Jan. 16, 1962 S. M. BEEKMAN **3,017,324**

ANTACID COMPOSITION

Filed April 6, 1959 5 Sheets-Sheet 1

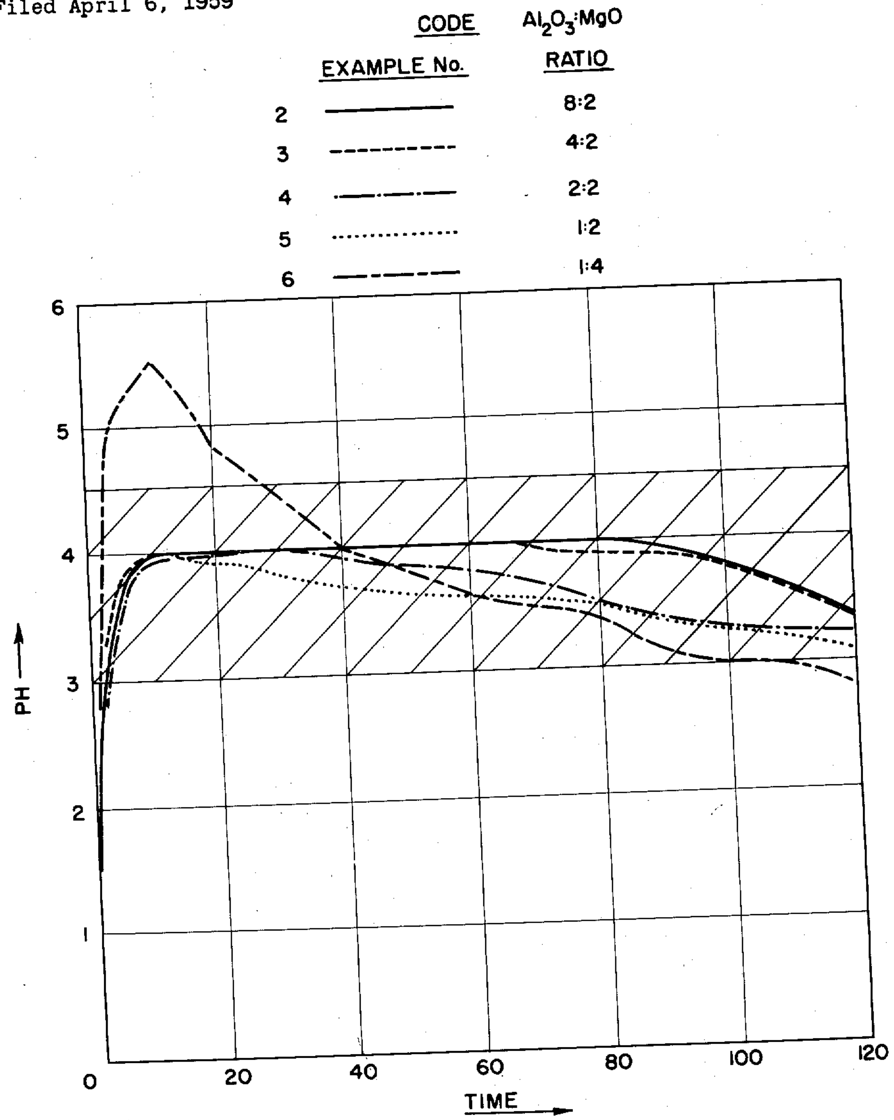

FIG. 1.

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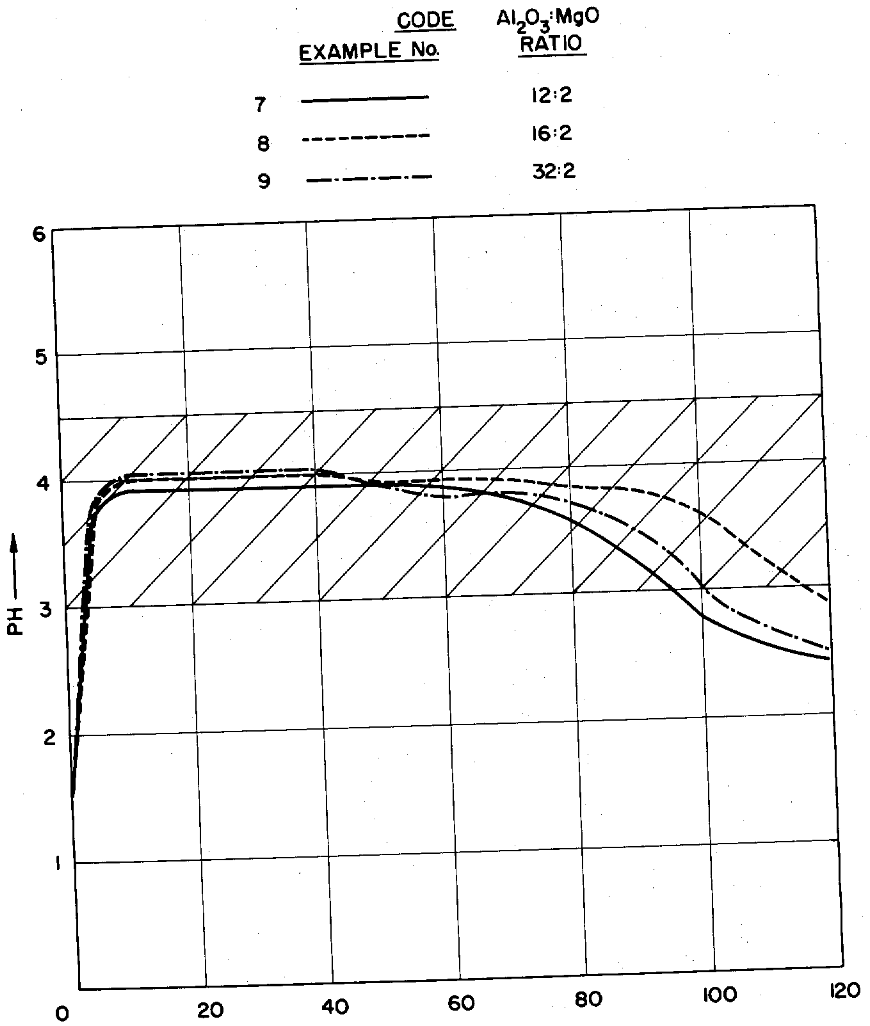

FIG. 2.

