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Employing design of experiment approach in the optimization of a generic drug product formula in reaction with the similarity index of dissolution profile for the drug product innovator

Ahmed Rakha
Penta Pharma Egypt, Egypt

Design of experiment (DOE) concept was conducted thoroughly during the optimization of drug formula (using half factorial 2^3 design). An investigation matrix of active substances including Paracetamol, PhseudoePh.D.rine and Pholcodine with a concentration of 500 mg/cap, 30 mg/cap and 5 mg/cap respectively was mixed with three excipients which affect dissolution profile of the drug. Factors of this experiment comprises different concentrations specified for three excipient coded as A, B & C, these concentration were changed systematically to determine the optimum concentration for each excipient to define the optimum dissolution profile matches the innovator's drug product profile. The dissolution test is preformed according to matrix design between different pH media 2, 4.5, 6.8 and different time intervals 10, 20, 30 minutes, then the dissolved amount of each active substances are calculated in reference to the predefined matrix design. Innovator dissolution is the reference result which is compared with experiments response. Accordingly, using design of experiment approach provides the researcher with the ability to study the effect of each excipient concentration and their interactions. The most similar dissolution profile of generic drug product to the innovator product concluded the excipients ratios in the generic drug formula as A, B and C are 16.3 mg/cap, 2.8 mg/cap and 5.6 mg/cap respectively.

Biography

Ahmed Rakha is working from about 7 years in pharmaceutical industry field. He worked in Production department and Research and development department. He participated in development of many drug products. He completed his Master degree in quality management with thesis title "Quality by design in pharmaceutical field"

ahmed.rakha@pentapharma.com