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Salpekar et al.

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[54] **N-ACETYL-P-AMINOPHENOL COMPOSITIONS CONTAINING PARTIALLY GELATINIZED STARCH AND METHOD FOR PREPARING SAME**

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[58] **Field of Search** **424/80; 514/629**

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[57] **ABSTRACT**

An N-acetyl-p-aminophenol composition capable of being directly formed into a tablet having high hardness, short disintegration time and short dissolution time is disclosed. The composition includes N-acetyl-p-aminophenol, a pharmaceutically acceptable partially gelatinized starch, a pharmaceutically acceptable lubricant, water and optionally an auxiliary binder, an auxiliary disintegrant or both of these optional components. Also disclosed is a method for preparing the essential components (and optional components if desired) and spray drying the slurry.

16 Claims, No Drawings

**N-ACETYL-P-AMINOPHENOL COMPOSITIONS
CONTAINING PARTIALLY GELATINIZED
STARCH AND METHOD FOR PREPARING SAME**

The present invention relates to an N-acetyl-p-aminophenol composition containing partially gelatinized starch, to a method for preparing the composition and to orally administerable analgesic tablets formed from the composition.

N-acetyl-p-aminophenol (hereinafter referred to sometimes as acetaminophen or simply APAP) is generally non-compressible, especially in forming orally administerable tablets.

Accordingly, there is a substantial need in the art for a direct tableting, free-flowing particulate APAP composition capable of being directly formed into a tablet having high hardness, short disintegration time and short dissolution time.

It has now been found by practice of the present invention that such APAP composition can be formed.

Advantageously, the composition of the present invention can be directly formed into tablets by tablet operators without need for admixing tableting adjuvants or aids.

In various embodiments of the present composition described hereinbelow, the mutually conflicting needs for tablets having high hardness and low disintegration and/or dissolution times can be met.

DESCRIPTION OF THE INVENTION

Generally stated, the present invention provides a direct tableting, free-flowing particulate pharmaceutical composition capable of being directly formed into a tablet having high hardness, short disintegration time, and short dissolution time, the composition comprising as components thereof:

- (A) N-acetyl-p-aminophenol,
- (B) a pharmaceutically acceptable partially gelatinized starch having a Percent Gelatinization of from about 50 to about 75% and in an amount effective for imparting said hardness, disintegration time and dissolution time,
- (C) a pharmaceutically acceptable lubricant in an amount at least sufficient to impart effective mold release properties to said tablet, and
- (D) water in an amount from about 0.5 to about 1.5% based on the total weight of the composition, said components being distributed throughout the particles of said composition in at least approximately the same distribution achieved when the composition is prepared by spray drying an aqueous slurry including said components (A), (B), and (C).

In another aspect, generally stated, this invention provides a method for preparing a direct tableting, free-flowing particulate N-acetyl-p-aminophenol composition capable of being directly formed into a tablet having high hardness, short disintegration time and short dissolution time, said method comprising:

- (a) forming a slurry containing components dispersed substantially uniformly throughout an aqueous medium, said components comprising:
 - (A) N-acetyl-p-aminophenol,
 - (B) a pharmaceutically acceptable partially gelatinized starch having a Percent Gelatinization of from about 50 to about 75% and in an amount effective for imparting said hardness, disintegration time and dissolution time,

(C) a pharmaceutically acceptable lubricant in an amount at least sufficient to impart effective mold release properties to said tablet,

(b) spray drying said slurry under spray drying conditions such that the spray dried particles include water an amount from about 0.5 to about 1.5% based on the total weight of the composition, said components being distributed throughout the particles of said composition such that at least a portion of said lubricant is dispersed within said particles and at least a portion of the lubricant is disposed on the outer surfaces of said particles.

In yet another aspect, generally stated, this invention provides an orally administerable analgesic tablet formed from the pharmaceutical composition described above.

**DETAILED DESCRIPTION OF THE
INVENTION AND OF THE MANNER AND
PROCESS OF MAKING AND USING IT**

The N-acetyl-p-aminophenol component of the present invention is preferably provided in finely defined form, i.e., the APAP is preferably of small particle size. For example, it has been found that if more than 50% by weight of the APAP particles are larger than 200 mesh (U.S. standard sieve) then the spherical conformation of the particles of the composition is adversely affected. For use in the present invention, preferably all of the APAP particles will pass through a 200 mesh screen, more preferably 75% will pass through a 325 mesh screen and most preferably all will pass through a 325 mesh screen.

