorphous odorless powder
Physical			
Apparent Density (Info only)	0.30–0.40 g/mL	NMT 0.20 g/mL	0.30–0.59 g/mL
Chemical			
Aluminum Assay Al ₂ O ₃	38.0–45.0%	39.0–44.0%	34.0–38.0%
Assay MgO	6.0–10.0%	6.0–9.0%	11.0–15.0%
pH	8.5–9.5	8.5–9.5	8.5–9.5
Acid Neutralizing Capacity	NLT 25 mEq/g	NLT 25 mEq/g	NLT 25 mEq/g
Acid Consuming Capacity	NLT 260 mL N/10 HCl/g	NLT 260 mL N/10 HCl/g	
Chloride	NMT 0.85%	NMT 0.20%	NMT 0.20%
Sulfate	NMT 0.6%	NMT 0.6%	NMT 0.6%
Arsenic	NMT 8 ppm	NMT 5 ppm	NMT 5 ppm
Heavy Metals	NMT 60 ppm	NMT 50 ppm	NMT 50 ppm
Microbial			
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)
<i>E. Coli</i>	Absence	Absence	Absence

Other Notes

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

Antacid Actives Typical Product Properties

Aluminum Magnesium Compounds

Magaldrate Gel and Powder	Magaldrate Fluid Gel 10%	Magaldrate Fluid Gel 20%	7000 Mgal Powder USP	7000 Mgal Powder EP
Characteristics				
Description	White to light pink suspension	White to light pink suspension	White or almost white, crystalline powder	White or almost white, crystalline powder
Physical				
⁽³⁾ Viscosity (Haake)	50 – 100 mPas	50 – 150 mPas		
Chemical				
% Magaldrate	9.8% – 10.5%	20.0% – 23.0%	90.0% – 105.0%	90.0% – 105.0%
⁽²⁾ Al ₂ O ₃ in Magaldrate	32.1% – 45.9%	32.1% – 45.9%	32.1% – 45.9%	32.1% – 45.9%
⁽²⁾ Mg(OH) ₂ in Magaldrate	49.2% – 66.6%	49.2% – 66.6%	49.2% – 66.6%	49.2% – 66.6%
⁽¹⁾ Sulfates	16.0% – 21.0%	16.0% – 21.0%	16.0% – 21.0%	16.0% – 21.0%
⁽¹⁾ Soluble Sulfates	NMT 1.9%	NMT 1.9%	NMT 1.9%	NMT 1.9%
⁽¹⁾ Soluble Chlorides	NMT 3.5%	NMT 3.5%	NMT 3.5%	NMT 3.5%
⁽¹⁾ Arsenic	NMT 8 ppm	NMT 8 ppm	NMT 8 ppm	
⁽¹⁾ Heavy Metals	NMT 60 ppm	NMT 60 ppm	NMT 0.006%	NMT 30 ppm
Loss on Drying			10.0% – 20.0%	10.0% – 20.0%
Sodium			NMT 0.11%	NMT 0.10%
Microbial				
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)
<i>E. Coli</i>	Absence	Absence	Absence	Absence

Other Notes

(1) These tests are on a 100% Magaldrate basis.

(2) These tests are calculated to a dry basis.

(3) These tests are measured at the time of release and are not indicative of stability.

This product is manufactured under cGMP conditions.

This product meets the Residual Solvents specification as described in USP Chapter <467>.

**Preformulated
CoBlend
Pumpable
Gels**

Antacid Actives Typical Product Properties

Aluminum Magnesium Compounds

CoBlend	AMS 035	AMS 106	AMS 123	AMS 138
Characteristics				
Description	White to off-white suspension	White to off-white suspension	White to off-white suspension	White to off-white suspension
Chemical				
Aluminum Assay $Al_2(OH)_3$	12.7–14.9%	9.2–10.8%	11.2–13.0%	8.2–9.5%
Aluminum Assay Al_2O_3	8.3–9.7%	6.0–7.1%	7.3–8.5%	5.4–6.2%
Assay $Mg(OH)_2$	4.1–4.8%	9.2–10.8%	13.1–15.1%	10.8–12.5%
Assay MgO	2.8–3.3%	6.4–7.5%	9.1–10.4%	7.5–8.6%
pH	7.3–8.5	7.5–8.5	7.5–8.8	7.3–8.5
Sorbitol	2.0–4.0%	6.7–8.0%	4.9–6.1%	6.7–8.0%
Arsenic	NMT 0.6 ppm	NMT 0.6 ppm	NMT 0.6 ppm	NMT 0.85 ppm
Chloride	NMT 0.23%	NMT 0.35%	NMT 0.23%	NMT 0.23%
Heavy Metals	NMT 5 ppm	NMT 5 ppm	NMT 5 ppm	NMT 7 ppm
Sulfate	NMT 0.1%		NMT 0.1%	NMT 0.17%
Microbial				
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)	NMT 100 (cfu/g)
<i>E. Coli</i>	Absence	Absence	Absence	Absence

Other Notes

This product is manufactured under cGMP conditions.

Preservative system is paraben based.

