

- Treatment with drugs known to alter the major metabolic systems such as barbiturates, phenothiazines, cimetidine, omeprazole, rifampicin and phenytoin etc. within the last 30 days.
- Major surgery of the gastrointestinal tract except for appendectomy.
- Donation of blood or plasma within the last two months.
- Supine blood pressure, after resting for 5 min, higher than 140 /90 or lower than 90/60 mmHg.
- Supine pulse, after resting for 5 min, outside the range of 60-90 beats/min.
- Body temperature higher than 37.7 °C or lower than 36.4 °C.
- Smoking more than 10 cigarettes or equivalent per day.
- Consumption of more than 4 cups of coffee or equivalent per day or 24 hours before dosing and through hospitalization period.
- Persistent diarrhea (>3 stools/24 hours) or use of laxatives.
- Vegetarian.
- Known to have a Hepatitis B, C and HIV infection or carrier of the respective antigens (HBs Ag, positive).
- Evidence of an uncooperative attitude.
- Alcohol Abuse i.e. consumption of more than 10 units of alcohol per week or a history of alcoholism or drug/chemical abuse.
- Legal incapacity and /or other circumstances rendering the subject unable to understand the nature, scope and possible consequences of the study.
- Vigorous exercise was undertaken beginning 2 days before the initial screening laboratory test until after the follow-up laboratory safety tests.