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Pharmaceutical and Cosmetic Uses of Talc.

Shabbir Dawoodbhai and Christopher T. Rhodes

Department of Pharmaceutics

University of Rhode Island

Kingston, RI 02881.

1. Introduction.

Talc is a mineral with the composition of $3MgO.4SiO_2.H_2O$, and referred to as hydrous magnesium silicate (1). The structure consists of MgO sheet sandwiched between two silica sheets. Each layer is electrically neutral, and the adjacent layers are held together by only weak van der Waals forces (1). The mineral composition of talc may vary depending on the geographical source of the deposit (1,2). Impurities in the form of calcium silicate and calcium carbonate makes the powder abrasive, while iron oxide or magnesium ferric silicate makes talc greyish in appearance (1,2). Very finely powdered talc is boiled in 2% hydrochloric acid and subsequently in weaker hydrochloric acid solution to remove iron and other soluble impurities. Finally the talc is thoroughly washed with water and dried at $100^{o}C$ (2). (For the variety of cosmetics products in which talc is a major component, see Table 1.)

2. Cosmetic Uses of Talc

Talc is used as face, body and foot powder to keep skin smooth, cool and dry (3). The smoothness of talc felt by human hands is dependent on its slip characteristic. The slip characteristic is dependent on particle size and shape. Talc has lamellar particle shape and this produces the slippery feel (1). The larger the individual plate the better the slip. Italian talcs have excellent slip characteristics (1). More than 98% of the talc particle

Table 1. Utilization of Talc in Cosmetic Products.

Product	Percent Talc	Purpose of Talc	Ref #
Face powder	10-75	Keeps skin smooth and dry	3
Foot powder	70-85	Keeps skin smooth and cool	3
Baby powder	45-97	Keeps skin smooth and dry	3,4
Pressed powder	40	Easy spread of rougher color	3
Bleaching mask	52	Absorbs sebaceous secretions	3
Dry shampoos	60	Absorbs sebaceous secretions	3
Pre-electric Talc sticks	5	Absorbs sebaceous secretions and provides slip for shaver	3,6
Foot spray	10-15	Cooling and refreshing	3
Dusting powder	90	Keeps skin cool, smooth, dry and fragmented	7

size, especially in baby powders, should be less than 74 um (1). Apparent bulk and tap density of talc is proportional to particle size distribution. The finer the distribution the lower the apparent density (1). Baby powders are like talcum dusting powders, but contain an antiseptic, with less perfume and more absorbent for example 20% rice starch and 15% zinc oxide to increase the covering power of talc (4).

Talc has low water wettability (5), absorption (3) and adsorption capacity (5), so it is common to include starch, kaolin, precipitated calcium carbonate or magnesium carbonate to increase absorbancy for products such as face powders (1,3,6,7). These carbonates also serve as the carrier for perfume (6). To enhance powder adherance and thereby improve powder feel on the skin, the metallic stearates for example magnesium stearate or zinc stearate are added (3). Magnesium stearate is prefered over zinc stearate because it is less toxic if powder is accidentally ingested (3). Substances such as kaolin, titanium dioxide, magnesium oxide, zinc oxide may be included in formulation to improve the covering power of talc (3). Currently available alternatives to talc include rice starch (3) and Pullulan (3), however, they are expensive. Since talc absorbs sebaceous secretions it is used in dry shampoos (3), and in pre-electric shave talc sticks (3,6). Veegum or colloidal magnesium aluminum silicate is used as a binder for pre-electric shave talc sticks (3,6). Skin exhibits higher friction when rubbed on smooth surface as compared to relatively rough surface because of skins flexibility (8). A decrease averaging 50% in frictional force was observed with a polished or rough metal probe after application of talc to the skin (8). This effect of talc is attributed to its low shearing strength per unit area and the talcs ability to adhere to stainless steel surface of metal probe (8).