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ANTACID COMPOSITION

Filed April 6, 1959 5 Sheets-Sheet 3

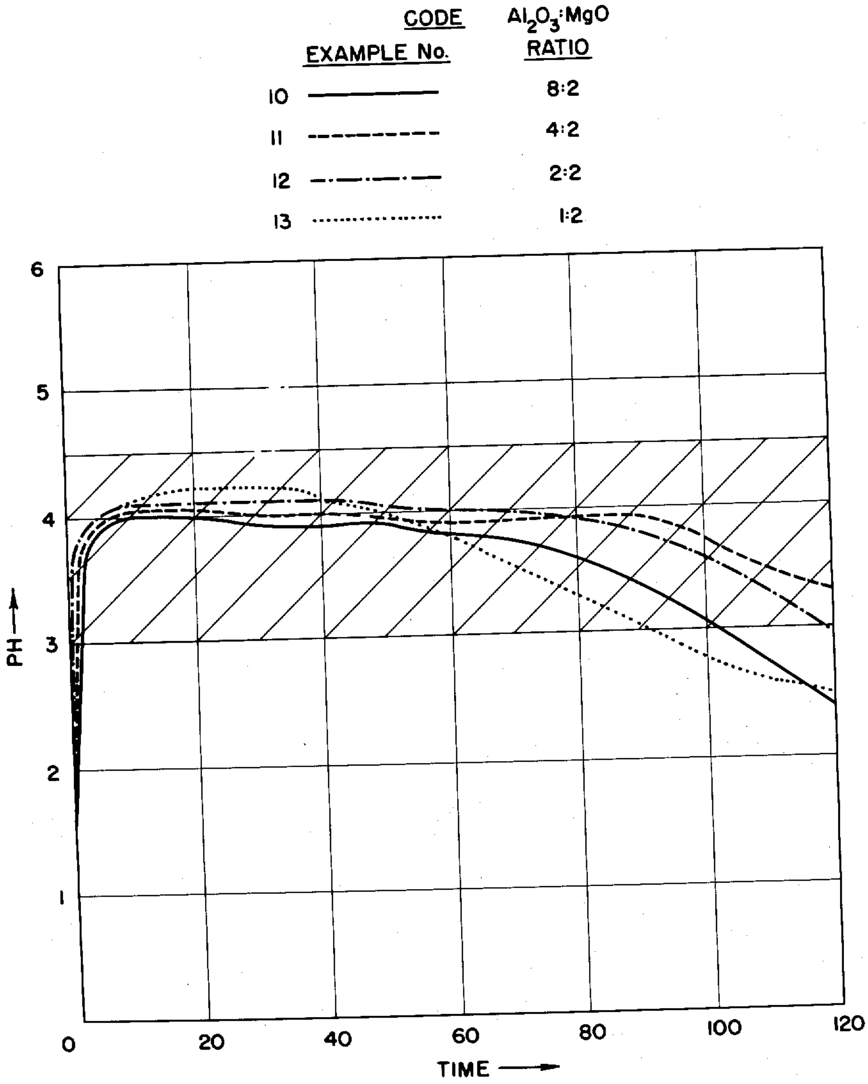

FIG. 3.

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Jan. 16, 1962 S. M. BEEKMAN **3,017,324**

ANTACID COMPOSITION

Filed April 6, 1959 5 Sheets-Sheet 4

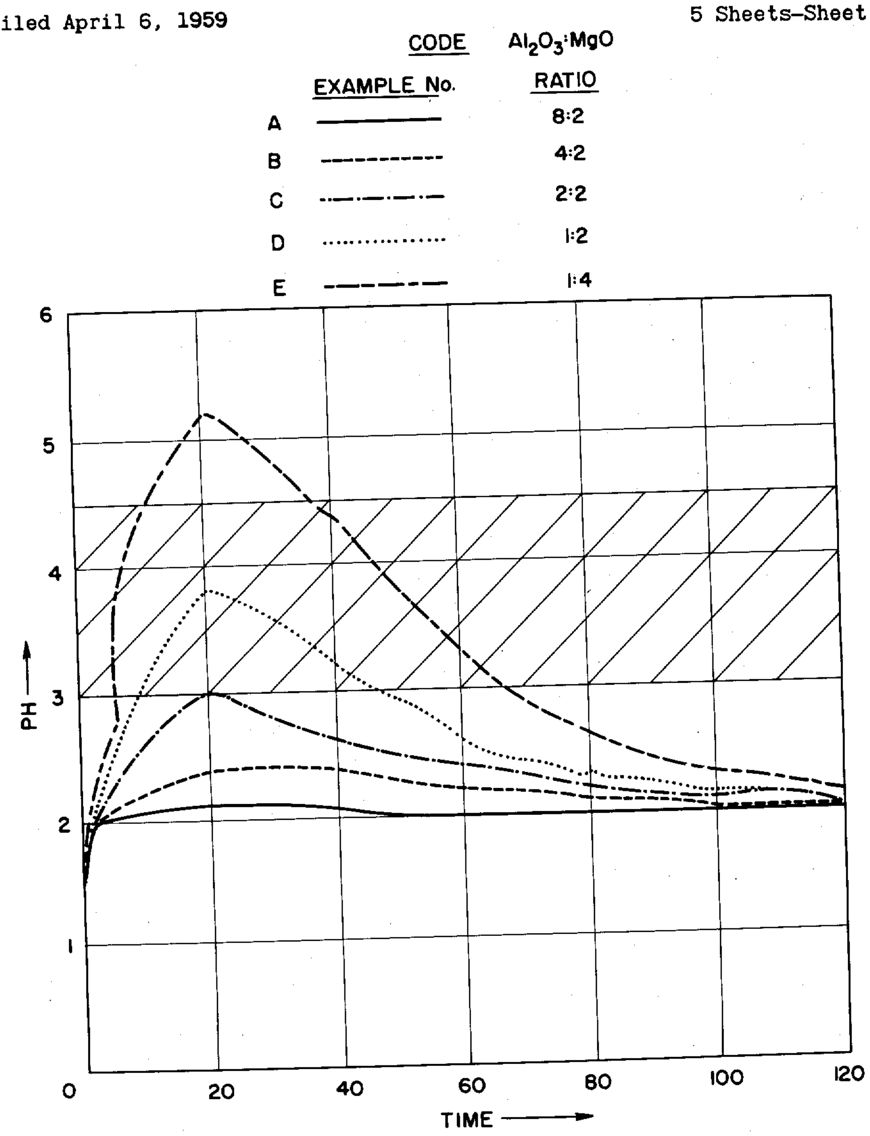

FIG. 4.

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ANTACID COMPOSITION

Filed April 6, 1959 5 Sheets-Sheet 5

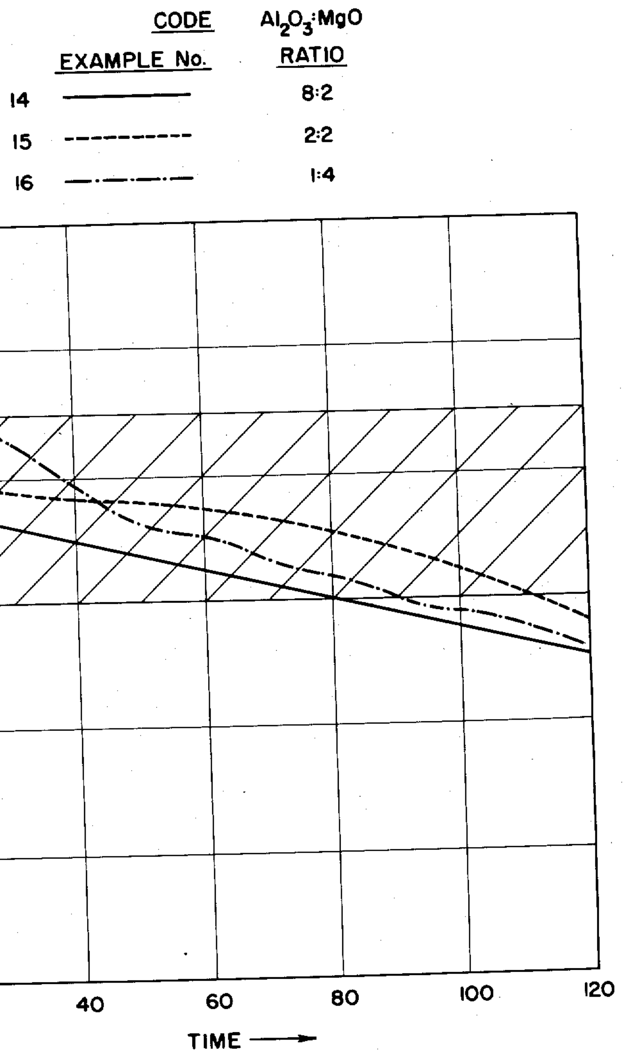

FIG. 5.

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United States Patent Office

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3,017,324

ANTACID COMPOSITION

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Reheis Company, Inc., a corporation of New York

Filed Apr. 6, 1959, Ser. No. 804,414
10 Claims. (Cl. 167—55)

This invention relates to an antacid composition, and re particularly to an antacid composition comprising minum hydroxy carbonate and magnesium silicate, and a process of preparing the same.

Antacid preparations are now quite generally employed the treatment of peptic ulcers, gastric hyperacidity and spepsia. Gwilt, Livingstone and Robertson in the Jourl of Pharmacy and Pharmacology, X, No. 12, 770–775 958), describe the characteristics of an ideal antacid. ey point out that it should show its maximum neualizing effect in the shortest possible time, that it should utralize an adequate amount of gastric hydrochloric id and maintain its action during the normal period of stric digestion, that any excess however great beyond e amount required to neutralize free gastric acid should ot cause alkalization, that it should raise the pH of the astric contents to a level at which pepsin activity is reuced significantly but not totally inhibited, that adequate nd repeated doses should be palatable to the hyperacid atient, and that its use should not lead to laxative, conipating or other side effects such as gastric irritation. In ddition to these factors the antacid composition should e inexpensive and it should not deteriorate significantly n any respect on aging. These workers summarize the arious statements in the literature as to the pH ranges esirable for the ideal antacid, and conclude that a pH within the range from about 3.5 to about 4.5 is apparntly the optimum to ensure adequate relief from hyperctidity, particularly if an ulcer site is present, and at the ame time permits sufficient residual pepsin activity to void secondary digestive disturbances.

