

# ANTACID COMPOUNDS

ELEMENTIS



## INTRODUCTION

Elementis GmbH is a leading manufacturer of antacid compounds offering the widest range of products available from one supplier. Elementis Pharma's manufacturing facilities operate to the highest standards under a total quality concept which is an integral part of the company's philosophy.

The antacid production facility is a GMP, FDA and ISO 9001, ISO 14001, BH OHSAS 18001 certified plant and is licensed to manufacture bulk antacid formulations according to §13 of the German Drug Law.







#### ALUMINIUM HYDROXIDE

Aluminium hydroxide or aluminium hydroxycarbonate, is the most widely used antacid active. It is available as both a suspension and powder and maybe used alone or in combination with magnesium hydroxide.

The widespread use of aluminium hydroxide gel in the formulation of antacids is based on its excellent pharmacological properties, which have been proven repeatedly over many years of administration. Aluminium hydroxide gel is an effective neutralizer and buffer of gastric hydrochloric acid, with no known harmful side effects.

We offer a vast selection of aluminium hydroxide grades with a variety of properties.

#### DRIED ALUMINIUM HYDROXIDE GELS

Dried Aluminium Hydroxide Gels which are also known under the names Aluminium Oxide, hydrated or Aluminium Hydroxide Gel Powders are manufactured from suspensions via defined drying processes which result in powders with varying density and particle size characteristics. The powders are primarily used in the production of antacid tablets, preferably after pre-granulation.

#### Alugel® A 211

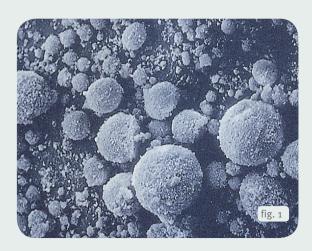
Alugel® A 211 is the most widely used active for tablet, granulate or powder manufacture. Its high reaction capacity with hydrochloric acid ensures rapid onset and prolonged action in the stomach. The typical morphology of this spray dried gel can be seen in fig. 1.

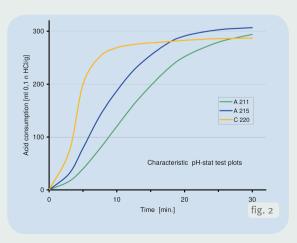
Assay	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
Al(OH) <sub>3</sub> = min. 76,5 %	0,28 - 0,38 g/ml	10 – 20 μm	USP
Al <sub>2</sub> 0 <sub>3</sub> = 47,0 - 60,0 %			PhEur, BP

## Alugel® A 215

Alugel<sup>®</sup> A 215 has the fastest reaction rate of all aluminium hydroxide powders, requiring only a few minutes to achieve full reactivity (see fig. 2). It is very stable on storage, with physical and chemical properties similar to those of Alugel<sup>®</sup> A 211.

Assay	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
Al(OH) <sub>3</sub> = min. 76,5 %	0,25 - 0,35 g/ml	10 – 20 μm	USP
$Al_2O_3 = 47,0-60,0\%$			PhEur, BP





## Alugel<sup>®</sup> A 225

Alugel® A 225 is an aluminium hydroxide powder with a low bulk density making it the active of choice when formulating with low density additives.

It is particularly suitable for use in candies and soft tablets due to its very fine particle size distribution. The small particles are easily mixed into the gum matrix of these types of products.

The fine particle size distribution of Alugel® A 225 also make it ideal for resuspending in liquid formulations.

Assay	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
Al(OH) <sub>3</sub> = min. 76,5 %	0,17 – 0,20 g/ml	4 – 12 μm	USP
Al <sub>2</sub> O <sub>3</sub> = 47,0 - 60,0 %			PhEur

#### ALUMINIUM HYDROXIDE GELS

Aluminium Hydroxide Gels which are also known under the names Aluminium Hydroxide Wet Gels, Aluminium Hydroxide Suspensions or Pastes are used predominantly in the manufacture of liquid antacid preparations. Their ease of administration, Pleasant taste, high active content and rapid onset of action compared to tablets, as well as the availability of practical packaging, e.g. dosed sachets, make liquid preparations a well-accepted dosage form for antacids.