Pressure packaging of talc formulated powder for use as a foot spray is not necessary because of reasonably good delivery to skin using conventional packaging (3). Talc containing foot sprays are mainly used for their refreshing fragrance and cooling effect (3). They are not used as antiperspirant sprays because talc has poor adherance to the skin and its antiperspirant effect is small (3). As a *fragrance carrier*, cosmetic talc must hold the fragrance oil on its surface and release it unchanged (1).

Total powder in an aerosol formulation should be less than 15% to avoid blockage of valve activator, and the powder size of all particles should be fine enough to pass through the mesh size 200 (6). Some of the ingredients that are often combined with talc in a formulation for example zinc oxide, zinc stearate, kaolin, and calcium carbonate cannot be used because they all agglomerate in presence of propellant (6). However, talc presents no great problem in getting satisfactory valve function, because of the lubricating characteristics of talc (9).

Talc particle size in aerosol formulations should be 50m or less to aid in dispersion (1,6,9,10). The dispersibility of talc becomes better as zeta potential increases above 70 mV (11). In propellant mixtures, propylene glycol monoisostearate was the most effective suspending agent and dispersing agent. Other dispersing agents showed little differences among themselves and were less effective (10). Talc sprays have to be shaken vigorously (3) since talc has a high density and therefore it settles faster than starch or aluminum chlorhydrate (10). Talc settling velocity can be reduced and final sedimentation volume can be increased by using long hydrocarbon chain alcohols, glycerol and sorbitol, any type of surfactant in low concentration of 0.005 to 0.1%, or small quantities of water immiscible liquids e.g. 0.2% to 5.0% of caprylic acid, capronic acid, or oleic acid (12).

3. Talc As Glidant

Free and uniform flow rate of powder mixtures is an important formulation consideration for the manufacture of solid dosage forms. Gold et al. (13) has shown the importance of uniformity of powder flow using two formulations both of which had similar flow rates. The tablets made on single punch press from the formulation which did not flow uniformly had a higher coefficient of weight variation compared to formulation which did flow uniformly. Presence of talc decreased the capsule weight variation by making the powder flow more uniform(14). However, talc had no effect on mean capsule weight (14).

Optimal talc concentration for improving flow has been reported to be about 0.5% (15) and 2% (16,17,18) using powder flow and shear cell studies. The percent of fines (particle sizes smaller than 40 to 200 mesh) can be a major factor that influences the percent of glidant required for improving the powder flow rate (15,18). Therefore, glidants should mainly consists of very fine particles. To a certain extent talc in concentration of 2 to 3% can increase the flow rate of powder lacking in percent fines (18). Gold et al. (19) has shown that addition of talc does not always result in an increase in flow rate. This stresses the importance of powder particle size distribution on flow.

Magnesium stearate was able to increase flow factor (16) and flow rate (15,19) of tablet excipients such as lactose to a greater extent compared to talc. However, magnesium stearate causes a much sharper decrease in flow rate when used above its optimum concentration compared to talc (15,19).

3.1 Mechanism for Improved Powder Flow

It has been suggested that cornstarch (15), talc of fine particle size (15,16) and also siliconized talc (21) form a mono particulate layer onto host powder particles. The smoothing out of the host particle surface that takes place, helps to decrease both the friction and mechanical interlocking of host particles (15,16,21). In addition, the host-host interactions at particles contact points would be replaced by weaker glidant-glidant forces (15,16,21). Glidants such as magnesium stearate and talc tend to reduce van der Waals interparticulate cohesive forces among host particles (15). The interparticulate van der Waals forces increase as particle size decreases. Talc and cornstarch also tend to fill the void spaces between particles (15).

Talc has a laminar crystalline structure, which rolls up into a spherical or roller structure when subjected to low shearing forces as generated by flow. These spheres of talc improve flowability of powders (16,20). Siliconized talc was able to improve flow rate of powder (as measured using a flowometer) to a greater extent compared to non-siliconized talc. The latter produced higher flow rates compared to unlubricated powder (21). In addition talc is also able reduces the static charges on powder particles surfaces (22,23).

