

P 4. IMPROVEMENT OF DRUG PRODUCTION PROCESSES: EFFECT OF ACTIVE SUBSTANCE PARTICLE SIZE DISTRIBUTION ON THE PRODUCT DISSOLUTION RATE

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ABSTRACT: One of the most prominent features of our age is the effects of strong changes that affect almost everything. So, the companies should adapt to their environment and obtain competitive advantages by renewing at the required levels, improving their processes and offering the products with high quality level at the optimum cost [1]. When the critical parameters in the processes are taken under control, it is known that the inefficient processes are reduced by rejection of inappropriate products and limitation of waste in the companies [2]. When the factors affecting the solubility and dissolution rate of molecules are listed, it has been reported that organic molecules with higher molecular size have less solubility in water than small molecules. And also, the solubility of the molecules generally reduces with increasing molecular weight [3]. In this study, a nonsterile solid form finished product including active substance named “moxifloxacin” was used and tested. The effects of particle size of the active substance on the quality of a film tablet form product including moxifloxacin were investigated. The data as shown in Table 1 were statistically analyzed and supported by case studies. As a result, optimum particle size distribution for product dissolution rate in the drug production process was determined.

Table 1. Optimum particle size distribution for moxifloxacin

Sieve analysis (Process optimization)	100 g	Sieve size (μm)	Amount remaining on the sieve (%)
		710 μm	0.3 – 4.0
		250 μm	20.0 – 40.0
		106 μm	30.0 – 55.0
		25 μm	20.0 – 30.0
		<25 μm	0

Keywords: Particle size distribution, high quality production in the pharmaceutical industry, continuous improvement, critical process control parameters

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