Pharmacokinetics of Novel Oral PTH 1-34 Dosage Form (Tablet) in Rodents
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Methods
Experiments were conducted in S.D. rats with an average weight of 250 gr. Animals were administered either a s.c. injection of the commercially available human PTH1-34 (2.5 µg per rat) or a synthetic human PTH1-34 mini tablet (200 µg per rat) administered orally. Blood samples were withdrawn at regular intervals for PK analysis using the immutopics High Sensitivity Human PTH-34 ELISA Kit.

Results
Following an injection of Human PTH1-34 a typical absorption profile was achieved, consisting of a sharp increase in serum PTH levels followed by a somewhat slower decrease back to base line levels. When the same rat was dosed with an oral formulation of human PTH1-34 using EnteraBio’s novel drug delivery technology a similar profile was obtained with a slight delay.

Conclusions
PTH1-34 administered orally in rodents demonstrates consistent enteral absorption with a PK profile characterized by a rapid Tmax and rapid elimination to optimally simulate the desired PTH profile required for its anabolic effect. Our first non-optimized formulation of oral PTH1-34 shows that with 200 µg per rat we can achieve exposure levels exceeding those of injectable PTH1-34 at 2.5 µg per rat, albeit with some variability in overall bioavailability. Oral drug absorption in general, has inherent greater variability in absorption compared to parenteral administration. The main causes of such variability is the different feeding patterns, food effect, stomach emptying and transit time in the GIT.

References
3. http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021318s015lbl.pdf. reference to the optimal kinetics of oral PTH (Forteo)