Static charges on particles surfaces is one of the reasons for poor powder flow. Static charges on particles can be reduced by decreasing the percent of fines (22) and by increasing the percent of humidity (22). However, increase in humidity may decrease the chemical stability of some drugs and physical stability of the dosage form. Furthermore, increase in humidity and/or change in particle size distribution may have detrimental effects on mixing, flow and tablet compaction of powders.

Tablet lubricants in relatively low concentrations can significantly lower static charges on powders (22,23). Talc and magnesium stearate were equally effective in concentration ranging from 0.1% to 5%, in progressively decreasing electrostatic charges on materials (23). It is interesting to note that stearic acid was found to be ineffective for reducing electrostatic charges on powder materials evaluated (23).

These substances may be decreasing static charges by decreasing friction and forming a protective coat on surface of particles thereby minimizing contact between host particles. Since magnesium stearate has a more deleterious effect on tablet hardness and dissolution, it appears that talc is the better choice for reducing electrostatic charges on powder material flowing through hopper.

3. Talc As A Lubricant

In tableting, lubricants are required for reducing friction and preventing the binding between the tableting mass and die wall during compression and ejection. Lubricants also prevent picking and sticking of tableting mass to upper and lower punches respectively. Lubricants can help to reduce capping and laminating. Properly lubricated formulation will provide unblemished tablets of good appearance and uniform weight. In addition the tablet press tooling can operate with minimal wear and stress.

Lubricant efficiency of tablet lubricants have been evaluated mainly using single punch press (24-27) and rotary press (28) and more specialized equipment (29,30). It has been observed that after addition of lubricant, values of compression force decreased and the difference between compression and transmitted force became significantly reduced (24). The majority of studies have measured R values and/or ejection force for evaluation of lubricant efficiency.

Magnesium stearate in concentration of about 1 or 2% provides maximal lubricant efficiency as evaluated by R values (25,30). Magnesium stearate is a more efficient lubricant compared to talc on equal weight basis. However, increasing the concentration of talc decreases ejection force and increases R values (24-27). Talc should preferably be used in concentration greater than 0.5% (30). Compared to incorporation method the mixing of lubricants with formulation prior to compaction yielded better lubrication (30).

There are conflicting reports about the use of talc in combination with magnesium stearate (28). The

Mechtersheimer et al. (28) study offers the following observations on interactions between talc and magnesium stearate with the flat face punch tooling. Talc used alone or mixed simultaneously in combination with 0.3% magnesium stearate led to an increase in ejection forces. Further increase in talc concentration progressively lowered values of ejection force close to that obtained with 0.3% magnesium stearate alone. Talc added before or after magnesium stearate did not lower the ejection force values below those obtained with 0.3% of magnesium stearate alone (28). The residual die wall forces behaved similarly to ejection force values. However, increasing concentration of talc beyond 2% reduced the residual die wall forces below that obtained with 0.3% magnesium stearate (28). Talc used alone or mixed simultaneously with magnesium stearate led to an increase in the die wall force. However, by increasing talc concentration beyond 1% or by adding talc before or after magnesium stearate, the die wall forces decreased below that obtained with 0.3% magnesium stearate used alone (28). It is not clear whether these observations were due to the sequence of mixing or partially different mixing times for magnesium stearate and talc. The recommendation that talc should be added before magnesium stearate needs to be further validated.

Additional observations of interest reported by Mechtersheimer et al. were that with addition of increasing concentration of talc, the residual die wall force increase were not as pronounced with curved face punches as compared to flat face punches (28). With curved face punches, therefore, one can decrease residual die wall force, by compensating the reduced amount of magnesium stearate used with an increase in the concentration of talc. The die wall pressure and the residual die wall pressure generated in response to increase in compression force is greater for curved face punches than that for flat face punch tooling and are not significantly altered by increasing the talc concentrations (28).