Alugel® suspensions are produced with a range of solid contents and rheological properties enabling the customer to choose the grade most suitable for his particular requirements.

## Alugel® A 611

Alugel® A 611 is a standard, low viscosity, pumpable paste with an Al(OH) $_3$  content of 14,5-16,8%. It is used primarily in formulations requiring good flow characteristics and a high active content. The low viscosity allows the incorporation of additional antacid components in powder form.

Assay	Viscosity (Brookfield)	Pharmacopoeia
$Al(OH)_3 = 14,5 - 16,8\%$	3000 – 7000 mPa s	USP
$Al_2O_3 = 9,5 - 11,0\%$	(LV, 3/12)	

#### Alugel® A 621

Alugel® A 621 is more reactive and has a higher viscosity than A 611 making it suitable for formulations where no additional actives or viscosity regulators are foreseen. If required, additional substances may be incorporated after dilution. Alugel® A 621 provides remarkably stable suspensions with minimal sedimentation.

Assay	Viscosity (Brookfield)	Pharmacopoeia
Al(OH) <sub>3</sub> = min. 13,6 %	30 – 130 mPa s	USP
Al <sub>2</sub> O <sub>3</sub> = min. 8,9 %	(LV, 2/60) at 6,1% Al(OH) <sub>3</sub>	

## Alugel® A 651

Alugel® A 651 is a highly concentrated gel which reacts rapidly with hydrochloric acid and has an Al(OH) $_3$  content of 19,1 – 20,6%. It has a limited flow capability, but after dilution to approx. 15,3% Al(OH) $_3$ , Alugel® A 651 becomes a free flowing suspension with minimum sedimentation characteristics.

Туре	Assay	Viscosity (Brookfield)	Pharmacopoeia
LV	Al(OH) <sub>3</sub> = 19,1 - 20,6 %	min. 6000 mPa s (LV, 3/12)	USP
HV	Al(OH) <sub>3</sub> = 19,1 - 20,6 %	min. 150 mPa s (LV, 2/12) at 6,1% Al(OH) <sub>3</sub>	USP

## Alugel® A 661

Alugel® A 661 is the most viscous of the Alugel® grades and has an Al(OH) $_3$  content of more than 13,6%. Alugel® A 661 is an outstanding product in terms of reaction velocity and storage stability. Even on dilution to 6,1% Al(OH) $_3$  the suspension is extremely viscous and resistant to sedimentation, making it the product of choice for the formulation of stable suspensions without additional thickening agents.

Assay	Viscosity (Brookfield)	Pharmacopoeia
Al(OH) <sub>3</sub> = min. 13,6 %	500 – 2500 mPa s (LV, 2/12)	USP
Al <sub>2</sub> O <sub>3</sub> = min. 8,9 %	at 6,1% Al(OH) <sub>3</sub>	

## Alugel® A 671

Alugel® A 671 is a free flowing, pumpable suspension with an Al(OH) $_3$  content of 19,1 – 20,6 %. It is suitable for use in double and triple strength antacid preparations which retain good flow characteristics. Alugel® A 671 displays only slight sedimentation even after extremely long periods in transit or storage.

A low sodium grade of Alugel® A 671 is available upon request. This special type enables the production of antacids which are classified as "sodium free" according to FDA regulations.

Assay	Viscosity (Brookfield)	Pharmacopoeia
$Al(OH)_3 = 19,1 - 20,6\%$	max. 5000 mPa s (LV, 3/12)	USP
$Al_2O_3 = 12,5 - 13,5\%$		

## Alugel® A 681

With an  $Al(OH)_3$  content of 24,5 – 27,5 %, Alugel<sup>®</sup> A 681 is the most highly concentrated aluminium hydroxide suspension available today. Alugel<sup>®</sup> A 681 is a pumpable gel with an extremely low sodium content and a neutral taste, allowing the formulation of particularly pleasant tasting products.

