



Effect Of Fine Particles On The Formulation Of Drugs In Pharmaceutical Manufacturing.

Author- Avi Saini (Scholar Researchers), Smt Tarawati Institute Roorkee.

Abstract - This is the new age of Pharmaceutical industry, in which Pharmaceutical industry Many different types formulation is prepared such as liquid, tablets, capsule and Dry syrup. If we are talking about the formulation then fine Particles have important role in the Pharma. In polymer fields, fine particles are used for coating or encapsulations in drug formulations, food applications, and soft-hard electronic and magnetic materials. In material science fields, inorganic particles are used in semiconductor, sensor, catalyst, abrasive, optics, and electronic applications. In biomedical fields, nanoparticles are used in bio-imaging for studying drug delivery systems, in therapies for cancer treatment via heat treatment (magnetic hyperthermia) and neutron capture.

Fine particles exhibit properties which are drastically different from the bulk. This opens up an area of research that is very challenging scientifically and technologically. Fine particles have been widely used for magnetic recording media, ferro-fluids, catalysts, medical diagnostics, drug delivery systems and pigments in paints and ceramics. Enhanced magnetic properties of fine ferromagnetic or ferrimagnetic particles make them very promising candidates for high density magnetic recording media. A large number of techniques have been used to prepare magnetic fine particles including chemical reduction, hydrothermal, sputtering, SMAD (solvated metallic atom deposition), gas evaporation and aerosol synthesis.

In these various stages of drug formulation and delivery, particle size matters because it informs whether the drug is suitable to be formulated into the required dosage form, its stability profile, and whether it is small enough to overcome the biological barriers for it to be absorbed or internalised.

There is a lot made of particle size in pharmaceutical products, and rightly so. Particle size dictates how APIs and excipients behave which, in turn, determines drug efficacy. In short, a pharmaceutical must deliver predictable, repeatable outcomes. Anything less is a failure and potentially harmful.

Just as no two pharmaceutical drug formulations are the same, so it is with pharmaceutical ingredient blending. The constant in pharmaceutical blending, however, is the impact of drug stability, visual appeal, and efficacy.

Keywords - Surface area, Fine Particles, Solubility.

INTRODUCTION

Fine particles are needed in many technological fields. In pharmaceutical fields, fine particles are used into tablets and capsules to provide reliable and stabilized drug delivery drug formulation processes. Fine particles can be used to increase a drug's bioavailability, to allow the drug to have sustained-release properties, or to allow drug delivery via inhalable aerosols or skin patches.

In polymer fields, fine particles are used for coating or encapsulations in drug formulations, food applications, and soft-hard electronic and magnetic materials. In material science fields, inorganic particles are used in semiconductor, sensor, catalyst, abrasive, optics, and electronic applications. In biomedical fields, nanoparticles are used in bio-imaging for studying drug delivery systems, in therapies for cancer treatment via heat treatment (magnetic hyperthermia) and neutron capture.

Fine particles exhibit properties which are drastically different from the bulk. This opens up an area of research that is very challenging scientifically and technologically. Fine particles have been widely used for magnetic recording media, ferro-fluids, catalysts, medical diagnostics, drug delivery systems and pigments in paints and ceramics. Enhanced magnetic properties of fine ferromagnetic or ferrimagnetic particles make them very promising candidates for high density magnetic recording media. A large number of techniques have been used to prepare magnetic fine particles including chemical reduction, hydrothermal, sputtering, SMAD (solvated metallic atom deposition), gas evaporation and aerosol synthesis.

Evaporated fine Fe particles ($\sim 200 \text{ \AA}$) have been reported to have coercivities up to two orders of magnitude higher than bulk Fe and their saturation magnetization varied from 20 – 90% of the bulk value depending on particle size. Particles in their fine form (few 100's of \AA) are pyrophoric and hence require a controlled surface passivation. The magnetic properties of the particles are strongly dependent on the form and constituents of the surface layers which constitute a major volume fraction in ultra-fine particles. Thus a greater understanding and control of the surface layer would result in optimum magnetic properties. The systems we have studied include Fe-B, Fe-Ni-B, Fe-Co-B, and Co-B particles. The magnetic properties of fine particles prepared by chemical reduction have also been found to be different from the bulk. The results on Fe-B particles are discussed below.

