

The PK study for systemic safety



Bioequivalence study for substances with oral availability

If substance has negligible oral availability –BE with or without charcoal may be used to support efficacy plus safety, cut-off not given (<5%?)

- Healthy volunteers OK if FPD is not flow dependent
- Full curve blood sampling, many time points initially to catch Cmax
- Optimal strength chosen, based on DD for safety (F>5%), FPD otherwise?
- Representative batches of test and reference chosen
- Key parameters: Cmax, AUC_{0-t}

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May equivalence *in vitro* related to orally available particles support safety?

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