INNOVATIVE APPROACHES TO THE CREATION OF MODERN PHARMACEUTICAL PRODUCTION OF PHARMACEUTICAL FORMS

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Successful project management of an industrial pharmaceutical company is based on innovative engineering approaches to creating modern pharmaceutical production.

Solving the problem of improving the organization of modern pharmaceutical production in terms of innovative development of new pharmaceuticals requires new methodological and organizational approaches [1 - 5].

The main principle of pharmaceutical development of a generic drug - through the properties of the active substance, selection of functional ingredients, process engineering - to model and verify the biopharmaceutical profile of the drug.

To improve technologies, optimize production and modernize process schemes are: modeling and optimization of production schedules; increasing the shelf life of bulk tablet forms; enlargement of the sizes of series; intensification of parameters of separate technological stages and cycles; alternative methods of obtaining mass tablets; relocation of technologies to other existing schemes; additional equipment; point modernization of work centers; by increasing project and design decision and solving bottleneck to detect hidden extra capacity.

Conceptual example of continuous production: the product flows between each stage; the product is analyzed at the stages of the process; the process is adjusted on the basis of measured indicators; the total duration of the cycle from minutes to hours.

The advantages of the introduction of continuous production are: to reduce the size of technological premises by ~ 70%; reduce the cost of construction of new facilities ~ 30%; reduce the time required to create new capacity ~ 33%; reduce production costs ~ 50%; reduce the duration of the process; ensure product quality in real time; significantly reduce development efforts; reduction of API consumption in the process of pharmaceutical development ~ 80%; screening of process parameters; automation of experiments; minimization of scaling; reducing the overall duration of pharmaceutical development.

The results of the study of the conversion of discrete technology for solid dosage forms into continuous: of the 16 pharmaceutical compositions obtained by wet granulation in the transition to continuous production, 8 products were fully consistent in pharmaco-technological, analytical parameters and release kinetics of the tablet obtained by traditional technology.
The main tactical and technical characteristics of the implemented continuous production are: implementation period of 24 months; design capacity of 1.5 billion doses units per year; successful transfer and scaling of 20 pharmaceutical products; in the short term transfer and introduction of 20 more pharmaceutical products; GMP certification.

Thus, the realized continuous production has engineering and technological advantages for the industrial production of solid dosage forms.

First, it is a number of innovative solutions in technological equipment that have no precedent for implementation in our country.

Secondly, it is the exceptional performance of the technological scheme. So the size of the series reaches 500 kilograms and above, which can be 2 million dosage forms; for example, from under the rotor of a new tablet press can come more than 200 tablets per second.

The main tactical and technical characteristics of the implemented continuous production are: implementation period of 24 months; design capacity of 1.5 billion doses. units per year; successful transfer and scaling of 20 pharmaceutical products; in the short term transfer and introduction of 20 more pharmaceutical products; And thirdly, the commissioning of the new site formalizes the existing on JSC Farmak the size of technological schemes for solid dosage forms in a complete line with a series size from the experimental few hundred grams – to full-scale hundreds of kilograms; and the existing industrial areas for the production of solid dosage forms – combines into a single production and economic complex, which receives even greater benefits through the vertical integration of the company, which allows the use of a number of active pharmaceutical substances of its own synthesis.

Finally, the industry quality standards implemented in our company at a consistently high level and allow the successful passage of numerous international inspections and audits of customers, will be fully implemented in the new production.

Prospects for maximizing the technological potential of the implemented project of continuous production are: introduction of elements of process analysis technology (PAT); in-house bar coding system; transition to the electronic dossier of series production; further transfer and scaling of technologies of products of current production; launch of a new high-performance sacheting line; introduction of new drugs and technologies: sparingly soluble API, prolonged release and fixed combinations based on matrix tablets; development of export markets; localization of licensed technologies; purposeful reduction of total production costs.

Reference: