

# SOTALOL VALIDATION TELEMETRY STUDY

**Reference Compound:** Sotalol, known to prolong the QT interval.

**Study Design:** A total of 4 male animals were used, each of which had previously been implanted with telemetry transmitter devices. The study consisted of four different sessions. In each experimental session, all animals received the same treatment using an escalating dose approach. Each animal was orally administered with the Control (size 0 gelatine capsules loaded with lactose monohydrate) and the test item (SOTAPOR® 80 mg (Sotalol)) at doses of 3, 10 and 30 mg/kg on days 1, 4, 11 and 18, respectively. The interval between the days of treatment was chosen to allow adequate washout periods between treatments (at least 5 half-lives).

**Data acquisition by telemetry for 24-hours:**

Arterial blood pressure and Heart rate	
SBP (mmHg)	Systolic blood pressure
DBP (mmHg)	Diastolic blood pressure
MAP (mmHg)	Mean arterial pressure
HR (bpm)	Heart rate, derived from blood pressure
Lead II Electrocardiogram (ECG)	
RP interval (ms)	
PR interval (ms)	
QRS duration (ms)	
Uncorrected QT interval (ms)	
QT correct for heart rate using	
-QTcB [Bazett's]	
-QTcf [Fredericia]	

## Results:

Oral administration of Sotalol doses at 3, 10 and 30mg/kg to male Beagle Dogs caused a dose-related prolongation of the QT interval 1h after administration.

