3D Printed Ileum Targeted Tablet for the Treatment of IgA Nephropathy

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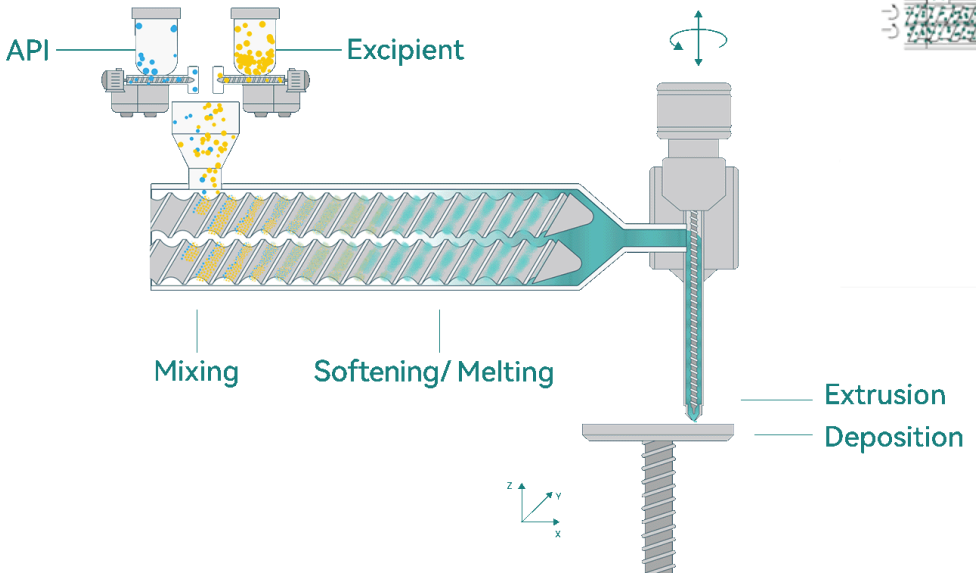
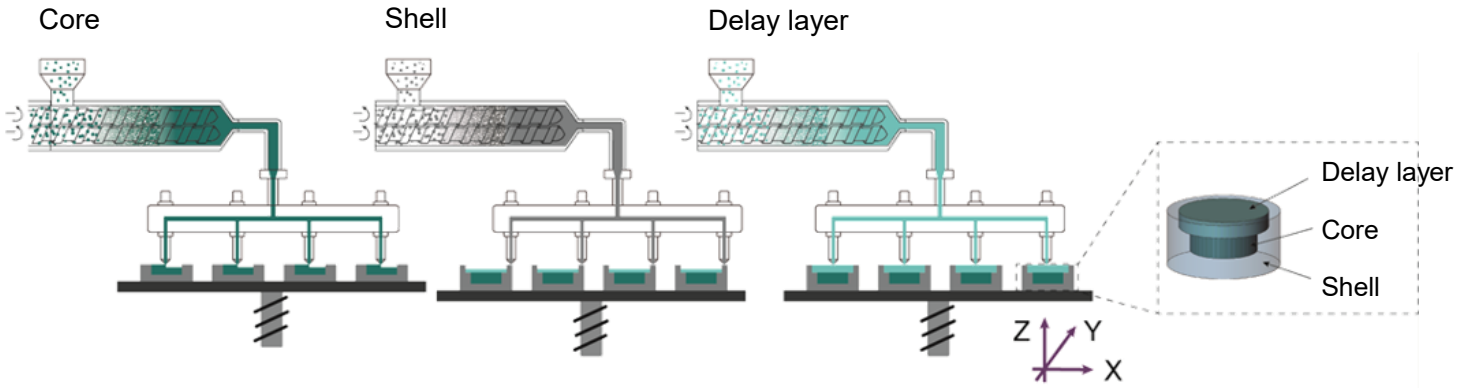
NEXT-GENERATION DELIVERY INNOVATIONS

