# IMPORTANCE OF STUDY INFLUENCE EXCIPIENTS AND PROCESS PARAMETERS ON QUALITY CHARACTERISTIC DRUGS

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Study influence of excipients and process parameters on the quality of new or generic solid dosage forms during the conduct of pharmaceutical development and scale up process is very important for pharmaceutical companies. Particularly noteworthy are the drugs that are in its composition containing bed soluble substance, because of technology and their production significantly affect the ability to release the active substance in the body and consequently their bioavailability. Impact assessment excipients and process parameters on the pharmacological efficacy of drugs that contains in its composition bed soluble medicinal substance, most appropriate to carry out tests "Disintegration", "Dissolution" and comparative studies of the kinetics of dissolution in vitro, in which possibly track the release of substances in the environment close to the physiological and for their optimal dissolution choose appropriate excipients and production technology.

The aim of our research is to study the impact of excipients and parameters production process on quality characteristic solid dosage forms that in its composition containing bed soluble substance. The objects of study are generic and original drugs:

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- «Boryzol" and "Rilutek" tablets, film coated shell that contains in its composition 50 mg of drug substance ryluzol;
- «Nimodipine" and "Nimotop" tablets, film coated shell that contains in its composition 30 mg of drug substance nimodipine.

Because of the low solubility of the substances ryluzol and nimodipine problem creating acceptable dosage form that characterized by the need to improve

the solubility of active pharmaceutical substances and their stable uniform distribution in each tablet. Usually, increasing the solubility of these substances is achieved by adding appropriate excipients of the drugs or using technological methods of physical modifications substances.

During the pharmaceutical development of generic drugs "Boryzol" and "Nimodipine" studies on the effect of excipients and process parameters on quality tablets:

- influence of excipients on the solubility of substances ryluzol and nimodipine tablets of drugs was researched;
- influence of various technological methods of physical modification substances ryluzol and nimodipine on dissolution from solid dosage forms was researched;
- influence of excipients on pharmaco-technological properties powders and tablets was researched;
- influence of process parameters on dissolution of the substances ryluzol and nimodipine from tablets was researched.

The resulting enhanced scientific data make it possible to determine the effect of excipients and process parameters on the quality of generic drugs "Boryzol" and "Nimodipine "controlled during their industrial production, and is the key issue highly efficient pharmaceutical industry generic drugs.

Implementation of advanced scientific research at the stage of pharmaceutical development and in the process of scaling the technology of production of drugs in order to understand the product and process of its manufacture tion recommended requirements of ICH Q8 and Q10 for pharmacists, chnymy companies release highly efficient drugs for a period of the whole of their life cycle.