Edwards in The Chemist and Druggist, December 14, 957, page 647, also discusses the properties of an ideal antacid, and suggests that the nearest approach to the deal attained as of that date was wet activated alumina gel. Dr. Edwards' views ot the properties of the ideal antacid are in substantial agreement with those expressed by Gwilt et al.

Liquid aluminum hydroxide gel closely approaches the ideal for an antacid but its liquid form makes it inconvenient to use, especially in the case of ambulatory patients. The liquid gel is quite rapid in its action and gives a prolonged antacid effect in the optimum pH range. It is not significantly affected in its antacid properties by pepsin and it also does not significantly lose its antacid characteristics in aging. However, as Edwards and others have pointed out, it may have a mildly constipating effect which many have sought to remedy by combining it with other ingredients such as magnesium hydroxide or carbonate.

The advantages of the dried gel are obvious. However, the obvious material, dried aluminum hydroxide gel, is actually far from an ideal antacid. It exhibits a lag in its rate of reaction with stomach acids. It does not give a prolonged antacid in the optimum pH range and its antacid properties are severely affected by pepsin. Also, its antacid activity is less than that of the liquid

gel, being decreased by the drying and the reduced activity decreases further with aging. These disadvantages have been noted by Gwilt et al. and other workers in this field.

German Patent No. 941,864 describes an antacid composition composed of mixed coprecipitated aluminum and magnesium hydroxy silicates prepared from sodium silicate and sodium hydroxide by reaction with magnesium sulfate and aluminum sulfate. The product is described as having the formula $AlMg_2Si_3O_{9.5}$. This preparation is shown by the patent graph to be superior to sodium bicarbonate, calcium carbonate, magnesium carbonate and magnesium trisilicate. However, according to the test used, the pH shortly following its administration rises to 6 or above, and remains above 4.5 for approximately 80 minutes, which is too high for a satisfactory antacid preparation.

In accordance with the instant invention, there is provided an antacid composition composed of a mixture of magnesium silicate and aluminum hydroxy carbonate in certain proportions. This composition is capable of maintaining a pH in the stomach within the range from 3 to 4.5 for two hours or longer, and is thus characterized by a remarkably constant pH in the optimum range for a sufficiently long time per dose to enable the patient to avoid irritation with a minimum of medication.

The proportions of aluminum hydroxy carbonate and magnesium silicate are quite critical in maintaining a fast antacid action within this pH range. The molecular ratio $Al_2O_3:MgO$ of aluminum hydroxy carbonate calculated as Al_2O_3 to magnesium silicate calculated as MgO should be within the range of from 1:2 to 32:2. At $Al_2O_3:MgO$ ratios below this, the maximum pH following administration of the composition will rise to considerably in excess of 4.5, which is undesirable. Proportions of Al_2O_3 in excess of 32:2 can be used without disadvantageously affecting pH, but with the detriment that the composition is greatly slowed in its antacid action, so that the desired pH is not reached until a considerable time following administration, which also is undesirable. Thus, the stated range represents the optimum proportions of the essential ingredients for effective and prompt antacid action.

The composition can be prepared in any of several ways. The only prerequisite is that the aluminum hydroxy carbonate be in hydrous gelatinous form at the time of mixing with the magnesium silicate. The aluminum hydroxy carbonate must not have been dried prior to use, that is, it must be in moist, undried form. It must contain at least sufficient of the original gel water to make it moist. There are several magnesium silicates, with varying $MgO:SiO_2$ ratios, but the trisilicate $2MgO:3SiO_2\cdot{}_nH_2O$ is preferred The magnesium silicate can be in the form of a dry gel which is physically mixed with the moist aluminum hydroxy carbonate. It is usually more desirable, however, to blend the magnesium silicate in freshly precipitated moist gel form with the aluminum hydroxy carbonate, since the particles are then in a more finely-divided state. The magnesium silicate also may be coprecipitated with the aluminum hydroxy carbonate from a common reaction solution, if desired, containing silicate, hydroxyl, carbonate, magnesium and aluminum ions, such as a mixture of sodium silicate, sodium carbonate, sodium hydroxide, magnesium sulfate and aluminum sulfate, in proper stoichiometric proportions to give the desired precipitate. This procedure is somewhat more complicated, requiring more careful control of the precipitation conditions so as to obtain a good precipitate of both these salts, in the desired proportions, and therefore is less desirable than the others.

The resulting mixture prepared as above described is dried by any convenient method known to those skilled in the art, such as for example, spray or tray drying. The final composition is in the form of a dried gel which can be reduced to powdered form for convenience of packaging and marketing.

The following examples in the opinion of the inventor represent the best embodiments of his invention.

EXAMPLE 1

370 lbs. of precipitated magnesium trisilicate slurry (0.895% MgO, 2% SiO_2, pH 9.7) was blended with 525 lbs. of freshly precipitated basic aluminum hydroxy carbonate slurry (1.6% Al_2O_3 pH 5.3) in a 150 gallon Haveg cylindrical tank using a ¼ H.P. 425 r.p.m. portable type agitator employing two 5 inch marine type propellers. After fifteen minutes of agitation the pH of the blend was measured and found to be 7.35. Agitation was continued for a total of one hour.

The resulting slurry, which had an alumina content of 0.939%, was filtered through a 12 inch Shriver filter press equipped with plastic plates and frames. Three cycles were required for filtering and washing the entire batch. Each cycle required eighty minutes at 45 p.s.i.g. and eight hours washing time. The white filter press cakes obtained had a total weight of 116.31 lbs.