As a result of its thixotropic properties,  $Alugel^{\otimes} A 681 displays$  no signs of sedimentation even after long periods in transit or storage.

Assay	Viscosity (Brookfield)	Pharmacopoeia
$Al(OH)_3 = 24,5 - 27,5\%$	max. 6000 mPa s	USP
$Al_2O_3 = 16,0 - 18,0\%$	(LV, 3/12)	



#### MAGNESIUM HYDROXIDE

Magnesium hydroxide is the most widely used antacid active after aluminium hydroxide. It is used in both suspension and powder formulations, usually in combination with aluminium hydroxide, and has a high acid-binding capacity and rapid reaction profile.

The ingestion of pure magnesium hydroxide antacids leads to undesirably high pH values in the stomach, which can, in turn, stimulate acid production. For this reason it is recommended that magnesium hydroxide is combined with aluminium hydroxide in antacid formulations. Combination products also overcome the laxative effect of magnesium hydroxide as this is compensated for by the mild obstipative effect of aluminium hydroxide.

#### MAGNESIUM HYDROXIDE POWDERS

#### Gilumag® D 211 / D 212 / D 213 / D 214

Magnesium hydroxide powders are used in the production of tablets, granules and powder mixtures, often in combination with Alugel® A 211 or Alugel® A 215. They differ with respect to particle size and bulk density.

Туре	Assay	Density (tapped)	d <sub>90</sub>	Pharmacopoeia
D 211	95,0 - 100,5 % Mg(OH) <sub>2</sub>	0,40 – 0,60 g/ml	6 – 10 μm	USP, PhEur
D 212	95,0 - 100,5 % Mg(OH) <sub>2</sub>	o,6o – o,8o g/ml	10 – 25 μm	USP, PhEur
D 213	95,0 - 100,5 % Mg(OH) <sub>2</sub>	0,81 – 1,00 g/ml	18 – 35 μm	USP, PhEur
D 214	95,0 - 100,5 % Mg(OH) <sub>2</sub>	1,01 – 1,25 g/ml	20 – 45 μm	USP, PhEur

#### Gilumag® D 220

Gilumag $^{\text{@}}$  D 220 is an ultra-fine, low bulk density powder, with a particle size of less than 5 µm. The fine particle size makes Gilumag $^{\text{@}}$  D 220 ideal for the formulation of soft tablets and candies as it can be easily mixed into the gel matrix of these types of products.

Gilumag® D 220 is readily mixed with water. The resulting suspensions, after homogenization, are stable, highly viscous, and have a smooth, non-gritty mouth feel. These characteristics make Gilumag® D 220 particularly suitable for the formulation of antacid suspensions in combination with Alugel® pastes.

Assay	Density (tapped)	d <sub>90</sub>	Pharmacopoeia
95,0 – 100,5 % Mg(OH) <sub>2</sub>	max. 0,41 g/ml	4 – 8 μm	USP, PhEur

#### MAGNESIUM HYDROXIDE SUSPENSIONS

## Gilumag® D 611

Gilumag $^{\circ}$  D 611 is a pumpable paste containing approx. 30 % Mg(OH) $_{2}$ . It is ideally suited for the production of single and double strength, free-flowing suspensions. Even after long periods of storage D 611 is readily stirred to a homogeneous suspension.

Assay	Viscosity (Brookfield)	Pharmacopoeia
29,0 - 33,0 % Mg(OH) <sub>2</sub>	min. 4000 mPa s <i>(LV 3/12)</i>	USP

## Gilumag® D 661

Gilumag® D 661 is a highly viscous, slightly thixotropic paste containing approx. 30 % Mg(OH)<sub>2</sub>. The high viscosity guarantees excellent storage stability. Single strength or Milk of Magnesia type products can be formulated with Gilumag® D 661 without the need for additional thickening agents.