The partially gelatinized starch component of the direct tableting composition has a Percent Gelatinization of from about 50 to about 75%. As used herein, the term "Percent Gelatinization" is a measure of the extent of gelatinization of the partially gelatinized starch relative to fully gelatinized starch and means the percent of Starch 1551 by National Starch Company (a fully gelatinized starch) required in a two-component mixture thereof with fully non-gelatinized corn starch such that the value of spectrophotometric absorbance for the mixture at a wavelength of 340 nanometers is the same as the spectrophotometric absorbance value exhibited at such wavelength for the partially gelatinized starch being characterized as having a given value (%) of Percent Gelatinization, subject to the provisos (1) that the absorbance values for both such mixture and such partially gelatinized starch (PGS) are measured on samples prepared therefrom by the modified-Shetty procedure described hereinbelow and (2) that the percentage amount of moisture in the sample prepared from such PGS is at least substantially the same as that in the sample prepared from such mixture.

The modified-Shetty procedure referenced above is a modification of the procedure for determining the degree of starch gelatinization set forth in Shetty et al., "Determining the Degree of Starch Gelatinization," *Cereal Chemistry*, Vol. 51, No. 3, pp. 364-375 (1974), incorporated herein by reference. Briefly stated, the procedure set forth in the above-cited Shetty et al. article includes selective digestion of the starch with DIAZYME® glucoamylase (Miles Laboratories) to release D-glucose, working-up the digested starch, treating the digested and worked-up starch with Worthington Reagent to impart spectrophotometric absorbancy to the treated starch and subjecting the resulting

sample to spectrophotometry. In the modified-Shetty procedure the following modifications are employed:

(1) Initially, three portions of the starch are washed with 100 ml methanol and passed through a 5-micron Millipore filter. The washed starch portions are dried for about 16 hours at 50° C. prior to weighing and assaying.

(2) The glucoamylase starch digestion is incubated at 50° C. for 30 minutes.

(3) The spectrophotometric absorbancy is measured at a wavelength of 340 nanometers for each of the three treated portions of the starch and the arithmetic mean of the three absorbance measurements is taken as the "absorbance value" recited above.

Approximate Percent Gelatinization values can be conveniently determined using a correlation graph generated for the following starch standards: fully non-gelatinized corn starch (containing zero % gelatinized starch), fully gelatinized starch (Starch 1551-National), and a set of binary mixtures thereof containing different known amounts of the fully gelatinized starch. For example, absorbance was determined by the modified-Shetty method for a set of standards including such starches individually and binary mixtures thereof containing 20%, 40%, 60% and 80% of Starch 1551. The results were plotted on Cartesian coordinates and showed a substantially linear relationship between the amount, in percent, of fully gelatinized starch and the corresponding absorbancy. Three data-generation runs were made, with correlation factors found for the three runs of 0.9926, 0.9974 and 0.9952. The final correlation graph was a plot of the three-run average absorbances found for each of the six gelatinized starch amounts (0, 20, 40, 60, 80 and 100%) versus such amounts. The spectrophotometric samples prepared from each such standard had moisture contents in the range from about 3 to about 5%. Tests on spectrophotometric samples prepared from Starch 1500 (Colorcon, Inc.) had moisture contents in the 3 to 5% range and the Percent Gelatinization of that herein preferred partially gelatinized starch was approximated as 57.7%, the value of % fully gelatinized starch on the final correlation graph for the average absorbance found for the samples prepared from Starch 1500.

The partially gelatinized starch (hereinafter referred to as PGS) serves to impart good binder and disintegration properties as well as a good balance thereof to the composition, which can be directly tableted to form tablets having high hardness, short disintegration time and short dissolution time.

The term "direct tableting" and terms of like import, as used herein, mean that the composition can be formed into a tablet using well known tableting apparatus and processes without need for addition of any adjunct material to the composition. Inclusion of PGS having a Percent Gelatinization of less than about 50% (e.g., 45% or less) usually results in unacceptably lower compressibility (as evidenced, e.g., by unacceptably lower tablet hardness). Inclusion of PGS having a Percent Gelatinization of more than about 75% (e.g., 80% or more) usually results in unacceptably longer tablet disintegration time and/or unacceptably longer tablet dissolution time. The lower hardness, longer disintegration time and longer dissolution time are relative to the corresponding tablet hardness, disintegration and dissolution times obtained under identical tableting conditions for otherwise identical compositions except that

the Percent Gelatinization of the PGS component is within the above range.

