

The development and validation of dissolution method for donepezil tablet

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Background and Aims: Dissolution testing has emerged in the pharmaceutical field as a very important tool to characterize drug product performance. Donepezil is an acetylcholinesterase inhibitor used in Alzheimer's disease therapy. The neuroprotective effect of donepezil has been demonstrated in a number of different models of neurodegeneration including beta-amyloid toxicity. Donepezil HCl as a frequently used in Alzheimer's disease therapy has no dissolution method in its monograph in BP or USP. The main goal of this study was to develop a validated method of dissolution for donepezil tablet as an important quality control tool.

Methods: In vitro dissolution tests of tablets of donepezil were performed by various methods using different test conditions but always under "sink" conditions. Dissolution studies on three commercially available tablets of donepezil HCl were conducted using USP Apparatus 1 and 2. The dissolution medium was 500-1000 mL of either hydrochloric acid aqueous solution, or pH 6.8 phosphate buffer at 37 ± 0.5 °C and stirred at 50 -100 rpm. Samples were assayed by a simple spectrophotometric method and dissolution profiles were compared to a reference product (Yasnal® or Aricept®) by similarity (F1) or dissimilarity (F2) equations.

Results: Dissolution of almost all forms was complete at 45 minutes. A method using HCl as the dissolution medium in USP Apparatus 2 and stirring speed of 75 rpm, for all products could reliably discriminate among different products, if they are truly different. With these conditions, more than 80% of the label amount is released over 30 minutes.

Conclusions: Dissolution method as a very important invitro test of drug products for donepezil in a reliable condition and validated time and percent of dissolved material was developed.

Keywords: Donepezil HCl; Dissolution; F test; Yasnal; Aricept