Aerosols, which are particles dispersed in a gas, are used in agriculture, forestry, industry and medicine. Scientists also use the aerosol processes to prepare metal oxides, and ceramics. In our aerosol synthesis, often called aerosol spray pyrolysis, aqueous metal salts were sprayed as a fine mist, dried and then passed into a hot flow tube where pyrolysis converted the salts to the final products. In this paper, we will briefly summarize our efforts in the last three years to prepare fine magnetic particles using the techniques of vapor deposition, chemical reduction and aerosol spray pyrolysis. Particle size also greatly affects tableting and granulation processes. On the one hand, small particles aid dissolution, but are also more sensitive to over compression, leading to hard tablets which barely disintegrate.

HOW IS PARTICLE SIZE RELATED TO PHARMACEUTICAL PRODUCT QUALITY?

Likewise, particle size distribution plays a pivotal role in pharmaceutical product quality. Essentially, the finer the particle size the greater the surface area covered. And more surface area coverage means enhanced product quality and performance. Often, jet milling micronization is used to reduce particle sizes for best blending results, but exact grinding methods are aligned with pharmaceutical applications. The final form the pharmaceutical product takes can also partially decide how particle size impacts these factors and overall quality:

1. COMPRESSION

Tablets are formed by the application of pressure. How strong and how long compression cycles last depends directly on particle size and distribution. If there is an imbalance, tablet weight, quality, and dosing can be substandard.

2. DISSOLUTION

Pharmaceutical products such as tablets and time-release capsules are somewhat performance-dependent on their ability to dissolve. Tablets generally need a certain particle size formulation in order to maintain proper shape. Particles that are too small can lead to over-compression and an inability to dissolve. Time-release capsules, too, need precision particle size in order to effectively introduce the product when and as needed, according to the formulation.

3. BIOAVAILABILITY

Ingestible or topical pharma products generally need to be absorbed into the bloodstream or circulatory system to provide the intended dosage. Larger particles can inhibit bioavailability — how much medication and time it takes for a patient to receive appropriate effects.

4. FLOWABILITY

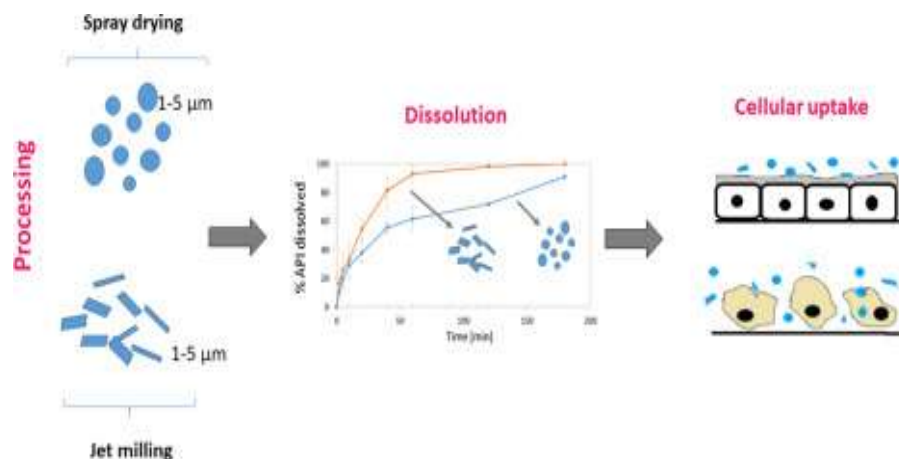
How APIs and excipients move through equipment and within capsules, liquids, etc., is all related to proportional particle size. Ingredient separation is indicative of improper flowability. For example, a liquid formulation with flowability issues may need to be vigorously shaken to partially reintegrate particles. This results in a suboptimal user experience and potential dosing and quality issues.

5. SHELF LIFE

Particle size distribution is particularly impactful when it comes to shelf life. It influences the performance of the APIs, certain production decisions such as filtration and drying rates, and material stability during storage. Maximizing all of these factors adds up to product integrity and duration of effectiveness.