Assay	Viscosity (Brookfield)	Pharmacopoeia
29,0 - 33,0 % Mg(OH) <sub>2</sub>	min. 1000 mPa s (at 25 %, LV 2/12)	USP

## Gilumag® D 671

Gilumag $^{\odot}$  D 671 is a pumpable suspension with a Mg(OH)<sub>2</sub> content of 34 % – 37 %. The high active content makes the material ideal for the formulation of double and triple strength products.

The chemical and physical properties of Gilumag® D 671 are similar to those of Gilumag® D 611.

Assay	Viscosity (Brookfield)	Pharmacopoeia
34,0 - 37,0 % Mg(OH) <sub>2</sub>	min. 4000 mPa s (LV 3/12)	USP

## MIXTURES

#### ALUMINIUM HYDROXIDE CO-DRIED / CO-BLENDED GELS

Co-dried or co-blended gels are mixtures of more than one material which are processed together and in the case of powders, spray dried. This guarantees a homogeneous mixture of the primary components which is not sensitive to demixing during transport. The antacid reactivity of the aluminium hydroxide can be increased and stabilized by the incorporation of additives into the co-blend.

Tailor made gels can be produced on request from simple co-blends up to final bulk formulations.

## Aluminium Hydroxide Magnesium Carbonate Co-Dried Gel C 220, C 225, C 221

C 220 is the most widely used co-dried gel. It contains 61,2-67,3% Al(OH) $_3$  and 8,7-13,0% Mg(OH) $_2$ . This standard product has been optimized to provide rapid and prolonged antacid action whilst maintaining the pH of the stomach in the optimum range of 3-5 and providing a balance between the laxative effect of magnesium and the obstipative effect of aluminium.

C 220 is ideal for use in antacid tablets.

C 225 is a low sodium grade of C 220 and C 221 is a micronized grade, suitable for use in soft tablets and candies.

Туре	Assay Al(OH) <sub>3</sub>	Assay Mg(OH) <sub>2</sub>	Density (tapped)	d50	Pharmacopoeia
C 220	61,2 - 67,3 %	8,7 - 13,0 %	0,25 - 0,35 g/ml	~ 10 µm	(USP)
C 225	61,2 - 68,9 %	8,7 - 13,0 %	0,25 - 0,35 g/ml	~ 10 µm	(USP)
C 221	61,2 - 67,3 %	8,7 - 13,0 %	0,15 - 0,25 g/ml	~ 5 μm	(USP)

#### LATTICE LAYERED COMPOUNDS

#### MAGALDRATE

 $Al_5Mg_{10}(OH)_{31}(SO_4)_2 \cdot x H_2O$ 

Magaldrate is a lattice layered, crystalline complex of magnesium aluminium hydroxysulphate. It has an exceptionally rapid reaction rate with gastric acid, whilst maintaining the stomach pH in the optimum range of 3-5. The reaction rate is unaffected by the presence of proteins and pepsin. Magaldrate acts cytoprotectively by adsorbing large quantities of bile acids, preventing these aggressors from attacking the mucous membranes.

#### Magaldrate Powder C 410 / C 411

C 410 / C 411 are spray dried powders consisting of agglomerations of very fine primary crystals, which are mainly spherical in nature, ensuring excellent flow characteristics.

C 410 / C 411 are found in the majority of magaldrate tablets in the market today.

Туре	Assay Al(OH) <sub>3</sub> (200°C/4h)	Assay Mg(OH) <sub>2</sub> (200°C/4h)	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
C 410	32,1 - 45,9 %	49,2 – 66,6 %	0,4 - 0,6 g/ml	15 – 30 μm	USP, PhEur
C 411	32,1 - 45,9 %	49,2 – 66,6 %	o,6 – o,8 g/ml	20 – 35 μm	USP, PhEur

#### Magaldrate Powder C 425

C 425 is a milled magaldrate powder, ideal for the formulation of soft tablets and candies as well as for powder mixtures intended for resuspension, for example, powder sachets.