The cakes were dried in a circulating air dryer in the pilot plant at 125° F. yielding 20.06 lbs. of dry product. The dried lumps were pulverized in a No. 1 Mikro pulverizer at 9600 r.p.m. using an 0.020 inch herringbone screen. The product analyzed as follows:

Al_2O_3:MgO ratio		2:2
Al_2O_3	percent	28.6
MgO	do	11.5
SiO_2	do	25.3
CO_2	do	4.6
Moisture (Dean & Starke)	do	13.6
Sulfates (SO_4)	do	0.03
Chlorides (Cl)	do	0.03
pH (4% aqueous dispersed)		9.8
Apparent density (g./ml.)		0.16
Screen analysis:		
Percent through 200 mesh		95.2
Percent through 325 mesh		83.3
Acid consuming capacity (ml. N/10 HCl/g.)		205

The antacid characteristics were determined by the method of Holbert, Noble and Grote, Journal of the American Pharmaceutical Association, 36, 149 (1947), 37, 292 (1948), Murphey, 41, 361 (1952). In this method, a test sample of antacid is added to 150 ml. of pH 1.5 hydrochloric acid containing 2 g. of pepsin N.F. per liter (artificial gastric juice) at 37.5° C. 20 ml. of the artificial gastric juice is withdrawn every ten minutes and replaced with an equal volume of fresh gastric juice. The test procedure used in the work reported in this and the following examples, however, was carried out by continuously introducing fresh artificial gastric juice and removing the antacid-gastric juice mixture by overflow at the rate of 2 ml. per minute. The antacid effect is determined by measuring the pH of the artificial gastric juice during the test period, which was two hours (120 minutes).

The pH data taken in this test, carried out on a 1 gram sample, are reported below in Table I.

Table I

ANTACID CHARACTERISTICS

Time:
0
1
2
3
4
5
10
20
30
40
50
60
70
80
90
100
110
120

The data show that the composition was capable maintaining the pH within the range from 3.2 to 4 f two hours.

EXAMPLES 2 TO 6

A group of five compositions was prepared by intimat ly blending moist basic aluminum hydroxy carbonate g with aqueous gelatinous magnesium trisilicate, followe by drying and reduction to powder. The proportions aluminum hydroxy carbonate as Al_2O_3 to magnesium tr silicate as MgO ranged from 8:2 to 1:4 (0.5:2).

The magnesium trisilicate gel employed in thes preparations was prepared from magnesium sulfat $MgSO_4 \cdot 7H_2O$ and sodium silicate Na_2SiO_3, (40° Baum 9.13% Na_2O, 28.2% SiO_2). 262.5 lbs. of magnesiu sulfate was dissolved in 232 lbs. of water. 4.935 lbs. o sodium hydroxide was dissolved in 20 lbs. of water, an these were mixed in 37.25 lbs. of the sodium silicat solution, and 200 lbs. of water then added. The solu tions were mixed in a Haveg reactor with a marine typ propeller. The solution was allowed to age for one hou after mixing had been completed, and the magnesium tri silicate separated by filtration; 44.5 lbs. of cake was ob tained.

The 8:2 product (Example 2) was prepared from a blend of 5000 g. moist aluminum hydroxy carbonate gel (containing 505 g. Al_2O_3) and 1210 g. of magnesium trisilicate gel (49.7 g. MgO). 2000 g. of deionized water was placed in a three gallon mixing tank, and the aluminum hydroxy carbonate was thoroughly dispersed therein using a 0.5 H.P. laboratory Dispersator. The magnesium trisilicate gel was added, and the slurry intimately blended at high speed for five minutes. The wet gel contained 5.79% Al_2O_3 and 0.57% MgO. The particles were spread out on a tray and dried in an atmospheric tray dryer at 150° F. for nine hours. The mixture was pulverized to a fine powder by one pass through a No. 1 Mikro Pulverizer at 5000 r.p.m. using a 0.020 inch herringbone screen.

The 4:2 product (Example 3) was prepared using the same procedure, from 400 g. aluminum hydroxy carbonate gel (404 g. Al_2O_3) and 1890 g. magnesium trisilicate gel (79.6 g. MgO). The wet mixed gel contained 5.1% Al_2O_3 and 1.01% MgO.

The 2:2 product (Example 4) was prepared by the same procedure, using 3000 g. aluminum hydroxy carbonate gel (303 g. Al_2O_3) and 2840 g. magnesium trisilicate gel (119.4 g. MgO). 1500 g. of water was used. The wet gel contained 4.13% Al_2O_3 and 1.62% MgO.

The 1:2 product (Example 5) was prepared from 2000 g. aluminum hydroxy carbonate gel (202 g. Al_2O_3 and 3790 g. magnesium trisilicate gel (159.5 g. MgO). 1000 g.

ater was used. The wet gel contained 2.97% Al_2O_3 2.35 MgO.

he 0.5:2 (1:4) product (Example 6) was prepared n 1250 g. aluminum hydroxy carbonate gel (126.25 l_2O_3) and 4730 g. magnesium trisilicate (199 g. MgO). two gels were blended at high speed, and additional er was not required. The wet gel contained 2.14% O_3 and 3.33% MgO.

he dried products analyzed as follows:

Table II

ample No.	Al_2O_3, percent	MgO, percent	SiO_2, percent	Acid[1] Consuming Capacity ml./g.	Cl, percent	SO_4, percent	Carbonates as CO_2, percent	Screen Test, Percent Remaining		Apparent Density, g./cc.	Mole Ratio	
								200 mesh	325 mesh		Al_2O_3	MgO
	43.2	5.5	10.3	270	<0.01	0.20	4.1	12.6	24.3	0.19	8	2.6
	36.9	7.9	17.4	246	<0.01	0.20	8.2	12.7	25.6	0.18	4	2.17
	28.1	11.9	26.4	211	<0.01	0.05	2.0	13.8	25.4	0.20	2	2.15
	19.0	17.0	36.1	178	<0.01	0.05	7.1	13.4	22.7	0.21	1	2.27
	11.2	19.5	43.0	148	<0.01	0.15	1.3	17.9	35.1	0.33	5	2.2

[1] No. of ml. of N/10 HCl neutralized by 1 gram sample at 37.5° C.

