In vitro characterization of model drugs (Aspirin and Candesartan Clexetile): Comparison between simulated physiologic conditions and pharmacopeial requirements

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Abstract

Quality control (QC) tests are set of routine analysis tests to guarantee the release of finished products. QC tests are designed by experienced professional teams. Typically, minor details were not clarified completely.

Herein, the effect of matrix were investigated for acetyl salicylic acid (ASA) for detection of maximum wavelength (λ) and absorptivity

(ε). Furthermore, the effect of physiological conditions on dissolution rate of candesartan cilexetil (CC) were investigated and compared against compendial tests. Two commercial brands were used in order to confirm the results.

Results showed definite effect of selecting solvent to detect λ and ε. For example, when ethanol (EOH) was used to dissolve ASA, ε was found to be 3.15 while it was 18.50 when NaOH was employed as solvent. Furthermore, the effect of fed and fasted pH was not significant on dissolution rate where both brands met the compendial requirement.

Moreover, the effect of variable physiological conditions such as viscosity, surface tension and pH affected dissolution rate of CC in both commercial products. In all cases dissolution rate in simulated physiological conditions were significantly slower than official USP conditions

The obtained results recommend that all specifications should be mentioned in order to compute accurately the required parameters. Furthermore, there has to be correlation between in vitro dissolution and in vivo absorption to ensure patient safety when following pharmacists' consultation.