C 425 may be resuspended for liquid formulations depending on process conditions and formulation requirements.

Туре	Assay Al(OH) <sub>3</sub> (200°C/4h)	Assay Mg(OH) <sub>2</sub> (200°C/4h)	Density (tapped)	d <sub>50</sub>	Pharmacopoeia	
C 425	32,1 – 45,9 %	49,2 - 66,6 %	0,4 - 0,6 g/ml	5 – 10 μm	USP, PhEur	

### Magaldrate Suspension C 632

C 632 is a viscous paste with a magaldrate content of 20-25 %. The viscosity borders on the limit of flow capability. The paste is stable on storage and transportation, displaying only slight sedimentation and no caking. C 632 is suitable for the production of both single and double strength formulations.

Other concentrations of C 632 are available on demand.

Туре	Assay Al(OH) <sub>3</sub>	Assay Mg(OH) <sub>2</sub> (200°C/4h)	Viscosity (Brookfield)	d <sub>50</sub>	Pharmacopoeia
	(200 C/411)	(200 C/411)			
C 632	32,1 – 45,9 %	49,2 - 66,6 %	max. 400 mPa s (LV 3/12)	6 – 10 μm	USP







#### HYDROTALCITE

 $\mathsf{Al_2Mg_6(OH)_{16}CO_3} \cdot \mathsf{xH_2O}$ 

Hydrotalcite is a lattice layered, crystalline complex of magnesium aluminium hydroxycarbonate. It contains a higher proportion of magnesium than magaldrate. Hydrotalcite reacts rapidly with gastric acid even in the presence of pepsin and proteins.

#### Hydrotalcite Powder C 300

C 300 is a spray dried powder for use in all tablet formulations, preferably after pre-granulation.

A milled quality is available on request which is suitable for the formulation of soft tablets and candies or for resuspending for liquid formulations.

Assay Al <sub>2</sub> O <sub>3</sub>	Assay MgO	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
15,3 - 18,7 %	36,0 – 44,0 %	0,4 – 0,6 g/ml	10 – 30 μm	BP

### **Hydrotalcite Suspension C 600**

C 600 has a hydrotalcite content of 14 - 20 %. It is ideal for use in liquid formulations giving excellent mouth-feel and stability compared to formulations containing resuspended hydrotalcite powders.

Assay Al <sub>2</sub> O <sub>3</sub>	Assay MgO	Pharmacopoeia
2,5 - 3,5 %	6,0 - 7,8 %	(BP)

#### ALMAGATE

 $Al_2Mg_6(OH)_{14}(CO_3)_2 \cdot x H_2O$ 

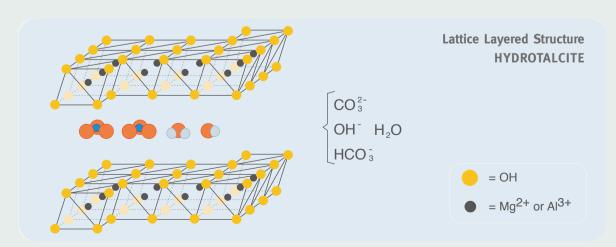
Almagate is a crystalline compound similar to hydrotalcite. It reacts very rapidly with gastric acid even in the presence of pepsin and proteins.

#### Almagate Powder C 310

C 310 is a spray dried powder with similar properties to hydrotalcite powder. It is suitable for the production of fast acting tablets.

#### **Almagate Suspension C 610**

C 610 has an almagate content of ca. 16 %. It is ideal for use in liquid antacid formulations.



#### COMPLEX ALUMINIUM COMPOUNDS

In nature there are numerous compounds of aluminium with alkaline and alkaline-earth metals, forming a whole series of basic substances which neutralize acids. Only a few of these substances are suitable, however, for the preparation of antacids. These are compounds which rapidly neutralize gastric acid with no, or only very minor, side effects.

