EFFECT OF POWDER PROPERTIES AND COMPACTION PRESSURE ON PARTICLE SIZE OF ROLL-COMPACTED GRANULATE

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This work deals with the compaction of raw powder materials and crushing produced compacts, that influence properties of produced granules. The study aimed to transfer the process of making granulates via roller compaction to laboratory-scale uniaxial compaction, therefore affording to test the granulation process in smaller scales before being used in industrial production. This would enable the prediction of the dry granulation product properties using a laboratory test.

The experimental study involved two model feed powders. Avicel PH 102 was the first one, having particles of plastic nature. Calcium hydrogen phosphate dihydrate, having brittle particles was chosen as the second alternative. To measure the influence of powder composition on the particle size of granulate, tablets were prepared using mixtures of these model substances. These tablets were then crushed through sieves with various mesh densities to evaluate the effect of mesh density and compaction pressure on the final particle size of the prepared granulate. Results showed that the effect of compaction pressure determining the compact strength was major compared to the effect of mesh density. The increased proportion of plastic components in the compacted mixture improved the firmness of final fragments, making the dry granulation process more effective.

Two parameters were introduced to describe the efficiency of the process: the granulation yield expressing the portion of material which were successfully converted into granules and the aggregation number expressing the particle enlargement in the process. The parameters were used in a case study to evaluate the granulation efficiency of industrial drug formulation and compare it to the plastic and brittle excipient benchmarks. The resulting comparison showed the granulation was highly ineffective in a wide range of pressures. This indicated the compaction efficiency problems for the industrial formulation cannot be alleviated by process parameter change only and the formulation change is required for the process improvement.

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