

6<sup>th</sup> International Conference on

# Biomarkers & Clinical Research

August 31-September 02, 2015 Toronto, Canada

## Development and validation of dissolution method of tolperisone hydrochloride and its *in vitro* dissolution comparison study

**Chetnaben Y Patel**

L.M. College of Pharmacy, India

The aim of this work is to develop and validate a dissolution method for 150 mg Tolperisone hydrochloride film coated tablets using a UV spectroscopic method. Tolperisone HCl, frequently used as centrally muscle relaxants, has no dissolution method in its monograph in Japanese pharmacopeia. After test sink conditions, dissolution medium, the best conditions were: Basket apparatus at 75 rotations per minute (rpm) stirring speed, 0.1 N HCl as dissolution medium volume of 900 ml. The quantitation method was also adapted and validated. More than 95% dissolution was achieved over 30 min in the basic one. The dissolution profile of three marketed brands of Tolperisone HCl 150mg tablets have been evaluated using dissolution test in 0.1N HCl media with the aim to assess bioequivalence. The dissolution test developed was adequate for its purpose and could be applied for quality control of Tolperisone hydrochloride tablets. The *in vitro* release profiles of various tests were compared for their similarity using model dependent and model independent methods. Results of this test indicate that in most cases dissolution profiles of the different marketed brands were significantly different from each other. The objective of this study was to assess the interchange ability of the available Tolperisone HCl products on the basis of their *in vitro* dissolution characteristics using USP Apparatus2 (Basket type).

[chetnaben\\_patel@yahoo.com](mailto:chetnaben_patel@yahoo.com)

Notes: