Comparative Pharmacodynamics and Pharmacodynamics Equivalence of Antareit 800 mg/10 ml Oral Suspension and Riopan 800 mg Chewable Tablets in Healthy Volunteers

NCT06098742

Status	RECRUITING
Phase	Not Applicable
Sponsor	Valenta Pharm JSC
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (17)

- Voluntary and handwritten informed consent form signed by a healthy volunteer to participate in the study prior to any of the study procedures;
- Healthy male and female caucasian volunteers aged 18 to 45 years (inclusive);
- Verified diagnosis "healthy" (without abnormal findings in the protocol-defined clinical, laboratory, and instrumental test data);
- pH according to hourly pH-metry in the screening period, carried out at least 3 hours after the last meal, is completely in the range from 1 to 3 inclusive throughout the entire astronomical hour of measurement;
- Blood pressure (BP) levels: 100 to 139 mm Hg, inclusive (systolic, SBP), 60 to 89 mm Hg, inclusive (diastolic, DBP);

... and 12 more (see full listing online)

Exclusion (31)

- A history of allergy;
- History of drug intolerance to the active and/or excipients included in the study drugs;
- History of drug intolerance of or hypersensitivity/allergic reactions to lidocaine, xylocaine or other topical anesthetics which will be used at the trial site for anesthesia during esophagogastroduodenoscopy (EGD) and insertion of the probe for the pH measurements;
- Chronic diseases of the circulatory, lymphatic, respiratory, nervous, endocrine, gastrointestinal, musculoskeletal, integumentary, immune, urogenital, and hematopoietic systems;
- Esophageal, gastric, and/or duodenal diseases based on EGC performed at screening and based on the medical history; a history of esophageal, gastric, and/or duodenal surgery;

... and 26 more (see full listing online)

Locations (2 total)

Llc "Certa Clinic", Moscow, Russia
Limited Liability Company "Research Center Eco-Safety", Saint Petersburg, Russia