3.1 Mechanism of Lubrication

Talc is classified as boundary type lubricant whose main action is to promote anti-adherance during compression (26). More precisely talc is a laminar type boundary lubricant (20). In tableting sufficient lubricant should be used to maintain a film on the surface of the die, so that the friction observed would be mainly due to shearing of lubricant - lubricant film. Therefore, the effectiveness of a lubricant coat will depend on its shear strength, the force with which it adheres to the metal of the die, its resistance to penetration by material of the compact and its resistance to wear (29).

The shear strength of stearic acid and its salts was reported to be almost constant with increase in compaction pressure (29). The shear strength of talc was higher compared to that of stearic acid and its salts when subjected to constraining loads (20).

The mechanism of lubrication by talc is attributed to loosely bound lattice layers sliding over each other when placed between moving surfaces (20). The laminar layers roll up in the direction of motion, to form a roller like structures. The roller mechanism explains the high coefficient obtained on alternating the direction of motion of sliding surfaces, since the roller would have to be unravelled and be reformed in opposite direction (20). For roller mechanism to act efficiently, sufficient space for roller to form must be available between sliding surfaces. This space becomes less available at high compaction forces because the relative density of tablet becomes high. This consequently results in greater radial die wall force and friction (20).

4.2 Effect of Talc on Tablet In Vitro Properties

4.2.1. Mechanical Strength

Mixing of lubricants with a formulation prior to compaction yielded harder tablets compared to the incorporation method (30). For brittle materials the axial and radial tensile strengths for dibasic calcium phosphate tablets (31) and the crushing strength of sucrose tablets (32) were not greatly affected by lubricants because of new surfaces generated by fracture of particles during compression.

For plastically deforming materials the axial and radial tensile and crushing strength of tablets were reduced by lubricants (31,32). This is because the coating of the particle surface by lubricants reduces the extent of bonding between particles during compression (25,31,32). Magnesium stearate markedly decreased the axial tensile strength relative to radial tensile strength for microcrystalline cellulose tablets even at 0.25% concentration, and progressively for aspirin and anhydrous lactose with increasing magnesium stearate concentration (31). While the effects with talc up to 6 to 8% on the axial to radial ratio of tensile strength was a moderate decrease for microcrystalline cellulose tablets and only a slight decrease for aspirin tablets (31). Jarosz and Parrott (31) concluded that for microcrystalline cellulose tablets the capping potential was greater with magnesium stearate compared to talc. However, with anhydrous lactose tablets a slight increase in ratio of axial to radial tensile strength was observed (31). Using microcrystalline cellulose as a direct compression excipient in formulation, it was shown that tablets lubricated with 1% of various talcs in combination with 0.25% magnesium stearate gave tablets of higher crushing strength compared to tablets lubricated with 0.5% magnesium stearate lubricated tablets (33).

4.2.2. Dissolution

Excipients used in a formulation can affect a products *in vitro* properties, such as the drugs dissolution rate and may also affect its bioavailability. Talc, although a hydrophobic lubricant, does not seem to have as deleterious effect on dissolution of drugs as does magnesium stearate (33,34,35). Levy et al. (34) reported that initial dissolution rate of salicylic acid from a rotating disk was faster with talc as a lubricant compared to magnesium stearate. Levy et al. (34) also concluded that hydrophobic lubricants retard dissolution rate of drugs contained in compressed tablets by prolonging disintegration time and by reducing the area of interface between drug particle and solvent. Using compressed disk of aspirin, salicylic acid and equimolar mixture of aspirin and salicylic acid an increase in concentration of magnesium stearate from 0.1 to 5% progressively slowed dissolution rate (35), while 0.1 to 5% of talc did not affect the dissolution rates of these drugs (35). It has been postulated that the stearates soften and spread under compression to provide a more coherent coverage of matrix than talc (34,35,36).

Another possible reason as to why talc has less deleterious effects than magnesium stearate is that due to its adsorption ability talc may not retard water penetration to the extent suggested by its hydrophobicity. Also an adsorbent like talc would provide a large surface area for adsorption of drugs from solution, thereby maintaining a high concentration gradient for the precipitated drug to redissolve. Wuster et al. (37) has shown that presence of an adsorbent increases dissolution by increasing the apparent saturation concentration for a drug.

