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DER SAMMLUNG WISSENSCHAFTLICHER ARBEITEN

DIE KUNST DES WISSENSCHAFTLICHE DENKEN

ZU DEN MATERIALIEN DER IV INTERNATIONALEN WISSENSCHAFTLICH-PRAKTISCHEN KONFERENZ

GRUNDLAGEN DER MODERNEN WISSENSCHAFTLICHEN FORSCHUNG

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COMPACTING AS A PROSPECTIVE TECHNOLOGY FOR OPTIMIZATION OF INDUSTRIAL PRODUCTION SOLID DOSAGE FORMS

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In the conditions of high competition in the market for the production of readymade medicinal forms, development of new recipes, pharmaceutical companies have to look for new solutions to optimize the production process, improve quality and reduce the cost of production [1; 2].

One of the possible solutions to this level of pharmaceutical production tasks is the application of powder compaction (dry granulation) technology, which can be an acceptable granulation method for the production of solid dosage forms with active pharmaceutical ingredients (APIs) for which the use of the wet granulation method is due to strong moisture absorption or negative influence dusting of the substance on the quality of the product is impossible.

The main purpose of compaction is to improve the flow characteristics of the powder mixture, avoid granulation-induced moisture degradation, improve product stability, prevent segregation, reduce the bulk volume, which leads to the

minimization of the volume for storage, and therefore increases the efficiency of transportation and reduces the potential danger to the environment [3; 4].

Compaction is the method of choice for processing physically or chemically moisture-sensitive medicinal products because it does not require binding fluids for granulation. With the help of compaction, it is possible to influence the physical properties (granule size, particle distribution, surface shape, bulk density, hardness and surface activity of granules) in such a way that the powder can be subjected to direct pressing [2-4].

Compaction is used to overcome the unfavorable physical properties of the powder mixture: poor fluidity, low bulk density, inhomogeneity after mixing, separation of powder mixtures by optimizing process parameters, choice of fillers. Compaction on rolls ensures reduction or increase in particle size with the formation of granules. The process of compaction on rolls significantly affects the distribution of particles by size, fluidity, homogeneity, compressibility, compaction of active pharmaceutical ingredients and auxiliary substances, and therefore can affect the dissolution of solid dosage forms. For tablets, affect the time of disintegration, resistance to crushing, wear ability and other technological parameters [3; 4].

Compared to the original powder, the granulate after compaction is characterized by significantly better fluidity and higher density due to the reduction in volume. This ensures the accuracy of dosage, reduction of health hazards for personnel, by reducing the formation of dust in the workplace, increasing the duration of use of the tablet machine due to the reduction of dust formation, positive effect on dispersion, solubility, uniform distribution [4].

In terms of process optimization and pharma engineering benefits, compaction is an extremely cost-effective granulation technology that does not require the installation of bulky and expensive equipment such as a high shear mixer or fluidized bed drying. Working with an intermediate product in the form of a powder has certain complications – increased dusting in the production area, which carries risks for personnel, product and equipment. Separate problems are the protection of personnel and cross-contamination, as well as the influence of the choice of the type of semi-finished product (powder or granulate) on the reliability of the technological equipment.

Compared to the use of granulate, sachet machines work with powder at a reduced speed (at lower productivity), an unstable weight of the final product is observed. In addition, the risk of damage to the equipment due to the impact of finely dispersed powder particles on the moving parts of the machines increases significantly, which is especially critical for expensive press tools and moving parts of screw dispensers. The most frequent problems in the operation of powder equipment are jamming and jamming of the press tool and auger, incorrect operation of the orientation unit, lack of sealing of the sachet. The use of a compactor in the technological scheme solves all the above-mentioned problems. The product after the compactor can be sent directly to the packaging machine in the case of making sachets, or to the encapsulation stage to obtain capsules; to the stage of tableting – in the case of tablet production.

In cases where both methods of granulation, both dry and wet, are acceptable for API, it has been technologically proven that compacting is technically simpler and much more cost-effective.

Compaction technology is widely used for products containing: hygroscopic materials; thermolabile materials; active substances that decompose in water; substances that have an acceptable fluidity, without the need to bind the particles

with a solution. In order for the powder to be granulated using a compactor, it must have the properties of internal sealing, the ability to bind particles together. The concentration of dry binders affects the necessary compaction of the compressive force, which in turn determines the maximum possible productivity for obtaining granulate of a given quality.

Therefore, the following tasks are solved with the use of compaction: dust reduction; improvement of supply and dosing of the product; increasing the homogeneity of the distribution of the active component of the mixture; increasing the density of powders with initially low density; increase in particle size, fluidity of the mixture; increasing the productivity of tablet presses; reducing the risk of equipment breakdown; reduction of granulation costs. To optimize the technological process in the conditions of continuous production – a flexible range of batch size due to the continuity of the process.

The design of experimental studies of the pharmaceutical development of solid dosage forms using compaction technology includes the logic and sequence of scientific research according to DoE [5], the use of methods for researching technological indicators of API, model mass for sachets, capsules, tablet mass, as well as comparative studies with the choice of an alternative dry compaction technology.

In order to optimize and ensure the quality of the technological process, to confirm the optimal choice of industrial dry granulation (compaction) technology for the production of sachets, capsules, tablets in the conditions of modern pharmaceutical production, it is necessary to substantiate the qualitative and quantitative indicators of the pharmaceutical product for the design of pharmaco-technological parameters.

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