## DIHYDROXY ALUMINIUM SODIUM CARBONATE (CARBALDRATE) A 265

 $NaAl(OH)_2(CO)_3 \cdot x H_2O$ 

Carbaldrate A 265 is a crystalline, complex basic carbonate of aluminium and sodium. Its rapid neutralization of gastric acid plus its high acid neutralizing capacity make Carbaldrate A 265 one of the most effective antacid substances available. The reaction velocity of Carbaldrate A 265 remains unaffected by the presence of proteins and pepsin. Bile acids and other aggressors are adsorbed by Carbaldrate A 265 preventing damage to the mucous membranes.

Assay	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
98,3 – 107,9 %	0,4 - 0,6 g/ml	3 – 6 μm	USP

#### ALUMINIUM PHOSPHATE

 $AIPO_4 \cdot x H_2O$ 

Amorphous, tertiary aluminium phosphate exerts its antacid action by building a protective film over the mucous membranes of the digestive system. This protective film prevents acid from reaching the stomach wall, creating favourable conditions for the healing of lesions. The astringent and anti-inflammatory action of aluminium phosphate also contributes to the healing of gastrointestinal lesions.

Aluminium phosphate does not alter the pH of the stomach. Hence the natural protection of the stomach and intestinal tract by the germicidal action of gastric acid is undisturbed.

#### Aluminium Phosphate hydrated Powder B 111

B 111 which is also known under the name Aluminium Phosphate Gel Powder or Aluminium Phoshate Powder is used in the production of tablets and dry powder formulations which dissolve in the stomach and release colloidal aluminium phosphate.

Assay	Density (tapped)	d <sub>50</sub>	Pharmacopoeia
Min. 80 % AlPO4	0,4 – 0,5 g/ml	20 – 35 μm	PhEur

#### Aluminium Phosphate Gel B 210

B 210 which is also known under the names Aluminium Phosphate Suspension or Aluminium Phoshate Paste is a viscous suspension of amorphous, tertiary aluminium phosphate, which due to its colloidal structure, is highly efficient in liquid preparations. The use of B 210 optimizes not only the formation of the protective film in the stomach, but also the adsorption of mucous membrane aggressors and gastric acid, thus facilitating the healing process.

Assay	Viscosity (Brookfield)	Pharmacopoeia
19 – 25 % AIPO4	max. 1000 mPa s <i>(LV 2/60)</i>	USP, PhEur

## MAGNESIUM ALUMINIUM SILICATE HYDRATE (ALMASILATE TYPES)

 $Al_{x}Mg_{y}(Si_{2}O_{6})_{z}(OH)_{(3X+2y-4z)} \cdot x H_{2}O *)$ 

Magnesium aluminium silicate hydrates are basic amorphous compounds prepared by co-precipitation. The acid binding capacity of the silicate hydrates increases with decreasing silicate content. The presence of the silicate fraction, which is insoluble in acid, not only facilitates the formation of a protective film on the mucous membranes, but also adsorbs mucous membrane aggressors such as pepsin and bile acids.

\*) The ratio of the components, Al, Mg, Si can be adjusted to meet individual requirements.

## Almasilate Powder C 212 Almasilate Suspension C 612

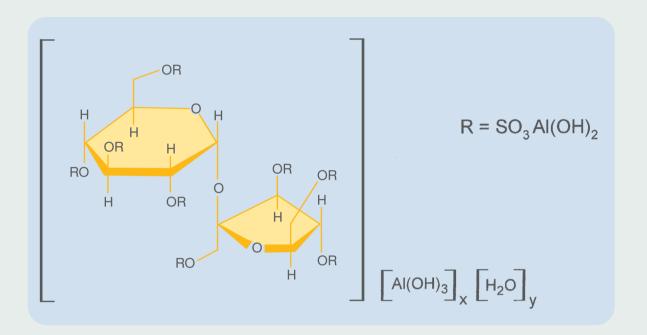
 $Al_3Mg_5(OH)_{15}(Si_2O_6) \cdot x H_2O$ 

Almasilate types C 212 and C 612 are standard grades of aluminium magnesium hydroxysilicate. They have a rapid reaction velocity and high acid neutralizing capacity compared to other silicates. Almasilate type C 212 is a fine powder used in the production of tablets and Almasilate type C 612 is a pumpable suspension suitable for liquid antacid formulations.

