19.12 COSMETICS AND PHARMACEUTICAL PRODUCTS

Fillers are used by the pharmaceutical industry for three main functions: as colorants, disintegrants, and glidants.[80-81] Each application demands special properties, as discussed below. Pharmaceutical grade fillers differ from those used by other industries in that they must comply with a high purity standard. The purity of material for pharmaceutical use is not only defined in terms of chemical composition but microbiological contamination is strictly limited.

The pharmaceutical industry uses organic dyes and lakes and inorganic pigments as common colorants. Red, yellow, and black iron oxides, titanium dioxide, calcium carbonate, and talc are typical examples of inorganic pigments used in tablet production in order to provide the user with distinctive colors for different products. Inorganic pigments used by the pharmaceutical industry are analyzed for particulate properties (particle size, specific surface area, etc.), refractive index, stability of with respect to heat, UV degradation, and effect of pH. Trace elements are analyzed. These include arsenic, lead, antimony, cadmium, chromium, mercury, copper, zinc, barium, and iron.

The term disintegrant is applied to a substance added to a tablet formulation for the purpose of causing the tablet to break apart in an aqueous environment. Starch is the most commonly used disintegrant but several other materials are also used including inorganic fillers, namely, kaolin and bentonite. These fillers are usually added in concentrations ranging from 5 to 15%. The filler should work in conjunction with the tablet binder and withstand physical forces of compression. A typical disintegrant should, on contact with water, swell, hydrate, change volume or position, or react chemically to produce disruptive changes in the tablet. Kaolin and bentonite swell in contact with water. Their major disadvantage is their off-white color.

Chitin/silica combination is a useful superdisintegrant.[82] It is an insoluble, hydrophilic, highly absorbent inert material. It has excellent water uptake and water penetration, with no gelling hindrance effects, as well as compatibility with pharmaceutical drugs.[82]

Water absorption into tablet containing partially pregelatinized starch was much slower compared to matrices containing microcrystalline cellulose or lactose.[85] This may explain the slower drug release from tablets containing starch compared to those containing microcrystalline cellulose or lactose.[85]

Glidants are substances added to cohesive powders in order to improve their flow properties by reducing interparticle friction. The effect produced by glidants depends on their chemical composition, which should be able to form permanent or temporary bonds with cohesive powder. Properties of glidants depend on physical factors such as grain size and shape, moisture content, hygroscopicity, etc. Talc and silica type fillers are typical examples of glidants. These materials, when added to the powdery composition, promote free-flow in the hopper and complete filling of tablet molds.

Effect of geometric structure and surface wettability of glidant on tablet hardness was investigated for several types of silica used as glidants.[84] With respect to hydrophilic silica, it is not hydrophilicity but geometric structure which has a decisive impact on tablet hardness both in unlubricated and lubricated tablets.[84]

The excipients are all components of the pharmaceutical formulation other than the active ingredient(s), including pigments, lubricants, disintegrants, and glidants.[83] A review discusses the most frequently used components of pharmaceutical compositions.[83]

Theories developed in the study of metal powder compression have been adapted to the compacting of pharmaceutical powders.[80] A mathematical model is used to explain the reasons for defect formation during powder compression because of sticking and capping.[81]

In the cosmetics industry, finely dispersed fillers, are used as abrasives (toothpaste, scrub cosmetics), for their light reflecting properties (sunscreen lotions), for their dehydrating and astringent effect (kaolin in face masks), for their cooling effect (zinc oxide in sunburn lotion), and as cosmetic color additives and extenders (makeup). The many different applications require an extensive range of filler properties.

Within this sector, dentifrice is the most important market for fillers. Traditionally, dentifrice abrasives included dicalcium phosphate dihydrate, calcium carbonate, and insoluble sodium metaphosphate.[32,33] But now, aluminum trihydrate and hydrated silica are the most important fillers in toothpastes. Aluminum trihydrate is used extensively in the European market, whereas hydrated silica dominates the American market. Fillers for toothpaste production are required to have a carefully controlled grain size distribution. It is this property which controls the abrasiveness and the rheology of the toothpaste. Oil absorption depends on grain size distribution and consequently the rheology of the paste is related to the oil absorption of the filler. The abrasiveness of silica is also related to its oil absorption. Since oil absorption increases as grain size distribution decreases, it is not surprising that abrasive RDA (radioactive dentin abrasion) decreases when grain size decreases, with oil absorption increasing. Commercially available pharmaceutical grades of aluminum hydroxide are compatible with humectants, flavoring compounds, detergents, and enzymes. Aluminum hydroxide is also used by pharmaceutical industry (as well as plastics industry) as an antiacid.

