This invention relates to the production of tablets by compression.

Difficulties are encountered in compressing certain tablet granulations on account of the tendency of the granulation to adhere to the punches and dies, resulting in malformation of the tablets and/or jamming of the machinery. Attempts have been made to obviate these difficulties by the use of lubricants for the compression; lycopodium powder, talcum powder, and liquid petrolatum, inter alia, being frequently used for this purpose. However, the lubricants heretofore employed have not been completely satisfactory, either being required in excessive amounts, or, as in the case of granulations embodying hygroscopic ingredients (such as ammonium mandelate and sodium salicylate), being partially or wholly ineffective.

It is the object of this invention to provide effective and economical lubricants for the production of tablets by compression, particularly tablets embodying hygroscopic ingredients.

It has been found that water-insoluble soaps, especially magnesium stearate, are suitable lubricants for the production of tablets by compression, being effective in much smaller proportions (e.g., as low as about 0.1% of the weight of the tablet) than those of the lubricants heretofore employed and enabling the production of tablets from granulations embodying hygroscopic ingredients (such as ammonium mandelate) which could not heretofore be made by compression.

The effective soaps comprise, inter alia, the magnesium, calcium, zinc, aluminum, lithium, bismuth, copper, iron, and manganese salts of higher fatty acids or mixtures such as stearic, palmitic, lauric, myristic, and coconut-oil fatty acids. In addition to their lubricating property, these soaps have water-repellent properties, and it is apparently this combination of properties that enables the production of tablets by compression from granulations embodying hygroscopic ingredients such as ammonium mandelate. Manifestly, the particular soap employed should be inert to, or compatible with, the other ingredients of the tablet, and, in the case of pharmaceuticals, should also be innocuous.

Preferably, the soap is incorporated into the granulation by dusting it in finely divided form over the granulation prior to compression, thus covering the granules with a thin layer of the soap. Granulations embodying a water-insoluble soap as a lubricant are readily compressed and ejected from the die; moreover, the use of these lubricants results in an increase in speed of tableting, since operations need not be stopped for cleaning of the punches and dies.

The following examples are illustrative of the invention:

**Example 1**

Ingredients for making one thousand 7½-grain ammonium mandelate tablets:

- Ammonium mandelate: 486 g
- Magnesium stearate: 19.5 g

486 g, lumpy ammonium mandelate is granulated and thoroughly admixed with part of the magnesium stearate; the mixture is regranulated, compressed into small slugs, again granulated, thoroughly admixed with the remainder of the magnesium stearate, regranulated, and compressed into tablets. The compression is readily effected, the tablets being easily and cleanly ejected. The resulting tablets are, moreover, relatively stable in the atmosphere.

The ingredients named in the following examples are mixed and granulated in the usual manner, the water-insoluble soap is dusted over the dry granulation, and the granulation compressed into tablets. Compression and ejection are readily effected without encountering any sticking to the punches and dies, and the resulting tablets are hard, smooth, and unbroken.

**Example 2**

Ingredients for making 18,750 tablets each containing 0.1 gram of 2,4-diamino-4'-ethoxy-azo-benzene hydrochloride:

- 2,4-diamino-4'-ethoxy-azo-benzene hydrochloride: 30 kg
- Lactose: 1.875 kg
- Binder: 0.47 kg
- Sucrose: 0.175 kg
- Starch: 0.200 kg
- Magnesium stearate: 0.19 kg

The tablets may be coated in the usual manner.

**Example 3**

Ingredients for making 10,000 5-grain yeast tablets:

- Brewer's yeast: 0.324 kg
- Malted-wheat-germ-extract: 0.159 kg
- Sucrose: 1.235 kg
- Citric acid: 0.61 kg
- Magnesium stearate: 0.75 kg

**Example 4**

Ingredients for making 2,750 5-grain sodium salicylate tablets:

- Sodium salicylate: 0.891 kg
- Sucrose: 0.137 kg
- Acacia: 0.385 kg
- Lactose: 0.20 kg
- Magnesium stearate: 0.20 kg
Example 5

Ingredients for making 1,000 2.5-gram sodium hydroxide tablets:

- Sodium hydroxide (granular) \[\text{kg} \] 2.500
- Aluminum stearate \[\text{kg} \] 100

The lubricants of this invention may be substituted generally for the heretofore employed lubricants. In addition to those detailed in the foregoing examples, the following tablets, inter alia, may be readily prepared when using the lubricants of this invention:

- Cascara sagrada
- Quinine sulfate
- Aloe and mastic (NF VI)
- Aloin, strychnine, and belladonna (NF VI)
- Asafoetida (NF VI)
- Camphor, quinine sulfate, and belladonna
- Sodium glycero phosphate and calcium glycero-phosphate

The invention may be variously otherwise embodied, within the scope of the appended claims.

We claim:

1. In the process of preparing tablets by compressing granulations, the step of incorporating in the granulation a lubricant consisting of a water-insoluble soap.
2. In the process of preparing tablets by compressing granulations, the step of incorporating in the granulation a lubricant consisting of a finely-divided water-insoluble soap.
3. The process of preparing tablets which comprises dusting a tablet granulation with a lubricant consisting of a water-insoluble soap, and compressing the granulation into tablets.
4. The process of preparing tablets which comprises dusting a tablet granulation with a lubricant consisting of magnesium stearate, and compressing the granulation into tablets.
5. In the process of preparing tablets by compressing a granulation embodying a hygroscopic ingredient, the step of incorporating in the granulation a lubricant consisting of a water-insoluble soap.
6. The process of preparing ammonium mandelate tablets which comprises dusting a granulation of ammonium mandelate with a lubricant consisting of a water-insoluble soap, and compressing the granulation into tablets.
7. The process of preparing sodium salicylate tablets which comprises dusting a granulation essentially comprising sodium salicylate with a lubricant consisting of a water-insoluble soap, and compressing the granulation into tablets.
8. The process of preparing sodium hydroxide tablets which comprises dusting a granulation of sodium hydroxide with a lubricant consisting of a water-insoluble soap, and compressing the granulation into tablets.

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