The PGS is included in an amount effective for imparting to the composition the capability of being formed into tablets having high hardness (e.g., about 8 kp or more), short disintegration time (e.g., about 10 minutes or less) and short dissolution time (e.g., about 20 minutes or less for 80% or more of the APAP to dissolve).

As used herein, the term "kp" means kiloponds, a well known unit of force for expressing hardness or crushing strength of pharmaceutical tablets when such hardness is determined on a Schleuniger Tablet Hardness Tester.

In general, such effective amount of PGS is from about 5 or less to about 15 or more parts per 100 parts of the composition.

Advantageously and unexpectedly, tablets formed from the compositions of this invention are generally found to exhibit little or no variation in tablet disintegration time with variation in tablet hardness, especially in higher hardness ranges, e.g., from about 8 kp to about 15 kp and in some instances to about 20 kp. This substantial independence of disintegration time is highly advantageous in aiding tablet formulators to produce large commercial quantities of tablets of requisite disintegration time with minimal concern for tablet-to-tablet variations in hardness as typically result from the inherent limitations of tablet-forming equipment or human error of operators thereof.

Partially gelatinized starch suitable for use in the composition can be prepared using any suitable starch-gelatinization method and stopping the gelatinization when the desired Percent Gelatinization has been obtained. A suitable PGS is also commercially available from Colorcon, Inc., West Point, Pa. as Starch 1500 (preferred).

The lubricant component may be any pharmaceutically acceptable lubricant, which may be, e.g. hydrophilic or hydrophobic. This component is present in a lubricating amount at least sufficient to impart mold release properties to tablets formed of the compositions and preferably insufficient to increase disintegration time and dissolution time of such tablets, and preferably insufficient to decrease the hardness obtainable for tablets formed from compositions of this invention containing lower lubricating amounts of the same lubricant.

Suitable lubricants for use as the lubricant component include, for example, stearic acid; metallic stearate (such as sodium, calcium, magnesium and zinc stearate, etc.); sodium lauryl sulfate; polyethyleneglycol; hydrogenated vegetable oils; talc; and compatible mixtures of two or more such materials. Stearic acid is preferred.

In general, the stearic acid or other lubricant component may be present in an amount from about 0.10 to about 0.4%, preferably from about 0.15 to about 0.25%, based on the total amount of the composition. In order to avoid decreasing the hardness of the tablets formed from compositions including stearic acid, it is critical that the amount of stearic acid does not exceed about 0.25%.

The composition also includes water in an amount effective for aid in direct tableting. Such effective amount is, in general, found to be from about 0.5 to about 1.5% based on the total weight of the composition, preferably about 1.0% on the same basis.

Optionally, the composition may further include a pharmaceutically acceptable compressibility-promoting

binder as an additional binding agent in an amount effective for increasing the obtainable hardness of tablets formed from the composition.

Materials suitable for use as the optionally included, but preferably included additional binder agent include, for example, starch paste (fully gelatinized starch); pre-gelatinized starch (a fully gelatinized starch); polyvinylpyrrolidone; hydroxypropylmethylcellulose; hydroxypropylcellulose; gelatin; natural gums (e.g., gum acacia, gum tragacanth, etc.); sucrose; mannitol; ethylcellulose; synthetic polymer binders commonly used in the industry; and compatible mixtures of two or more such materials. Polyvinylpyrrolidone (PVP) is preferred (preferably PLASDONE® PVP by GAF Corp.).

In general, such effective amount of optional binder is from about 0.5 or less to about 1.4 or more parts, preferably not more than 1.4, more preferably about 1.2 parts, per 100 parts of the composition.

Optional or auxiliary binders preferably are not included in an amount in excess of 25 parts per 100 parts of the PGS component, especially where fully gelatinized starch (pregelatinized or otherwise) is employed as the optional binder.

As a further option, the composition may further include a pharmaceutically acceptable disintegration-promoting material as an additional disintegration agent in an amount effective for decreasing the obtainable disintegration time of tablets formed from the composition.