Scrub cosmetics use abrasives to remove old horny cells, to massage, to smooth the skin surface, and to remove dirt from skin pores. Natural scrubbing agents are obtained from plant shells, seeds, and oils, and from animal shells and fats. Several inorganic materials are also in use, such as aluminum oxide, silica, kaolin, talc, calcium carbonate, and zirconium dioxide. An inorganic scrub agent should be carefully analyzed for grain size distribution, grain shape and the presence of crystalline forms. Some materials used in scrub agents have a high hardness, and, if they are present in the form of abrasive particles, may cause severe skin damage. Iron oxides, titanium dioxide, and mica are the most frequently used color additives for cosmetics. Zinc oxide and titanium dioxide, in addition to their use as colorants, play the role of UV absorbers, protecting skin from radiation. Talc, kaolin, iron oxides, titanium dioxide, and fumed silica are popular colorants, extenders, and rheology modifiers. Talc is commonly used in formulations where softness and slip are required. A caution: if talc penetrates a wound it may cause talcum granulomae; therefore, in products which may come into contact with wounds, talc should be replaced by aluminum hydrosilicate.

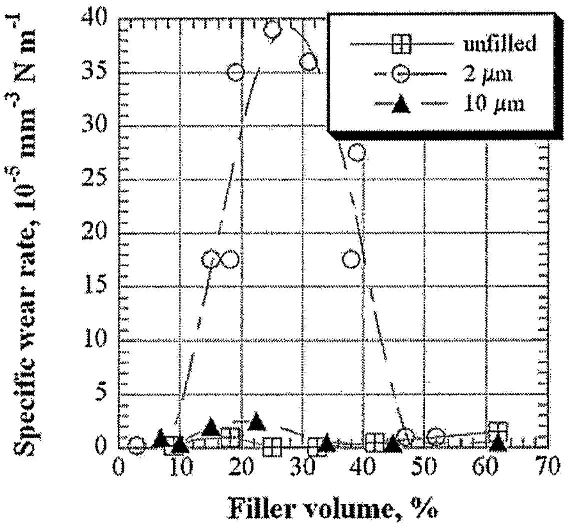

Figure 19.14. Specific wear rate of dental composites vs. filler volume. [Adapted, by permission, from Friedrich, K, *J. Mat. Sci. Mat. In Med.*, **4**, 3, 266-72, 1993.]

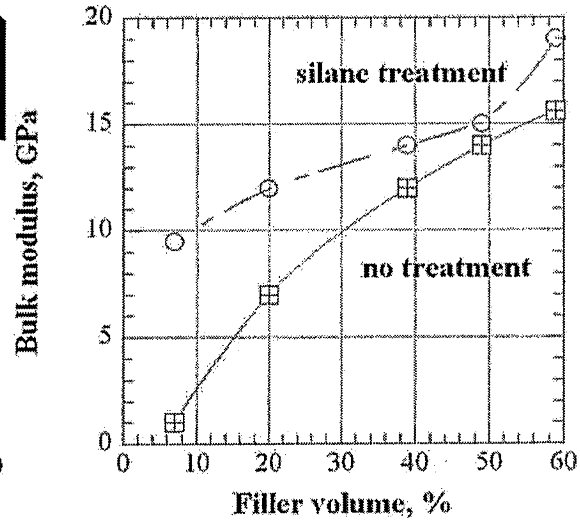

Figure 19.15. Bulk modulus of dental composite vs. filler concentration. [Adapted, by permission, from Jones, D W, Rizkalla, A S, *J. Biomedical Mater. Res. (Appl. Biomater.)*, **33**, 2, 89-100, 1996.]

Cosmetic powder composition with improved moisturizing properties contains filler powder such as talc and mica, in which talc is glycerin-coated for better moisturizing properties.[86]

19.13 DENTAL RESTORATIVE COMPOSITES

Adhesion, filler/matrix adhesion, dimensional stability, reinforcement, and wear resistance are the most important concerns in the development of dental composites.[87-91] These requirements are shared with composites used for many other purposes. So much as the methods of testing, mathematical models, methods of interpretation, and remedies developed in other applications may be applied to dental composites.

