

AHMH 3535

Directly Compressible Aluminum Hydroxide and Magnesium Hydroxide for antacid tablets



With our specialized spray dry technology, we provide our customers with a highly compactable, directly compressible, pre-formulated product to facilitate manufacturing of chewable antacids tablets with excellent smooth and creamy mouthfeel.

Easy to use saving you time and money

- AHMH 3535 is ready to use and directly compressible pre-formulated Al Hyd and Mg Hyd based formula for a chewable antacid tablets
- Reduce R&D and product development costs
- Only add flavor of choice and lubricant

Excellent for tableting by direct compression

AHMH 3535 + Flavor + Lubricant



Blend



Tablet

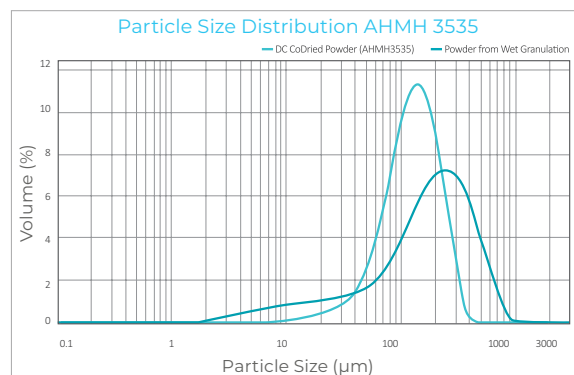
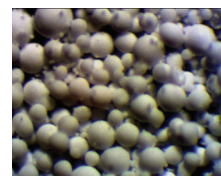
- Avoid granulation – improve productivity, by saving time and high costs

Good Compactibility

- At compression force between 10-20 kN AHMH 3535 tablets have ideal hardness for chewable tablet

Excellent Flowability

- Our specialized spray drying technology provides very consistently shaped spherical particles that ensures good flowability for tableting.
- Narrow particle size distribution for AHMH 3535 ensures good content uniformity and homogeneity during dry blending with no risk of segregation
- Consistent feed to the tableting machine



AHMH 3535

SPI Pharma's technical expertise will help you formulate an antacid tablet using direct compression.

Starting formulas for chewable antacid tablets

AL HYD. / MG HYD. with simethicone using DC codried powder AHMH 3535

	LABEL CLAIM per Tablet	
Aluminum Hydroxide	200 mg Al. Hyd. Dried Gel USP (Powder form) equivalent to: 153 mg $Al(OH)_3$ 100 mg Al_2O_3	
Magnesium Hydroxide	200 mg $Mg(OH)_2$	
Simethicone	25 mg	
INGREDIENTS	% by weight	Qty per Tablet
DC Co-dried Powder AHMH 3535	86.92 %	564.97 mg
DC Simethicone (SIM DC 100)	5.92 %	38.46 mg
DC Sucrose	5.66 %	36.82 mg
Magnesium Stearate	0.50 %	3.25 mg
Flavor	1.00 %	6.50 mg
Total Tablet Weight 650.00 mg		

AL HYD. / MG HYD. using DC codried powder AHMH 3535

	LABEL CLAIM per Tablet	
Aluminum Hydroxide	400 mg Al. Hyd. Dried Gel USP (Powder form) equivalent to: 306 mg $Al(OH)_3$ 200 mg Al_2O_3	
Magnesium Hydroxide	400 mg $Mg(OH)_2$	
INGREDIENTS	% by weight	Qty per Tablet
DC Co-dried Powder AHMH 3535	94.16 %	1129.94 mg
DC Sucrose	4.34 %	52.06 mg
Magnesium Stearate	0.60 %	7.20 mg
Flavor	0.90 %	10.80 mg
Total Tablet Weight 1200.00 mg		

Composition of AHMH 3535:

Aluminum Hydroxide; Magnesium Hydroxide; Sorbitol; Mannitol; Sucrose; Sodium Saccharin

Manufacturing Guidance

- 1. Screening / Weighing:** screen through # 20 mesh sieve and weigh the ingredients listed in the above recipe
- 2. Blending:** blend the ingredients for approximately 10 minutes on a Turbula Blender Type
- 3. Tableting:** compress the blend to the targeted tablet characteristics on a rotary tablet press

Great Mouth Feel

- Our specialized spray dried powder provides tablets with smooth and creamy mouthfeel with no fines or coarseness experienced when tablets are made using wet granulation method.



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*

AHMH 3535

- ✓ Technical File
- ✓ Non-GMO
- ✓ Gluten Free
- ✓ Aflatoxin Free
- ✓ cGMP†
- ✓ Compendial grade ingredients (USP and/or EP)
- ✓ Nanomaterial Free
- ✓ Components Origin
- ✓ Latex Free
- ✓ Absence of Residual Solvent
- ✓ 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.

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

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