For a given adsorbent the affinity and extent of adsorption will depend on nature of drug (molecular weight, pKa, lipophillicity) and its environmental conditions (pH, ionic strength and temperature). Adsorption studies of drugs by talc have shown that talc has a much lower adsorption affinity and capacity compared to adsorbents like kaolin (38) and activated charcoal (39,40). Using activated attapulgite (41), which is a similar mineral to talc, it was shown that the rate of drug absorption was less rapid compared to an aqueous solution but much faster compared to formulation containing activated charcoal. In addition, the drug bioavailability in presence of attapulgite was complete as with aqueous solution, but incomplete in presence of activated charcoal. Monkhouse et al. (42,43) have reported that rapid dissolution of drugs by rapid desorption from an adsorbent surface of silica type compounds occurred and that H-bonding and van der Waals forces accounted for this rapid desorption. So the adsorption by talc of a drug with poor aqueous solubility would facilitate the drugs dissolution rate and the desorption will allow full availability of drug. The desorption of drug and adsorption of solvent molecules onto adsorbent surface will occur as the contents at adsorption site becomes diluted.

4.3. Effect of Talc on Chemical and Physical Stability of Tablets.

Aspirin in presence of talc showed 1% decomposition compared to 15% decomposition in presence of magnesium stearate, when tablets containing aspirin, phenacetin, and caffeine were stored at 45°C for 5 weeks (44). Of the four

USP talcs that were studied only one of the talc induced aspirin instability to the maximum extent of producing about 1% salicylic acid when the tablets were stored for 4 weeks at 40°C and at relative humidity of 90% (2). The pH of the talcs did not appear to be related to aspirin stability, and washing talcs with hydrochloric acid greatly reduced the influence of talcs on aspirin stability (2). It was concluded that impurities in talc responsible for reducing aspirin stability were calcium carbonate, calcium silicate, but not aluminum silicate or ferric oxide (2). Nazareth et al. (45) reported that formulations containing calcium succinate alone or in combination with calcium carbonate, but not calcium carbonate alone accelerated decomposition of aspirin into salicylic acid in tablets stored at room temperature or 45°C at unspecified humidity conditions. Physical stability of tablets, containing acetaminophen, stored at 40°C in dry condition for ten weeks, showed that those tablets lubricated with 1% talc plus 0.25% magnesium stearate had better appearance compared to tablets lubricated with 0.5% magnesium stearates only. In addition the hardness and rapid disintegration times of these tablets did not change (34).

5. Miscellaneous Uses of Talc

Polymer films use dispersed insoluble solid filler materials such as talc to accelarate the build up of film coat structures on particles or tablets, thereby reducing coating time and costs (46). Talc gave a more varied and complex surface than titanium dioxide (46), and it was suggested that this may be due to variation in elemental content of talcs as determined by their source of deposit (46).

Talc in the range of 0 to 50% was included as an additive in the formulation of an enteric-coated microcapsules prepared by spray drying. Presence of talc greatly improved the microcapsules flow properties and compressibility for tableting. In addition, the greater the percentage of talc used the greater was the increase in tablets crushing strength (47).

6. Conclusions

Talc is extensively used in a wide variety of cosmetic products, particularly in powder products. Talc keeps the skin feeling smooth and dry. Talc in the pharmaceutical industry is used as a glidant and lubricant. The glidants such as talc improve flow properties of powder by decreasing interparticulate friction, by decreasing van der Waals forces and electrostatic charges, by changing particle size distribution, and probably by decreasing the effect of humidity on surfaces of host particles by forming a mechanical barrier. The loosely bound lattice layers slide over each other and form roller structures which explains its lubrication characteristics. Talc has less deleterious effect compared to magnesium stearate on tablet *in vitro* properties.

7. References

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