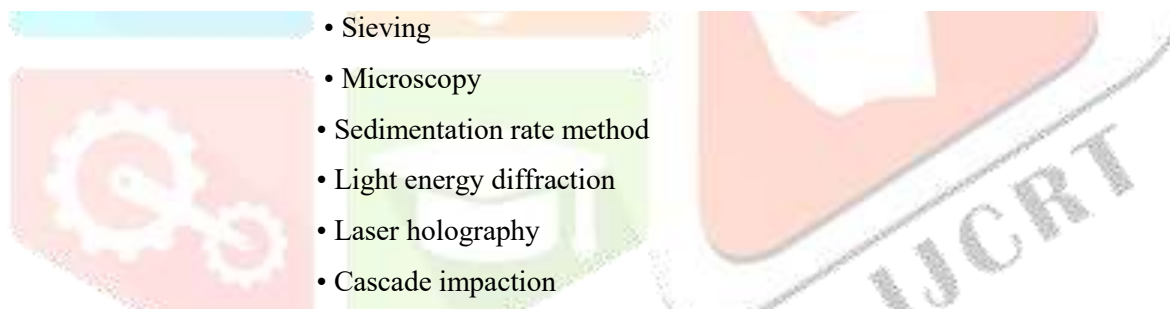
Just as no two pharmaceutical drug formulations are the same, so it is with pharmaceutical ingredient blending. The constant in pharmaceutical blending, however, is the impact of drug stability, visual appeal, and efficacy. Controlling all of these factors to consistently meet industry standards and product quality expectations is the responsibility of your toll processing partner. Their approach to raw materials milling and pharmaceutical blending processes will evidence itself in quality outcomes. Powders are often used as active pharmaceutical ingredients (APIs) and intermediates of

pharmaceuticals. The particle size of APIs and intermediates affects the efficacy of medicines since particle size has an impact on the absorption rate in the gastrointestinal tract after the medicine is taken. It is also important to measure the particle characteristics of raw materials to ensure stable quality production of pharmaceuticals.



(Figure of Particles Shape)

Methods to Determine Particle Size



REFERENCES

1. Cornelia Krüger, Markus Thommes, Peter Kleinebudde, „Spheronization mechanism of MCC II-based pellets“, Powder Technology, 238:176-187, April 2013
2. Grant Heinicke and Joseph B. Schwartz, “Particle Size Distribution of Inert Spheres and Pelletized Pharmaceutical Products by Image”, Pharmaceutical Development and Technology Vol. 9, No. 4, pp. 359-367, 2004
3. Grant Heinicke, Frank Matthews, Joseph B. Schwartz, „The Effects of Substrate Size, Surface Area, and Density on Coat Thickness of Multi-Particulate Dosage Forms”, Pharmaceutical Development and Technology, 1:85-96, 2005

4. Grant Heinicke, Joseph B. Schwartz, “Assessment of Dynamic Image Analysis as a Surrogate Dissolution Test for a Coated Multiparticulate Product”, *Pharmaceutical Development and Technology*, 11:403-408, 2006
5. Carl Moritz Wagner, Miriam Pein, Jörg Breitzkreutz, „Roll compaction of mannitol: Compactability study of crystalline and spray-dried grades”, *International Journal of Pharmaceutics*, 453(2) June 2013.
6. M.E. Fayed and L. Otten, *Handbook of Powder Science & Technology*, 2nd, Chapman & Hall, 1997.
7. A. J. Hlinak, K. Kuriyan, K. R. Morris, G. W. Reklaitis, and P. K. Basu. Understanding critical material properties for solid dosage form design. *Journal of Pharmaceutical Innovation*, vol.1, 2006, pp.12–17.
8. B.Y. Shekunov, P. Chattopadhyay, H.H.Y. Tong, and A.H.L. Chow, Particle Size analysis in *Pharmaceutics: Principles, Methods and Applications*, *Pharmaceutical Research* Vol. 24, No.2, 2006, pp.203-227.
9. S.M. Snorek et al., PQRI Recommendation on Particle Size Analysis of Drug Substances Used in Oral Dosage Forms, *Journal of Pharmaceutical Science*, Vol. 96, No.6, 2007, pp.1451-1467.
10. ICH Guideline Q6A, *Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances*, 2000.
11. H.A.Lieberman, L. Lachman, and J.B. Schwartz, *Pharmaceutical Dosage Forms: Tablets*, 2nd, Marcel Dekker, 1989
12. N.A. Armstrong, *Tablet Manufacture*, *Encyclopedia of Pharmaceutical Technology*, Marcel Dekker, 2002