

B'SYS is ready for the new ICH recommendations

Assay conditions:

- o recordings at near-physiological temperatures (35 to 37°C)
- o CiPA voltage protocol at a physiological relevant frequency
- O Application of specific blocker (1 μM E-4031) at end of each experiment
- Available under GLP standard

Data / Reporting:

- Current inhibition for each cell and concentration reported
- o IC_{50} in (μM and mg/mL) and Hill coefficient determined if applicable
- Raw data provided to the customer (compliant with FDA requested format)

• Dose formulation analysis:

Same day analysis of dose formulations, without any freeze thaw cycle

<u>Positive and negative controls:</u>

- Two concentrations of the GLP-validated positive control Verapamil
- Appropriate vehicle controls (time-matched) included in experiments

• Reference compounds:

o Library of more than 10 reference compounds available