Туре	Assay Al <sub>2</sub> O <sub>3</sub>	Assay MgO	Density (tapped)	d <sub>50</sub>	Viscosity (Brookfield)
C 212	15 – 25 %	25 - 35 %	0,25 - 0,35 g/ml	25 – 40 μm	
C 612	min. 2,3 %	min. 3,5 %	-	-	max. 10 <sup>4</sup> mPa s (LV 3/12)



#### SUCRALFATE



## $\mathsf{Al_8(OH)_{16}(C_{12}H_{14}O_{35}S_8)}\left[\mathsf{Al(OH)_3}\right]_X\left[\mathsf{H_2O}\right]_V$

Sucralfate is the hydrous basic aluminium salt of sucrose octasulfate (SOS). The therapeutic effect of Sucralfate in gastric complaints is based on an increase in the protective mechanisms of the mucous membranes in the stomach and duodenum against exogeneous and endogeneous aggressors.

The cytoprotective action of Sucralfate includes the neutralization of acid, the selective formation of a protective layer over eroded surface areas, specific protection of lesions and adsorption of pepsin and bile acids, resulting in inhibition of peptic activity.

#### Sucralfate Powder S 215, S 225 and S 235

Sucralfate S 215 powder is suitable for use in tablet formulations. Sucralfate S 225 is a milled powder ideal for use in soft tablet and candy formulations or for powder mixtures intended for resuspending (powder sachets). Sucralfate S 235 is available for direct compressible tablet formulations.

Туре	<i>Assay</i> Al	Assay SOS	Density (tapped)	d <sub>50</sub>	Pharmacopeia
S 215	15,5 - 18,5 %	30,0 - 38,0 %	0,55 – 0,75 g/ml	30 – 45 μm	USP
3 21)	16,5 – 18,5 %	30,0 - 36,0 %			PhEur
S 225	15,5 – 18,5 %	30,0 - 38,0 %	o,30 – o,48 g/ml	3 – 5 μm	USP
	16,5 – 18,5 %	30,0 - 36,0 %			PhEur
S 235	15,5 - 18,5 %	30,0 - 38,0 %	o,6 – o,8 g/ml	90 – 130 μm	USP
	16,5 – 18,5 %	30,0 - 36,0 %			PhEur

## **Sucralfate Suspension S 611**

 $Sucral fate \ S\ 611\ is\ a\ suspension\ with\ an\ active\ content\ of\ 30\ \%\ Sucral fate.\ It\ is\ ideal\ for\ use\ in\ liquid\ antacid\ formulations.$ 

Assay Al	Assay SOS	d <sub>50</sub>	Pharmacopoeia
4,7 - 6,0 %	8,3 - 13,4 %	4 – 6 μm	(USP)

## FORMULATION SUGGESTIONS

#### TABLETS

Antacid tablets are best produced by combining the antacid actives with the excipients in a suitable powder mixer. The mixture is then either dry or wet granulated and dried at a low temperature (less than 60 °C) to ensure product reactivity is maintained. The granulate is milled or sieved to the required particle size and the lubricants are added. Flow capability is maintained. Flavours are incorporated into the granulate mixture, preferably by combining with one of the additives, e.g. mannitol, and then adding the concentrate to the granulate. This facilitates a more homogeneous distribution of the flavours. The granulate can be compressed into tablets in the usual tablet presses.