Materials suitable for use as the optionally included, but preferably included, additional disintegration agent include, for example, starch (e.g., corn starch and other non-gelatinized starches); sodium carboxymethyl starch (sodium starch glycolate); microcrystalline cellulose; cross-linked cellulose; cross-linked polyvinylpyrrolidone; soy protein; alginic acid and compatible mixtures of two or more of such materials. Cross-linked polyvinylpyrrolidone (hereinafter referred to as XL-PVP), sometimes referred to in the art as cross-linked povidone, is preferred (preferably POLYPLASDONE XL™ cross-linked N-vinyl-2-pyrrolidone from GAF Corporation).

In general, such effective amount of the optional or auxiliary disintegration agent is from about 1 or less to about 5 or more parts, preferably about 2.2 parts, per 100 parts of the composition.

In a number of important applications, it is desired that the APAP composition have the capability of being directly tableted into tablets having a hardness of at least 12 kp (preferably at least 14 kp and, when formed into tablets having a hardness of 12 kp, such tablets to have a disintegration time of 5 minutes or less).

In general, such very high hardness/very low disintegration time compositions capable of being directly tableted into tablets having a hardness of at least 12 kp, are provided by compositions embodying this invention wherein both the auxiliary binding agent and the auxiliary disintegration agent are included in amounts from about 0.5 to about 1.4 parts per 100 parts of the composition and from about 1 to about 5 parts on the same basis, such amounts being for the two optional agents in the order given.

In a preferred embodiment, a composition having such very high hardness and very low disintegration time includes the following components in the amounts indicated (together with water in an amount from about 0.5 to about 1.5% based on the total weight of the composition):

COMPONENTS	APPROXIMATE AMOUNTS
APAP (acetaminophen)	93-83
Partially gelatinized starch	5-10
Stearic Acid	0.1-0.4
Polyvinylpyrrolidone	0.5-1.4
Cross-Linked Povidone	1-5

The amounts shown are in parts per 100 parts (dry basis) of the composition.

The best embodiment composition of this invention contemplated at the time of executing this patent application is as follows, wherein the amounts given are in parts per 100 parts (dry basis) of the composition:

COMPONENTS	APPROXIMATE AMOUNTS
APAP (acetaminophen)	90
Partially gelatinized starch	6.45
Stearic Acid	0.15
Polyvinylpyrrolidone	1.2
Cross-Linked Povidone	2.2

The last-given embodiment includes water in an amount desirably from about 0.5 to about 1.5%, preferably about 1% based on the total weight (dry basis) of the composition. Such composition of the last-given embodiment can be repeatedly, in general, formed into tablets having hardness of 12 kp or more (often 14 kp or more) and having disintegration time of 5 minutes or less (often 4 minutes or less) at 12 kp hardness.

In use, the compositions of this invention advantageously may be composited with other active or inactive ingredients, either prior to compositing the components to form the composition or after the composition is formed (e.g., by dry blending the composition with such ingredients), and thereafter directly compressed into tablets having eminently suitable values of hardness and disintegration time for a variety of end-use applications.

The compositions of this invention are preferably made by the method set forth in the above section entitled "Description of the Invention", i.e., including a spray drying step.

The slurry preparation step is preferably carried out in a manner to achieve substantially complete hydration of the partially gelatinized starch component, preferably using a low shear mixing action so as not to increase the Percent Gelatinization of the PGS, at least not to increase it above the maximum desired percent gelatinization of about 75%. Preferably, the stearic acid is thoroughly mixed in the slurry, i.e., substantially uniformly dispersed throughout the aqueous medium (e.g., water) employed.

In the preferred embodiment of the method of this invention, the following procedure is followed.

Slurry Makeup

- (A) To a suitable blender add the partially gelatinized starch and an equal amount of acetaminophen. Thereafter, add a mixture of the stearic acid and cross-linked povidone with stirring until a uniform blend is obtained.
- (B) Dissolve the polyvinylpyrrolidone in water, and, thereafter, to the resulting PVP solution add the blend from step A with agitation or mixing.

- (C) To the mixture resulting from step B add the balance of the acetaminophen while mixing is continued.
 (D) Preferably, the agitation is continued until the resulting slurry is smooth.

Spray drying conditions will be dependent on various factors, such as feed slurry concentration, method of atomization, type of spray dryer, desired rate of drying, relative humidity, and other factors which will be readily apparent to those skilled in the art.

