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TABLET MOLDING PROCESS

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The present invention relates generally to an improved molding process, and it relates more particularly to an improved method for producing pharmaceutical tablets, pills and the like.

The conventional method of manufacturing tablets for pharmaceutical or other uses includes the steps of producing granules of predetermined size of the material forming the tablets and compressing the material into a coherent mass of the shape of the finished tablet. The common methods of producing the granules of suitable size and configuration are the so-called slugging process and wet granulating process. Both these processes possess many disadvantages and leave much to be desired.

In accordance with the slugging process, the various ingredients, in intimately admixed powder form, are subjected to high pressures to produce large slugs of the material as a cohered solid mass. These slugs are then milled into granules of the desired size and configuration, the granules being thereafter recompressed in the conventional tablet-forming equipment to produce the finished product. The slugging process is generally employed where the tablet ingredients may not be wetted due to some incompatibility or where they are heat-sensitive and unstable. It is an expensive process which involves considerable labor and equipment and its application is limited and not always satisfactory.

The more common method is the wet granulating process. In accordance with this process, the ingredients which enter into the tablet are wetted down. The wetting agent generally consists of water, alcohol or other organic solvent with or without water, gum or other binder solutions, for example, acacia, tragacanth, methyl cellulose, gelatin, gelatinized starch, etc. The tablet ingredients, wetted as above, to the proper consistency are placed in a suitable drying oven. The dried solid cohered mass is then milled into granules of the required size, admixed with a suitable lubricant and formed into tablets as in the case of the slugging process. The wet granulating process is likewise expensive, requiring considerable labor. Moreover, where organic solvents are employed, these are evaporated and seldom recovered, thus adding to the production costs. The wet granulating process cannot be used when the tablet ingredients are incompatible to wetting or are heat-sensitive.

It is thus a principal object of the present invention to provide an improved molding process.

Another object of the present invention is to provide an improved process for the manufacture of pills, tablets and the like.

Still another object of the present invention is to provide an improved method of producing pharmaceutical pills, tablets and the like.

A further object of the present invention is to provide an improved tablet producing method characterized by the absence of any slugging or wetting steps.

Still a further object of the present invention is to provide an improved tablet producing method which may

be employed with materials sensitive to heat and wetting.

Another object of the present invention is to provide an improved inexpensive and versatile tablet producing process characterized by its low labor, material and equipment requirements and the use of standard apparatus. Following the general method contemplated by the present invention, a pharmaceutical pill, tablet or the like, is produced by admixing a physiologically active ingredient in a finely divided state with a molten, preferably water soluble binder, solidifying the resultant mixture, comminuting the solidified mixture into granules and forming said granules into tablets.

In accordance with a preferred embodiment of the improved method, the active ingredients and any desired excipients, such as powdered sugar, milk sugar, starch, etc. in a powdered intimately admixed state, are placed in a conventional mixer such as a pony mixer, change can mixer, tumbler mixer, or any other suitable mixer. The mixer is actuated and the molten binder is slowly added during the continued mixing at a rate to effect the formation of small balls or nodules. Upon cooling of the balls or nodules, a suitable lubricant such as talc, magnesium stearate, stearic acid or dry starch is added. For example, 2% to 3% magnesium stearate and ½% to 1% talc based on the final weight of the tablets may be advantageously employed. The balls or nodules are preferably of the order of about ⅛ inch in diameter and, in any event, larger than about a 20 mesh. The balls or nodules together with the lubricant are then granulated in any well known fashion, such as by means of a Fitzpatrick comminuter, to produce granules of between 20 to 60 mesh depending upon the size of the tablet to be produced. The granules are then formed into tablets in the usual manner.

The binding material employed in forming the granules, should preferably be water soluble and should have a low melting point compatible with the other ingredients entering into the tablet so as not to adversely affect or decompose these ingredients and the melting point should not be too high for convenient handling. Binders having melting points below 120° C. are generally satisfactory, although this temperature may vary depending upon the other constituents. It is also preferable that the binder be colorless or white and not char or otherwise become discolored upon melting. Sorbitol has been found to excellently serve the function of the binder. It has a melting point of 90° C. and is of a syrupy consistency or viscosity. Most satisfactory results have been obtained when the binder is from 10% to 15% by weight of the final mixture and is added to the other ingredients during the mixing or tumbling thereof at a rate preferably not exceeding 20 percent of the molten binder per minute, for example, 10 percent per minute.

An example of the present improved process is in the production of phenobarbital tablets having a running weight of 1.3 grains and each containing ¼ gram phenobarbital. The ingredients and quantities employed in the production of 1,050,000 of these tablets are as follows:

Phenobarbital powder	37 lbs. 8 oz.
Powdered sugar	85 lbs.
Milk sugar	22 lbs.
Starch	12 lbs.
Sorbitol	30 lbs.
Magnesia stearate	5 lbs.
Talc	2 lbs. 8 oz.
Dried starch	1 lb.

Except for the phenobarbital, the weights of the above constituents may be varied approximately 10%.

In forming the tablets, the phenobarbital powder, pow-

dered sugar, milk sugar and starch are placed in the mixer or tumbler and there intimately admixed. While continuing the mixing operation, the molten sorbitol is slowly added to the agitated mixture over a period of approximately 10 minutes, the ingredients balling up in small roughly spherical nodules of about ⅛ inch diameter. The spherical nodules are permitted to cool and solidify and the magnesium stearate, talc and dried starch added and uniformly distributed throughout the mass. The batch of lubricated nodules are then passed through a properly adjusted Fitzpatrick comminuter where the nodules are broken in granules of about 30 mesh. These granules are then formed into tablets in the usual and conventional manner.

While there have been described and illustrated preferred embodiments of the present invention, it is apparent that numerous alterations and omissions may be made without departing from the spirit thereof.

I claim:

1. The improved method of producing pills comprising the steps of slowly adding molten sorbitol to a finely divided active ingredient while agitating said active ingredient to produce nodules of the order of approximately ⅛" diameter of said sorbitol and said active ingredient, cooling and solidifying said nodules, comminuting said nodules to produce granules of between approximately 20 and 60 mesh and compressing said granules into said tablets, wherein the sorbitol constitutes between approximately 10% and 15% by weight of the product.

2. The improved method in accordance with claim 1, wherein said active ingredient is admixed with excipients in a finely divided state prior to the addition of said molten sorbitol.

3. The improved method in accordance with claim 1, including the step of adding a lubricant to said solidified nodules prior to comminution thereof.

4. The improved method in accordance with claim 1, wherein said molten sorbitol is added to said active ingredient at a rate not exceeding approximately 20% of the molten binder per minute.

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