Each of these products was tested according to the odified Holbert, Noble and Grote test procedure, using one gram sample as described in Example 1. The following pH data were obtained:

Table III

Time, Minutes	Example No.				
	2	3	4	5	6
	1.5	1.5	1.5	1.5	1.5
25	2.1	2.2	2.1	2.4	3.4
.50	2.2	2.4	2.4	3.1	3.6
0	2.4	2.8	2.9	3.6	2.0
	2.9	3.3	3.5	3.8	4.3
	3.3	3.6	3.7	3.8	4.7
	3.6	3.8	3.8	3.9	5.1
	3.7	3.9	3.9	3.9	5.2
0	4.0	4.0	4.0	4.0	5.5
0	4.0	4.0	4.0	3.9	4.8
0	4.0	4.0	4.0	3.8	4.4
0	4.0	4.0	3.9	3.7	4.0
0	4.0	4.0	3.9	3.6	3.7
0	4.0	4.0	3.8	3.6	3.6
0	4.0	4.0	3.7	3.6	3.5
0	4.0	3.9	3.5	3.5	3.4
0	3.9	3.9	3.4	3.4	3.1
.00	3.8	3.8	3.3	3.3	3.0
.10	3.6	3.6	3.2	3.2	3.0
.20	3.4	3.4	3.2	3.1	2.8

The pH curves corresponding to the above data appear in FIGURE 1.

The data show that compositions 2 to 5, inclusive, are capable of maintaining a pH within the range from 3 to 4 for a period of approximately two hours. The time initially required to reach a pH of 3 diminishes as the ratio of alumina to magnesium oxide decreases. However, in composition 6 the proportion of alumina is too small, because the pH of this composition rises to well beyond 4, reaching a maximum of 5.5 ten minutes after administration. The pH of this test solution was in excess of 4.5 during the first thirty minutes of the test, which is undesirable. This demonstrates that a ratio of 1:2 (Example 5) represents the minimum desirable proportion of alumina.

EXAMPLES 7 TO 9

Three compositions were prepared having Al_2O_3:MgO molecular ratios of 12:2, 16:2 and 32:2. These compositions were prepared according to the procedure set forth in Examples 2 to 6 by intimately blending a moist aluminum hydroxy carbonate gel and a magnesium trisilicate gel, followed by drying at 150° F. and pulverizing to powdered form. The gels were tested for antacid activity using the modified Holbert, Noble, and Grote test procedure.

The 12:2 product (Example 7) was prepared by adding 12 lbs. of aluminum hydroxy carbonate gel (10.1% Al_2O_3) and 1.91 lbs. magnesium trisilicate gel (4.21% MgO) with 2500 ml. of deionized water to render the mixture fluid enough to blend. Agitation was continued for ten minutes at high speed using a laboratory 0.5 H.P. Dispersator. The blended gel was spread out on a tray and dried in an air circulating dryer at 150° F. dry bulb temperature. Drying was continued until no more loss in weight was evident. The dried lumps were then pulverized in a No. 1 Mikro pulverizer at 9600 r.p.m. using a 0.020 inch herringbone screen.

The 16:2 product (Example 8) was prepared by the same procedure using 12 lbs. of the aluminum hydroxy carbonate gel, 1.42 lbs. magnesium trisilicate gel and 5.52 lbs. of water.

The 32:2 product (Example 9) was prepared in the same way using 12 lbs. aluminum hydroxy carbonate gel, 0.71 lbs. magnesium trisilicate gel and 5.52 lbs. of water.

The pH data obtained using 1 gram samples by the Holbert, Noble and Grote procedure as outlined in Example 1 was as follows:

Table IV

Time, Minutes	Example No.		
	7	8	9
0	1.5	1.5	1.5
1	2.3	2.3	2.2
2	2.6	2.6	2.6
3	3.0	2.9	2.9
4	3.4	3.3	3.3
5	3.7	3.6	3.7
6	3.8	3.8	3.8
7	3.8	3.9	3.9
8	3.9	3.9	3.9
9	3.9	3.9	4.0
10	3.9	4.0	4.0
20	3.9	4.0	4.0
30	3.9	4.0	4.0
40	3.9	4.0	4.0
50	3.9	3.9	3.9
60	3.8	3.9	3.9
70	3.8	3.9	3.8
80	3.6	3.8	3.7
90	3.2	2.8	3.5
100	2.8	3.6	3.0
110	2.6	3.2	2.7
120	2.4	2.9	2.5

The above data are graphed in FIGURE 2.

It is apparent that each of these compositions is capable of maintaining a pH within the range of 3 to 4 for approximately two hours.

For purposes of comparison, an aluminum hydroxide dried gel U.S.P. having a pH of 7.8 was tested. This was capable of raising the pH of the original gastric juice in this test to a maximum of 2.6, which is completely unsatisfactory.

EXAMPLES 10 TO 13

A group of antacid preparations were prepared by blending dried magnesium trisilicate U.S.P. with wet aluminum hydroxy carbonate gel in the Al_2O_3:MgO molecular ratios of 8:2, 4:2, 2:2 and 1:2, drying the mixtures in air at 150° F., pulverizing them to a powder, and then determining the antacid characteristics using the in vitro test method of Holbert, Noble and Grote as set forth in Example 1. The magnesium trisilicate used contained 22% MgO, and the aluminum hydroxy carbonate gel contained 10.1% Al_2O_3 and 4.3% carbonates as CO_2.

