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In vitro **ADME & PK**

Chemical Stability Assessment

Background Information

'At the drug discovery stage when drug candidates are screened against biological targets, compounds need to have sufficient stability in the assay buffers for enzyme, receptor, or cell-based assays to reliably measure biological activity.'

[1]Di L, Kerns E.H., Chen H, and Petusky SL. (2006) *J Biomol Screen*; **11(1)** 40-47.

- A compound is chemically unstable when it is degraded by non-enzymatic processes. Degradation may be caused by several mechanisms, the most common being hydrolysis, oxidation, or light-catalysed degradation.
- Compounds that are highly unstable may not be suitable as drug candidates since it may be difficult to maintain a therapeutically effective formulation.
- Compounds designed for oral administration must be chemically stable at the low pH values observed in the stomach in order for this to be an acceptable route. A range of different pH values are available.
- Cyprotex's Chemical Stability assay assesses degradation of the test article in buffer. The chemical stability assay can be performed using a range of different media including SGF (simulated gastric fluid), SIF (simulated intestinal fluid) or buffers at different pH values.

Protocol

Test Article Concentration
5 µM (different concentrations available)

Time Points
0, 15, 30, 60, 120 min

Number of Replicates
2

Test Article Requirements
50 µL of 10 mM solution

Analysis Method
LC-MS/MS

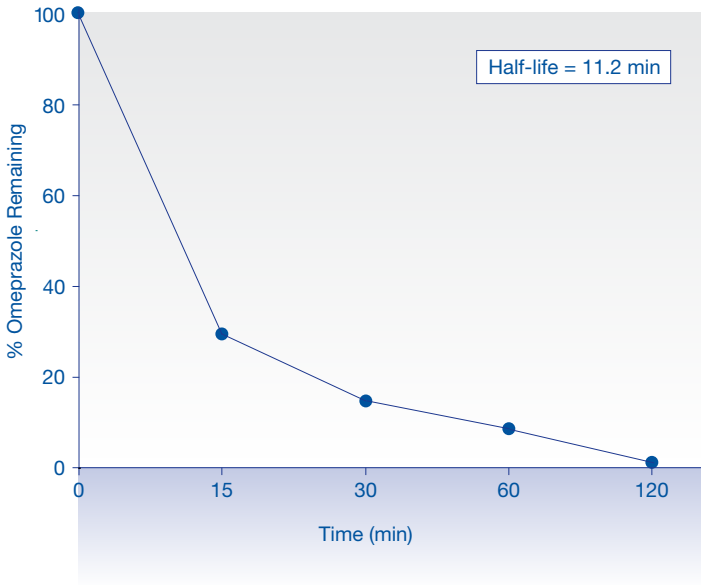
Data Delivery
% Parent compound remaining at each time point
Half Life

To find out more contact **enquiries@cyprotex.com**

Oral administration is the route of choice for new drugs. Compounds must be chemically stable at the low pH values observed in the stomach in order for this to be an acceptable route.

Figure 1

Degradation of omeprazole over 120 min in simulated gastric fluid.



References

[1] Di L *et al*. (2006) *J Biomol Screen* **11(1)**; 40-47.