**Preformulated
DC CoDried
Powders**

Antacid Actives Typical Product Properties

Aluminum Magnesium Compounds

DC CoDried Powders	AHMH 2743	AHMH 3535
Characteristics		
Description	White to creamy white, odorless, sweet taste powder	White to creamy white, odorless, sweet taste powder
Physical		
Tapped Density (Info only)		NLT 0.60 g/mL
Chemical		
Aluminum Assay Al ₂ O ₃	12.1 – 14.7%	16.4 – 19.0%
As Al(OH) ₃ dried gel USP at 50.0% Al ₂ O ₃	24.2 – 29.4%	32.8 – 38.0%
Assay Mg(OH) ₂	38.6 – 47.2%	32.8 – 38.0%
Ratio Al ₂ O ₃ / Mg(OH) ₂	0.297 – 0.328	0.475 – 0.525
Moisture at 80°C	NMT 5.0%	3.5 – 5.0%
Acid Neutralizing Capacity		19.9 – 24.3 mEq/g
Microbial		
Microbial Total Aerobic Count	NMT 100 (cfu/g)	NMT 100 (cfu/g)
<i>E. Coli</i>	Absence	Absence

Other Notes

This product is manufactured under cGMP conditions.

Calcium Carbonate Powders

Antacid Actives Typical Product Properties

Calcium Compounds

DC Calcium Carbonate	CM90	CS90	Vitasmooth
Characteristics			
Description	White to off-white granular powder	White to beige free flowing powder	White to off-white free flowing powder
Physical			
Tapped Density (Info only)		0.75 – 0.95 g/mL	
PSD – 60 mesh		NLT 60% Through	NLT 25% Retained
PSD – 200 mesh	NMT 25% Through		NMT 10% Retained
PSD – 230 mesh		NMT 25% Through	
Chemical			
Calcium Carbonate	88.0 – 93.0%	85.5 – 95.5%	54.0 – 60.0%
Loss on Drying	NMT 1%	NMT 2%	
KF Water			NMT 3%
Microbial			
Microbial Total Aerobic Count	NMT 1000 (cfu/g)	NMT 1000 (cfu/g)	NMT 1000 (cfu/g)

Other Notes

This product is manufactured under cGMP conditions.

Product is made using USP/Ph. Eur ingredients.

Product is made using USP/NF ingredients.

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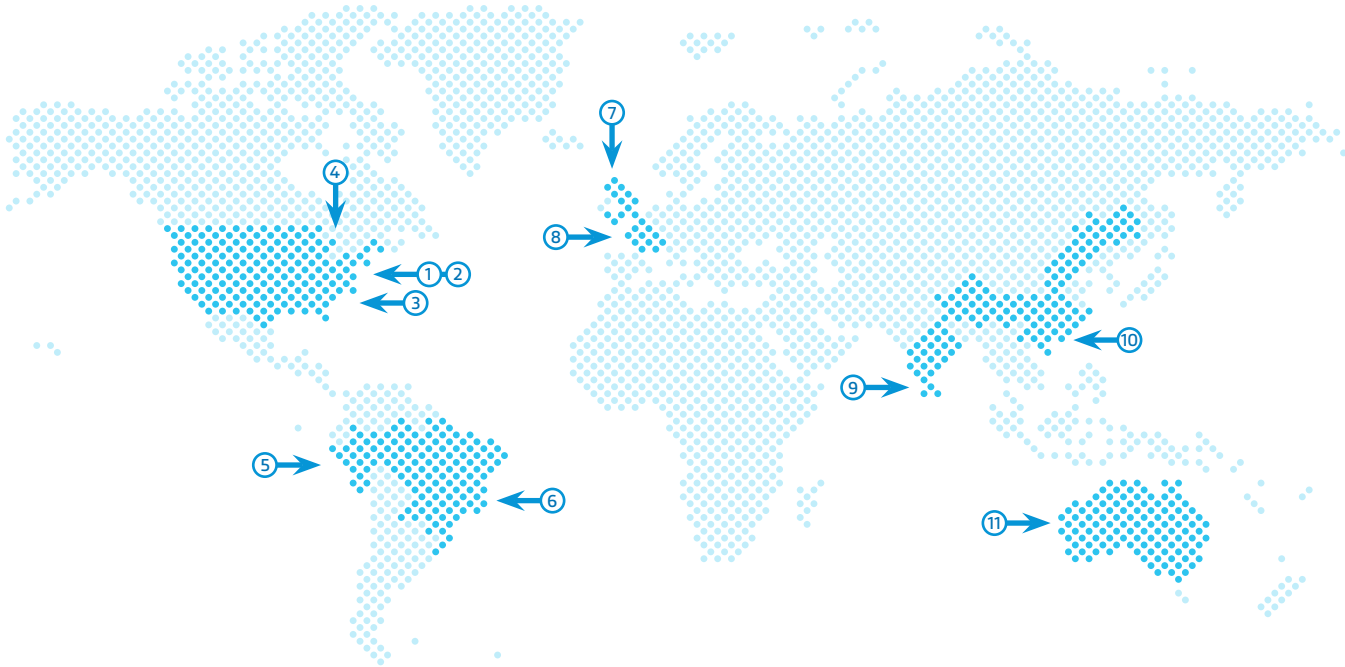
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