In each case, 50 g. of magnesium trisilicate powder was thoroughly mixed and blended with the aluminum hydroxy carbonate gel. 1100 g. of the gel was used to make the 8:2 product (Example 10), 550 g. for the 4:2 product (Example 11), 775 g. for the 2:2 product (Example 12) and 137 g. for the 1:2 product (Example 13). 250 ml. of deionized water was added to make the blend more fluid and to facilitate mixing. The mixtures were dried in an air circulating dryer at 140° F. until constant weight was reached, and the dried samples were finely pulverized in a Mikro pulverized sample mill.

The pH data obtained using 1 gram samples by the Holbert, Noble and Grote test procedure are set forth in the table below.

Table V

Time, Minutes	Example No.			
	10	11	12	13
0	1.5	1.5	1.5	1.5
0.25	2.0	2.0	2.0	2.0
0.50	2.1	2.0	2.0	2.1
1	2.3	2.2	2.3	2.5
2	2.7	2.7	3.2	3.9
3	3.2	3.4	3.8	4.0
4	3.7	3.8	3.9	4.0
5	3.8	3.9	3.9	4.0
6	3.9	3.9	3.9	4.0
7	3.9	3.9	4.0	4.0
8	3.9	3.9	4.0	4.1
9	3.9	3.95	4.0	4.1
10	4.0	4.0	4.0	4.1
20	4.0	4.0	4.1	4.2
30	3.9	4.0	4.1	4.2
40	3.9	4.0	4.1	4·1
50	3.9	3.9	4.0	3.9
60	3.8	3.9	4.0	3.8
70	3.7	3.9	4.0	3.6
80	3.6	3.9	3.9	3.3
90	3.4	3.8	3.8	3.0
100	3.0	3.7	3.6	2.8
110	2.6	3.6	3.2	2.7
120	2.4	3.3	3.0	2.5

The above data are graphed in FIGURE 3.

Each of these compositions is capable of maintaining the pH within the range of 3 to 4.2 for approximately two hours.

These results are to be contrasted with the results obtained when a dried aluminum hydroxide gel U.S.P. is mixed with the dried magnesium trisilicate U.S.P. to form a simple dry blend. Such blends were prepared using magnesium trisilicate U.S.P. (22% MgO) and dried aluminum hydroxide gel U.S.P. (53.7% Al_2O_3). 8:2 (blend A), 4:2 (blend B), 2:2 (blend C), 1:2 (blend D) and 0.5:2 (1:4) (blend E) products were prepared using 9.32 g. dried aluminum hydroxy gel to furnish 5 g. Al_2O_3, and 2.24 g., 4.50 g., 9 g., 17.95 g. and 35.95 g. magnesium trisilicate to furnish 0.494, 0.989, 1.975, 3.95 and 7.91 g. MgO, respectively. The

blends were then tested by the Holbert, Noble Grote procedure as outlined in Example 1, usin gram samples. The pH data obtained was as follows

Table VI

Time, Minutes	Blend A	Blend B	Blend C	Blend D	Ble E
0	1.5	1.5	1.5	1.5	
1	2.0	2.0	2.0	2.0	
2	2.0	2.0	2.01	2.04	2
3	2.0	2.0	2.05	2.13	2
4	2.0	2.00	2.11	2.22	2
5	2.0	2.02	2.19	2.34	2
6	2.0	2.04	2.25	2.48	2
10	2.05	2.21	2.60	3.22	4
20	2.12	2.38	2.99	3.78	5
30	2.12	2.42	2.90	3.66	4
40	2.08	2.38	2.67	3.20	4
50	2.02	2.30	2.49	2.88	3.
60	2.02	2.23	2.35	2.61	3.
70	2.0	2.16	2.25	2.45	2.
80	2.0	2.11	2.17	2.32	2.
90	2.0	2.08	2.11	2.21	2.
100	2.0	2.06	2.08	2.17	2.
110	2.0	2.02	2.05	2.10	2.
120	2.0	2.00	2.03	2.06	2.

These data are graphed in FIGURE 4.

It is apparent from the above data that these compos tions are incapable of meeting the requirements for satisfactory antacid composition. Blends A to C di not even reach a pH of 3. Blend D maintained a p above 3 only for thirty minutes and blend E maintaine this pH for only fifty minutes, while the maximum p reached 5.2 well beyond the desirable upper limit of 4.5 Thus, the data show the significance of mixing the mag nesium trisilicate with a wet aluminum hydroxy carbonat gel.

EXAMPLES 14 TO 16

Three compositions were prepared having Al_2O_3:Mg molecular ratios of 8:2, 2:2 and 1:4. These compositions were prepared from aluminum sulfate and magnesium sulfate by reaction thereof in alkaline aqueous sodium silicate solution, followed by coprecipitation of the two substances.

The magnesium sulfate and aluminum sulfate were both dissolved in deionized water in a tank equipped with a Lightnin' portable agitator with a 2 inch at blade turbine. The sodium silicate (40° Baumé 28.2% SiO_2) and caustic soda pellets were dissolved separately in deionized water and the magnesium silicate-aluminum hydroxide gels coprecipitated by the addition of the sodium silicate solution to the mixed sulfate solution at about 26 ml. per minute at room temperature. The precipitated slurry was aged for sixteen hours and filtered through a 24 cm. Buchner funnel under 23 inches of vacuum. The filtered cake was washed with deionized water until the effluent was sulfate-free. The wet cake was dried for twenty-four hours at 176° F. in an atmospheric tray dryer and the dried material pulverized in a Mikro sample mill.