Al-Mg-Hydroxide Tablets	%
A 215	29
D 211	29
Mannitol	33,5
Sucrose	2
Corn Starch	2
Talc	2
Mg Stearate	2
Flavours	0,5

Carbaldrate Tablets	%
A 265	31
Sucrose	61,5
Starch	5
Mg Stearate	2
Flavours	0,5

Magaldrate Tablets	%
C 410	67
Mannitol	21
Microcrystalline Cellulose	5
Dimethylpolysiloxane	4
Mg Stearate	2
Flavours, sweeteners	1

Hydrotalcite Tablets	%
C 300	61
Mannitol	31
Corn Starch	3
Talc	2
Mg Stearate	2
Flavours, sweeteners	1



#### SUSPENSIONS

The preparation of liquid products is usually performed by blending the antacid actives in a suitable mixer. The active concentrate is mixed with water under constant stirring. Sorbitol, sucrose or glycerine are then added to the mixture, normally resulting in a drop in viscosity, which facilitates homogenization. The preservatives, thickeners and flavours are added, taking care that a homogeneous distribution of the preservatives is achieved. Water insoluble preservatives may be dissolved in alcohol first.

All our liquid actives are standardly preserved with sodium hypochlorite. The free chlorine should be removed prior to further processing.

## **Al-Mg-Hydroxide Combinations**

Single strength	%
A 661	31,6
D 661	9,6
Sorbitol	5
Glycerine	3
Methylcellulose (6000 mPa s)	0,2
Methylparabens	0,1
Propylparabens	0,05
Flavours, sweeteners	1,0
Water	to 100

Double strength	%
A 671	45
D 611	14,5
Sorbitol	15
Glycerine	2
Methylcellulose (6000 mPa s)	0,1-0,2
Methylparabens	0,1
Propylparabens	0,05
Flavours, sweeteners	1,0
Water	to 100

Double strength	%
A 671	29
D 220	7,2
Sorbitol	8
Simethicone emulsion (33%)	1,77
Blanose (7M31CF or 12M31P)	0,1
Xanthan gum	0,1
Methylparabens	0,1
Propylparabens	0,05
Flavours, sweeteners	1,0
Water	to 100

Triple strength	%
A 681	43
D 671	20,5
Sorbitol	10
Glycerine	1
Methylcellulose (4000 mPa s)	0,1
Dimethylpolysiloxane	1
Methylparabens	0,1
Propylparabens	0,05
Flavours, sweeteners	1,0
Water	to 100

Magaldrate Formulation (8 %)	%
C 632	37,5
Sorbitol	7,5
Glycerine	1
Blanose (7M31CF or 12M31P)	2
Methylparabens	0,1
Propylparabens	0,05
Flavours, sweeteners	1,0
Water	to 100

Sucralfate Formulation (20 %)	%
S 611	66,6
Sorbitol	15,0
Glycerine	3,0
Na-Citrate	0,11
Xanthan gum	0,09
Methylparabens	0,05
Propylparabens	0,025
Flavours, sweeteners	1,0
Water	to 100

NOTE: The information herein is currently believed to be accurate. We do not guarantee its accuracy. Purchasers shall not rely on statements herein when purchasing any products. Purchasers should make their own investigations to determine if such products are suitable for a particular use. The products discussed are sold without warranty, express or implied, including a warranty of merchantability and fi tness for use. Purchasers will be subject to a separate agreement which will not incorporate this document. © Copyright 2019, Elementis Pharma GmbH. All rights reserved. Copying and/or downloading of this document or information therein for republication is not allowed unless prior written agreement is obtained from Elementis Specialties, Inc. ® Registered trademark of Elementis Pharma GmbH

V15







# **ELEMENTIS**

Elementis Pharma GmbH Giulinistrasse 2 D-67065 Ludwigshafen, Germany Tel: +49 621 5709 6990

Fax: +49 621 5709 6489

E-Mail: info@elementispharma.com