Chapter Two: Materials and Methods

A single dose parallel clinical trial was carried out in 6 healthy subjects to investigate the effect of glucosamine on the pharmacokinetic parameters of diacerein. Copies of study protocol, a sample of case report form (CRF), informed consent form, and subject information leaflet, were submitted to the Independent Ethics Committee (IEC) at AI Mowasah hospital responsible for conducting studies on human subjects were reviewed and approved, consequently written informed consent was obtained from all volunteers. Initiation of the study took place at Al Mowasah Hospital for the clinical part and Jordan Center for Pharmaceutical Research for the Laboratory analysis part. The study was conducted in compliance with ICH Good Clinical Practices guidelines and according to the ethical doctrines of the Declaration of Helsinki in Helsinki 1964 and amended in Scotland, 2000; updated in Washington 2002, note added in Tokyo 2004; General Assembly, Seoul, October 2008. Laboratory analysis was conducted in compliance with Good Laboratory Practices guidelines.

Subjects Selection

The criteria on which the 6 healthy subjects were chosen are:

1. Inclusion criteria:
    - Age between 18 and 50 years.
    - Physically and mentally healthy as judged by means of a medical and standard laboratory examination.