The 8:2 composition (Example 14) was prepared from 60.4 g. $MgSO_4 \cdot 7H_2O$ and 580 g. aluminum sulfate iron-free dissolved in 6500 ml. of deionized water, using as the precipitant 79 g. of the sodium silicate and 246 g. caustic soda pellets dissolved in 5868 g. of deionized water.

The 2:2 product was prepared from 121 g. $MgSO_4 \cdot 7H_2O$ in 580 g. of aluminum sulfate, iron-free, added to 6499.6 g. deionized water, using 316 g. sodium silicate and 278 g. sodium hydroxide pellets dissolved in 5602 g. deionized water.

The 1:4 product (Example 16) was prepared from 134 g. of magnesium sulfate and 79.0 g. of aluminum sulfate, iron-free, dissolved in 770 g. of deionized water, using as e precipitant 170.5 g. of sodium silicate and 56 g. caustic da dissolved in 631 g. deionized water.

The antacid characteristics of these three materials were termined by the Holbert, Noble and Grote procedure ing 1 gram samples as set forth in Example 1 above. he pH data obtained was as follows:

Table VII

Time, Minutes	Example 14	Example 15	Example 16
	Al_2O_3:MgO Ratio, 8:2	Al_2O_3:MgO Ratio, 2:2	Al_2O_3:MgO Ratio, 0.5:2
	1.5	1.5	1.5
.25	2.0	3.8	3.2
.50	2.3	3.9	3.6
	3.0	3.9	3.8
	3.6	4.0	4.3
	3.7	4.0	4.6
	3.7	4.0	4.8
	3.7	4.0	5.0
	3.7	4.0	5.1
	3.7	4.0	5.2
	3.7	4.0	5.2
	3.7	4.0	5.3
	3.8	4.0	5.3
0	3.7	4.0	4.6
20	3.6	3.9	4.3
30	3.5	3.8	3.9
40	3.4	3.7	3.6
50	3.3	3.7	3.5
60	3.2	3.6	3.3
70	3.0	3.5	3.2
80	2.9	3.4	3.0
90	2.8	3.2	2.9
100	2.6	3.1	2.7
110	2.5	2.8	2.6
120			

These data are graphed in FIGURE 5.

These data show the criticality of the Al_2O_3:MgO ratio. Examples 14 and 15 are capable of maintaining the pH within the range from 3 to 4.5 for approximately two hours. The Example 16 composition with a 1:4

Al_2O_3:MgO

ratio could not maintain an upper pH limit at 4.5 or below. The pH was in excess of 4.5 for most of the first twenty minutes of the test procedure, which is undesirable. Thus, in this composition there was too little aluminum hydroxide.

As previously indicated, the compositions in accordance with the invention are useful in the treatment of internal conditions where excess acidity is to be encountered, such as gastric acidity in the stomach, in, for example, the treatment of gastric and peptic ulcers. For this purpose, the dry compositions are readily administered in the form of slurries, or as dry powders or tablets, with an excipient, if desired, which are suitably taken orally or added to a liquid carrier such as water.

It is usually most convenient to prepare the compositions in tablet form, and since the compositions are relatively inert and store well, tablets are easily prepared by conventional procedures. The composition can be tableted as such, or with an excipient mixture of conventional type. The following is a typical tablet formulation:

	Grams
Antacid composition	32000
Lactose	62620
Starch	6800
Monosodium phosphate	1130
Stearic acid	1130

The quantity indicated is sufficient to prepare approximately 48,000 tablets, containing 10 grains each of the antacid composition.

Those skilled in the art will perceive other methods for the administration of the compositions, and it will be apparent that these are in no way critical but can be selected to meet any particular requirements.

I claim:

1. An antacid composition capable as determined by the Holbert, Noble and Grote test method of maintaining the pH of artificial gastric juice within the range from about 3 to about 4.5 for at least one hour, comprising the dried combination of hydrous gelatinous aluminum hydroxy carbonate and magnesium silicate, in a molecular weight ratio calculated as Al_2O_3:MgO within the range from about 1:2 to about 32:2.

2. An antacid composition in accordance with claim 1 in which the magnesium silicate is in the form of dry magnesium trisilicate gel.

3. An antacid composition in accordance with claim 1 in which the magnesium silicate is in the form of moist magnesium trisilicate gel.

4. A composition in accordance with claim 1 in which the aluminum hydroxy carbonate and the magnesium silicate are in the form of coprecipitated gels.

5. A composition in accordance with claim 1 in the form of a slurry of the gels in water.

6. An antacid tablet comprising a composition in accordance with claim 1 and an excipient.

7. A process for preparing an antacid composition capable as determined by the Holbert, Noble and Grote test method of maintaining the pH of artificial gastric juice within the range from 3 to about 4.5 for at least one hour, which comprises mixing hydrous gelatinous aluminum hydroxy carbonate and magnesium silicate in a molecular weight ratio calculated as Al_2O_3:MgO within the range from about 1:2 to about 32:2, and drying the resulting mixture.

8. A process in accordance with claim 7 in which the aluminum hydroxy carbonate gel and magnesium silicate are formed in situ by coprecipitation from a common solution.

9. A process in accordance with claim 7 in which the magnesium silicate is a dry magnesium trisilicate gel.

10. A process in accordance with claim 7 in which the magnesium silicate is a moist magnesium trisilicate.

References Cited in the file of this patent

UNITED STATES PATENTS

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,017,324 January 16, 1962

Stewart M. Beekman

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 5, line 41, Table III, Example No. 6, and opposite "1.0" for "2.0" read -- 4.0 --.

Signed and sealed this 15th day of May 1962.

(SEAL)
Attest:

ERNEST W. SWIDER
Attesting Officer

DAVID L. LADD
Commissioner of Patents