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THAPA, RUBINA: Comparison of Particle Sizing Methodologies in Non-clinical suspensions
Master's thesis, 82 pages
Pharmacology, Drug Development and Therapeutics
May 2017

Non-clinical suspensions can be prepared by several methods. Manual preparation of the suspension by mortar and pestle is one of the most commonly used methods. However, the force applied with the pestle may vary, which might cause variations in particle size distribution (PSD) between suspension batches. The main aim is to compare mortar and pestle, ultraturrax, ultrasonicator (using degas function) and ultrasonicator (using sweep function) on the basis of repeatability and homogeneity of the PSD in different suspension batches. Suspensions were prepared using Itraconazole and two discovery compounds of Orion pharma i.e. Compound A and Compound B as the test compounds. The suspensions were prepared at two concentration levels (1 mg/ml and 10 mg/ml) and in two different batch sizes (5 ml and 50 ml). PSD was analyzed by laser diffraction technique and additionally confirmed by optical microscopy.

Any of the used methods did not bring any drastic change in the quality (with respect to PSD range or variation in PSD) of Itraconazole suspensions or Compound A suspensions. For compound B, mortar and pestle produced repeatable and homogenous suspensions irrespective of the concentration and batch size. Ultraturrax produced repeatable suspensions only in 5 ml batch size suspensions of Compound B. Ultrasonicator (in case of both degas function or sweep function) produced repeatable and homogenous suspensions only in those suspensions that were in combination of high concentration and high volume i.e. 10 mg/ml in 50 ml batch. From the overall result, mortar and pestle was found to be the most versatile method for homogeneous suspension preparation.

Keywords: Mortar and Pestle, Ultraturrax, Ultrasonicator, Particle size distribution.