Figure 19.14 shows that wear rate depends on the concentration of filler and its particle size.[88] During the last decade, the particle size of fillers dropped from 8-30 μm to 0.7-3.6 μm in the restorative composites.[90] This has increased surface smoothness and decreased plaque retention on unpolished surfaces. The wear rate of the composites increases when fillers are added and small particle size fillers cause more rapid increase of wear rate at a certain range of concentrations. Outside this range, composites have wear rate similar to the unfilled matrix.

The most frequently used fillers are glass powder, lithium aminosilicate, and glass-ceramic. Figure 19.15 shows that properties of dental composites are enhanced by the use of silanes. Treatment with silane also improves water resistance.[91]

Polymethacrylate–silica chemical hybrid dental fillers has been prepared by the sol–gel reaction.[92] The polymethacrylate chains are uniformly distributed in and covalently bonded to the silica networks at molecular level.[92] The compressive testing results demonstrate that the dental composites prepared with the hybrid fillers have enhanced mechanical properties.[92]

Silver nanoparticles, which have antimicrobial activity, have been added to composite filling materials.[93] But depending on the size of the silver particles, the corresponding composite may show a dark coloration.[93] The particle size preventing this occurrence is below 40 nm.[93] Alternatively to the pure silver powder, silver-containing glass or silver-containing zeolite powder is added in the range of 0.01 to 10 wt%.[93]

In order to compensate for polymerization shrinkage, addition of fillers which expand during polymerization was proposed.[93] Exothermic effect of polymerization raises composite temperature to up to 80°C.[93] This causes expansion of ammonia-modified montmorillonite and counteracts shrinkage of composite.[93] It should be noted that even addition of simple fillers decreases shrinkage because there is less polymer to shrink.

An increase of the filler particle size may lead to an increase in the friction coefficient and subsequently of the contact forces.[94] Increasing the filler size may also increase the dimensions of the wear debris.[94] Hardness plays a negative role on the wear resistance, lowering the critical pressure for the onset of micro-cracking.[94]

19.14 ELECTRICAL AND ELECTRONIC MATERIALS

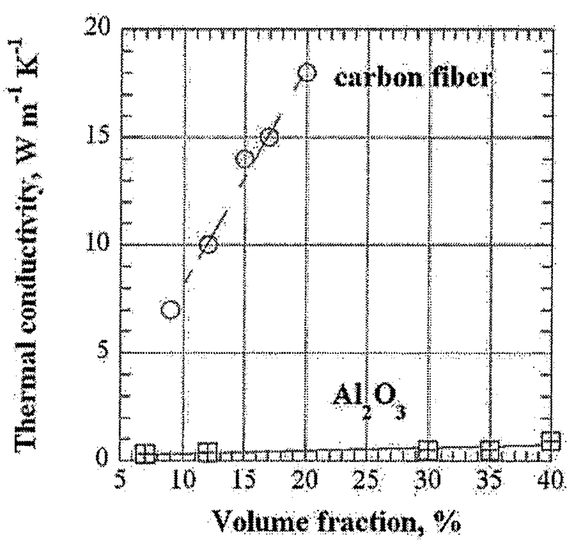

Figure 19.16. Thermal conductivity of PU vs. filler concentration. [Data from Lu, X; Xu, G, *J. Appl. Polym. Sci.*, **65**, 2733-8, 1997.]

An extremely large number of products contain components which must meet stringent requirements.[95-103] Such diversity prevents us from going beyond a general discussion. In the US and Canada products need the Underwriters Laboratories approvals and, in most cases, a V-0 rating is required. When brominated fire retardants were banned in Germany, some polymers such as polyester were affected. This generated a search for alternative fire retardants and different polymers (e.g., polyamide) for fire retardant applications. The opportunity for fire retarding fillers will continue to expand since in other countries (US, Japan, European countries) brominated flame retardants may also be restricted.

Various industries make efforts to introduce static control to work place, products, and packaging. As many as 10% of the failures of electronic equipment are related to static electricity. To control static electricity in the work place, many products should be conductive (coatings, mats, bench tops, etc.). Packaging has been developed using conductive fillers. This creates new opportunities for manufacturers of products and fillers.

Electrically insulating and thermally conductive qualities are important in computer chips fabrication. One approach taken is based on boron nitride fillers which offer these two properties. There is also a need to develop materials which are thermally conductive but electrically insulating at high humidity conditions. Polyurethane composites filled