

- c. Acetonitrile HPLC grade (Chromanorm).
- d. Phosphoric acid 85% (GPR Rectapur).
- e. Deionized water (Chromanorm).
- f. Human plasma (harvested from donors).
- g. Triethylamine (ACROS).

Methods

1. General Study Procedure

Prior to screening procedures, each subject received a copy of the informed consent form (ICF), available in both English and Arabic. Later, the clinical investigator read the information to all subjects explaining orally the nature, scope and possible consequences of the clinical study in a form comprehensible to the subjects. Each subject gave his consent to participate in the study by signing the ICF. The consent was certified by the signatures of the investigator as well as an independent witness.

Screening examination was performed upon acquiring the subjects' consent. These included physical and laboratory tests such as ECG, vital signs, and laboratory screening tests (blood hematology, blood chemistry, serology and urinalysis).

Vital signs were also measured before and after drug administration at 2, 4, 6, 8, 10 and 12 hours.

Adverse events were questioned before and after drug administration at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 hours.