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Ileum Delivery of Budesonide by 3D Micro-structure Design for the Treatment of IgA Nephropathy

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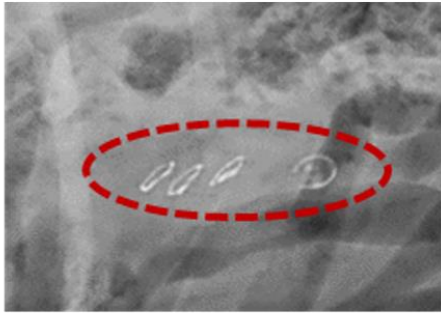
Objectives : 1. To achieve precisely delivery of Budesonide to ileum for immediate release 2. To reduce the in-vivo variability (Tlag and Tmax) of Budesonide compared with Nefecon 3. To reduce product size and dosage to improve patient adherence

Methods : 1. Using Triastek's 3D micro-structure design platforms and melt extrusion deposition (MED) technology for tablet design and product development and achieve precise delivery of Budesonide to ileum and modulate B-cell numbers and activity. 2. Compared with Nefecon, the tablet size is reduced/the dose is increased by increasing the drug loading 3. Tracking agents was 3D printed in the tablets for x-ray imaging during in-vivo study and tracking of the tablet GI transition and Budesonide release.

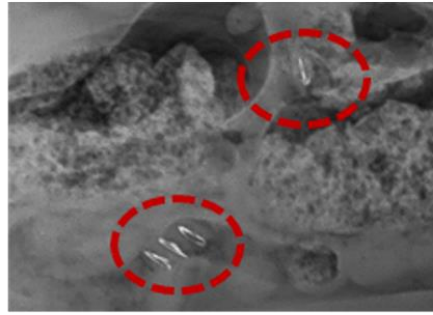
Results : 1. A delayed release tablet was developed using 3D micro structure design and MED 3D printing technology. 2. X-ray images captured in dog PK study demonstrated that 3D printed Budesonide delayed release tablets can deliver and release Budesonide in the distal small intestine. 3. Dog PK study results demonstrated that 3D printed Budesonide delayed release tablets reduced the in-vivo variability of release and absorption of Budesonide when compared with Nefecon.

Conclusions : 1. MED 3D printing technology and 3D microstructure can be used to develop products with desired release profile and deliver API to targeted GI location. 2. 3D printed Budesonide delayed release tablets achieved more precise delivery of Budesonide to the lower small intestine area and reduced in-vivo variability.

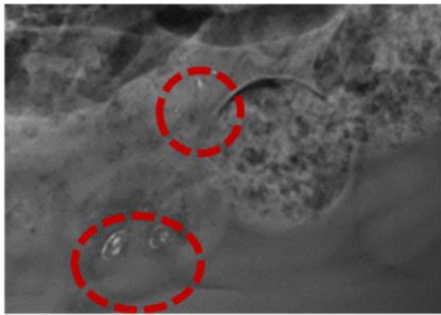
Figure 2. X - r a y I m a g e s .png



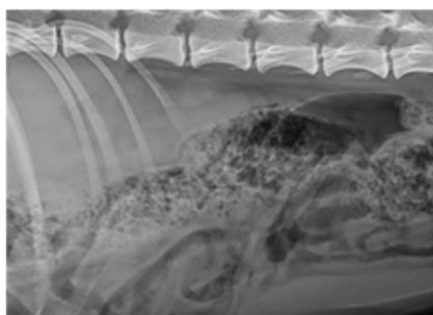
1h (4 duodenum)



2h (3 jejunum + 1 ileum)



3h (3 ileum + 1 released)



4h (all released)

Figure 2. X-ray Images.png