Preferred spray drying conditions are set forth in the table below, along with an effective range of conditions for each condition or parameter indicated, by way of example for a counter-current spray dryer operated at a slurry feed rate of about 10 kilograms per hour:

Spray Drying Conditions

	Preferred	Range
Feed slurry concentration	52%	35-60%
Inlet temperature	430° F.	375° F.-600° F.
Outlet temperature	200° F.	150° F.-250° F.
Atomization pressure	28 psi	22-35 psi
Feed Pressure	52 psi	45-60 psi

Practice of the present invention is illustrated by the following specific, but non-limiting examples. All amounts (including parts, %, etc.) given in the examples and throughout this disclosure, including the claims which follow, are by weight unless indicated otherwise.

Unless indicated otherwise, the compositions in each of the following Examples were prepared using the above described preferred method. This includes the steps of forming each slurry and spray drying the resulting slurry employing the preferred conditions set forth above or at least substantially such preferred conditions. Also, in each example unless indicated otherwise, spray drying was effected using counter current spray drying in a counter-current spray dryer manufactured by Niro Atomizer Company (Model No. 6903) in accordance with the manufacturer's instructions for use.

The PGS employed was Starch 1500 (Colorcon, Inc.) having an approximate Percent Gelatinization of 57.7%.

All tablets were formed on a Manesty B3B 16-station rotary tablet press (commercially available from Thomas Engineering Company) in accordance with the manufacturer's instructions for use. The press was fitted with a tablet tooling designed to make cylindrical tablets, each tablet having opposite bevel-edge flat faces and overall diameter of 13/32 inch. The press was operated to form tablets having a nominal weight of about 360 mg.

As used herein, the following terms have the meanings indicated:

(A) "disintegration time" means the time measured using the disintegration-time test method set forth in U.S. Pharmacopeia (hereinafter "USP") XX for uncoated tablets except that the disks are not employed;

(B) "dissolution time" means the time measured using the dissolution-time test method set forth in USP XX for APAP tablets;

(C) "hardness" means the hardness measured on a Schleuniger hardness tester;

(D) "maximum hardness" means the maximum hardness at which the tablets are substantially free of lamination;

(E) "friability" means the friability measured on a Roche Friabulator for 20 tablets and 100 revolutions.

In the Examples, unless otherwise indicated all tablet hardness values are averages for 10 tablets and all tablet weights are averages obtained by weighing 20 tablets as a whole and dividing by 20. Unless otherwise indicated, tablet disintegration times were measured for tablets having about 12 kp hardness.

EXAMPLES 1-3

Compositions of this invention were prepared following the example preparation method referenced above. Shown in the table below are the components employed in the indicated amounts, together with measured tableting results (i.e., tablet hardness, disintegration time and dissolution time).

Component	APPROXIMATE AMOUNTS % (Dry Basis)		
	Ex. 1	Ex. 2	Ex. 3
APAP	81.8	90	90
PGS	18.0	8.85	6.4
(Percent Gelatinization)	(57.7)	(57.7)	(57.7)
Stearic Acid	0.2	0.15	0.2
Water	1	1	1
PVP (Aux. Binder)	—	1.0	1.2
XL-PVP (Aux. Disintegrant)	—	—	2.2
<u>Tablet Results</u>			
Hardness (kp)	9.3	13	9.4
Disintegration Time (Minutes)	18.0	6	1.5
Dissolution Time (T85)	—	—	(a)

(a)less than 10 minutes

As indicated in these examples, Example 1 contains neither auxiliary binder nor auxiliary disintegrating agent; Example 2 includes an auxiliary binder but no auxiliary disintegrating agent; and Example 3 includes both an auxiliary binder and an auxiliary disintegrating agent. The disintegration time shown for Example 2 is for 13 kp hardness tablets.

EXAMPLES 4-8

Additional compositions of this invention were prepared following the example preparation method referenced above. Shown in the table below are the components employed (for each of these examples) in the indicated amounts, together with measured tableting results (i.e., tablet hardness and disintegration time).

Components	Approximate Amounts % (Dry Basis)				
	Ex. 4	Ex. 5	Ex. 6	Ex. 7	Ex. 8
Acetaminophen	90	90	90	90	90
PGS	7.75	5.45	5.4	4.45	4.45
<u>Lubricant System</u>					
Stearic Acid	0.15	0.15	0.1	0.15	0.15
Sodium Lauryl Sulfate NF	0.1	—	0.1	—	—
Auxiliary Binder	1.0	1.4	1.4	1.4	1.4

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