

How Powder Particles affect a Drug's Success

Only about 10% of drug products that enter human critical trials ever receive approval for further production. Surprisingly, the problem is often not the drug itself but whether it can be turned into a product that behaves properly during manufacturing.

Many medicines are produced as powders that need to pass through various manufacturing steps before they can reach patients. During production, it is important that the powder flows smoothly through equipment, mixes evenly and is stable during storage. If the particles stick together, absorb too much moisture or behave unpredictably, manufacturing can slow down or fail completely. Processability problems like these cost pharmaceutical companies both time and money, which can delay important medicines from reaching patients.

To improve how powders behave, pharmaceutical companies often add substances called excipients. Two common examples are mannitol and lactose monohydrate. These ingredients can help protect sensitive drug compounds and make manufacturing easier and at the same time, they can also change the properties of the powder.

In this project, a model protein called pepsin was mixed with mannitol or lactose monohydrate to change its size, shape and surface structure, all of which had a major impact on processability. To modify the powder, spray drying was used, which is a process where liquid droplets are dried into small particles.

The results from the study showed that spray drying made the powder stickier and more humid, which affected how it flowed and dissolved. Overall, it was the size, shape and surface structure of the particles what had the biggest impact on processability. The powders with mannitol showed the best flow and dissolution compared to those with lactose. Interestingly, even powders that looked very similar still behaved different just because of small changes to their surface structure.

The main conclusion is that there is not a magic recipe to make the perfect pharmaceutical product so instead it's important to carefully choose the process to make the powder, the excipients that are added, the shape of the particles, and other powder properties. By applying these findings to other protein-based medicines, researchers may be able to design drug products that are easier to produce, more stable and quicker to reach the patients who need them.