CHAPTER 3

OBJECTIVES
3.0 OBJECTIVES

Generic drugs are promoted to reduce the health care budget. Some countries do not have effective means of monitoring the quality of generic drugs in the market. Some small scale industries and even some large scale industries were non compliant to GMP, GLP and GCP procedures resulting in substandard quality of generic product in the market and moreover information about generic to generic drug interchangeability are unavailable to public.

The patient is unaware of the drug interchangeability and the physician/pharmacist is also unaware about the drug interchangeability; whether it is safe or not. The scope for appropriate drug therapy with reasonable health budget within the generic drug use is lost.

Therefore, this study was focused on drug interchangeability between three generic formulations available in the market which ultimately would help to achieve the goal of therapy in generic drug substitution with reasonable health care budget.

Hence the objectives were:

A. Primary Objective

1. To compare the single dose oral bioavailability, to determine the bioequivalence of three marketed generic Gabapentin 300 mg immediate release oral capsule formulations.

B. Secondary objective

2. In-vitro dissolution testing of three marketed generic products of Gabapentin 300 mg immediate release oral capsule formulations as per applicable pharmacopoeial standards.

3. To determine the drug interchangeability between three generic formulations based on bioequivalence status and dissolution properties.