MED® 3D Printing Technology

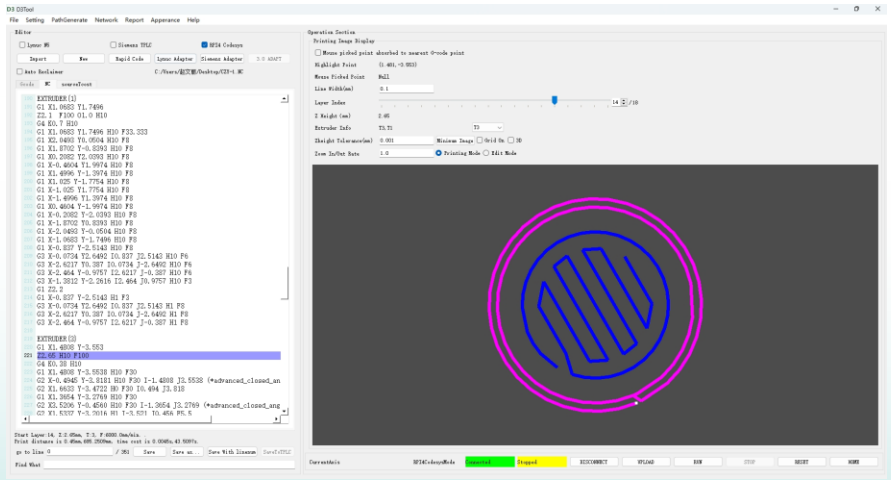
Melt Extrusion Deposition (MED®) 3D printing is a technology that continuously converts powder feedstocks into softened/molten states followed by precise layer-by-layer deposition to produce objects with well-designed geometric structures.





- NOT rely on filament
- NO post-printing process needed
- MED® array design enables mass production using multiple materials to fabricate complex structure

From R&D to Mass Production



The R&D process and manufacturing process share the same 3D printing code

3D Printing Code Transfer

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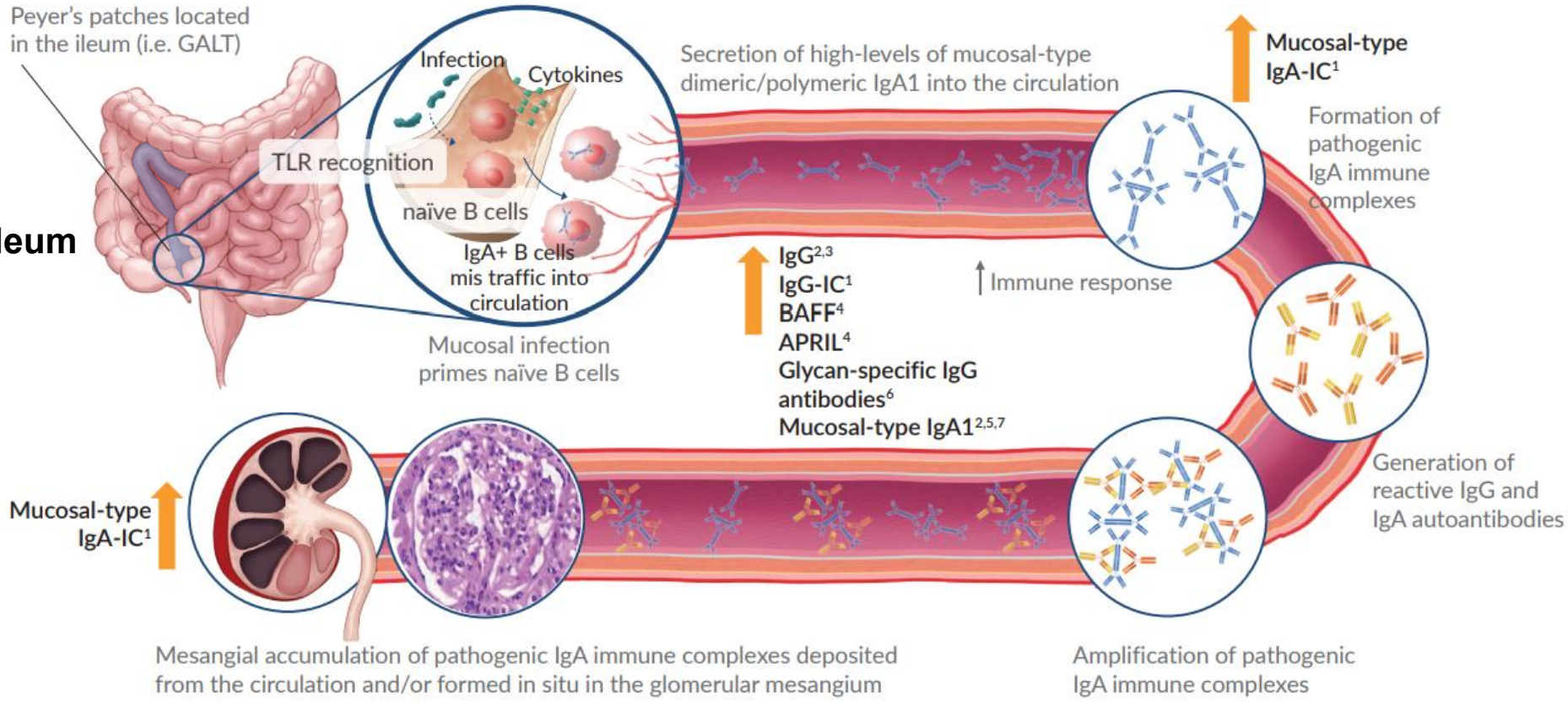
Production Flow of MED® 3D Printing System

The Pathophysiology of IgA Nephropathy

- Terminal ileum



The therapeutic target for IgAN is located in the Peyer's patches at the distal ileum.

3D Printing Formulation by Design (3DFbD®)

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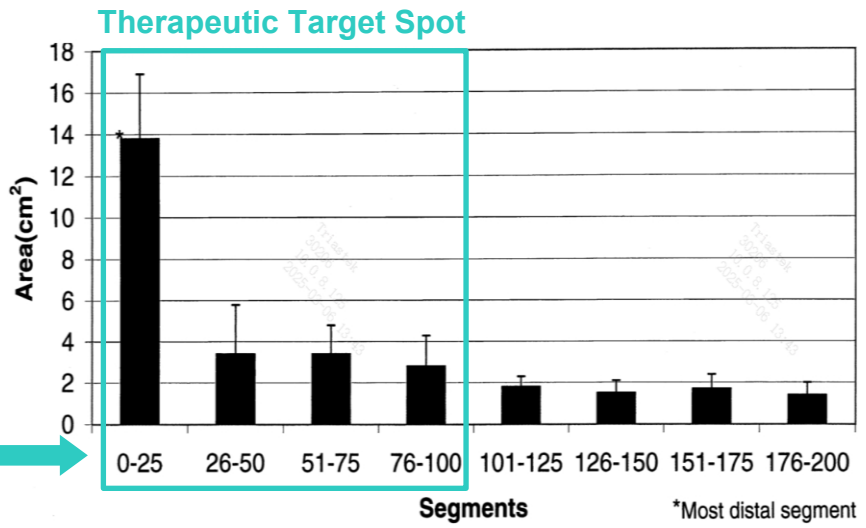
GastroPlus®
Human - Physiological - Fasted

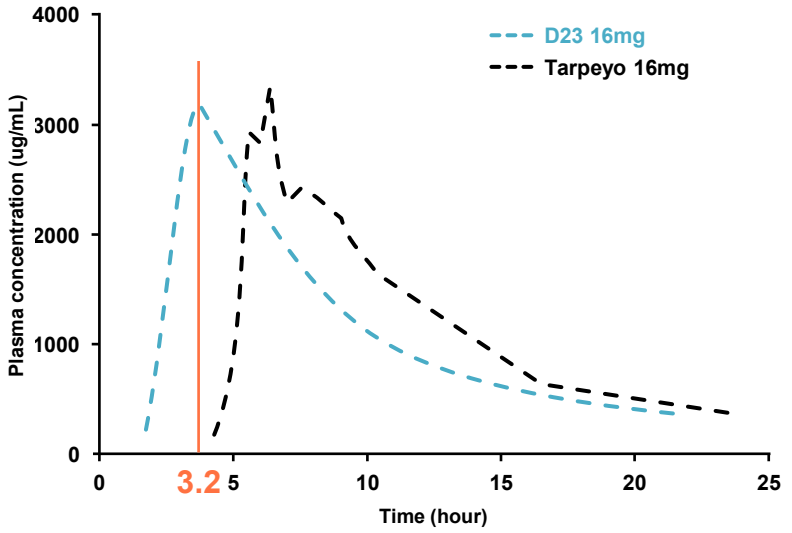
Compartment	pH	Transit Time (h)
Stomach	1.30	0.25
Duodenum	6.00	0.26
Jejunum 1	6.20	0.94
Jejunum 2	6.40	0.74
Ileum 1	6.60	0.58
Ileum 2	6.90	0.42
Ileum 3	7.40	0.29
Caecum	6.40	4.36
Asc Colon	6.80	13.07

3.2h

Distribution of Peyer's patches in the distal ileum



The comparison of the fitting PK curve of D23 with Tarpeyo



3D Printing Formulation by Design (3DFbD®)

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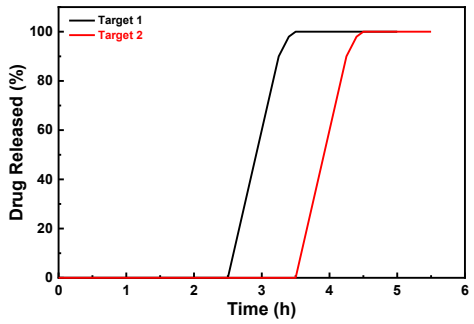


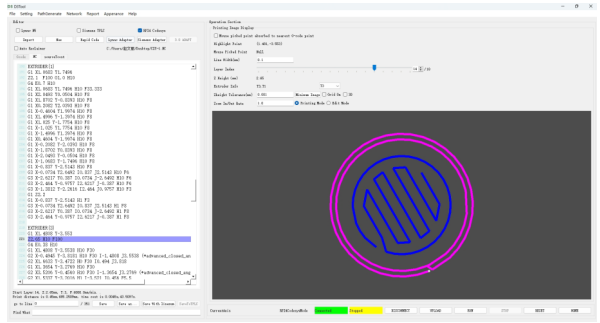
Prototype Design

2

Material Database		
Excip.	Manuf.	Chara.
A.	xxxx	xxxxxx
B.	xxxx	xxxxxx
C.	xxxx	xxxxxx
D.	xxxx	xxxxxx

G-code Generation

3

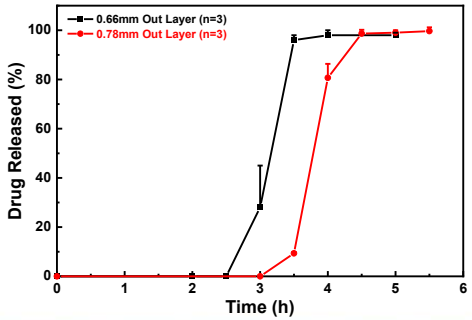


3D Printing

4

In Vitro Characterization

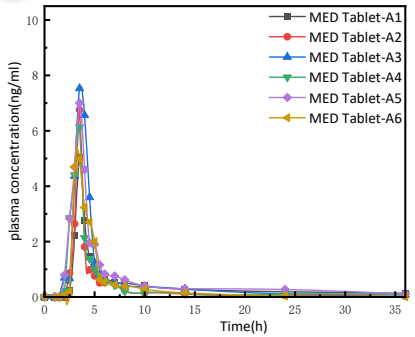
5



In Vivo Characterization

Yes

6



No

Formulation Optimization

Precise Distal Ileum Delivery

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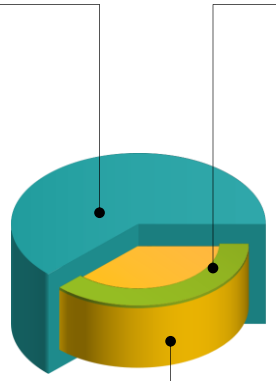
Delay Layer

Through material composition development and precise thickness control, the API release location in the gastrointestinal (GI) and the on-set tract release time can be well controlled.

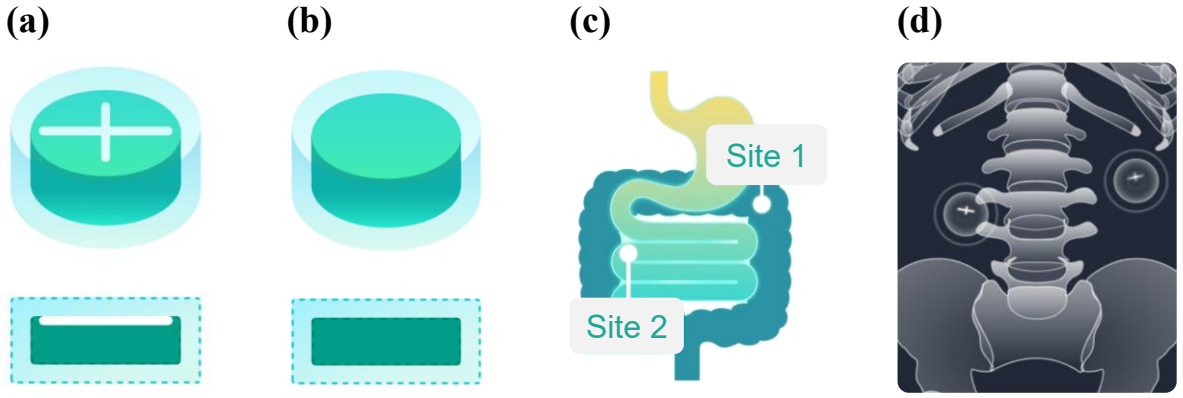


X-ray Imaging Layer

X-ray imaging materials can be 3D printed in the formulation for tracking in vivo drug delivery GI location and drug release behavior.
X-ray imaging agents will be removed without changes to the process or materials of other components in the formulation.
The Thinkness is 0.1 mm.

Drug Core

The drug core is designed with desired release behavior, such as immediate, sustained, controlled or pulsatile release, upon delivery of the API the targeted GI tract to achieve targeted absorption behavior.



(a) tablets in the R&D stage (tracking material is 3D printed in the tablets to track tablet GI transition and API release), (b) drug products in the commercialization stage (tracking material is removed from the tablets), (c) schematic of the drug release site, and (d) schematic of the captured X-ray images showing the location of the tablets in GI tract.

Human X-ray Imaging Result

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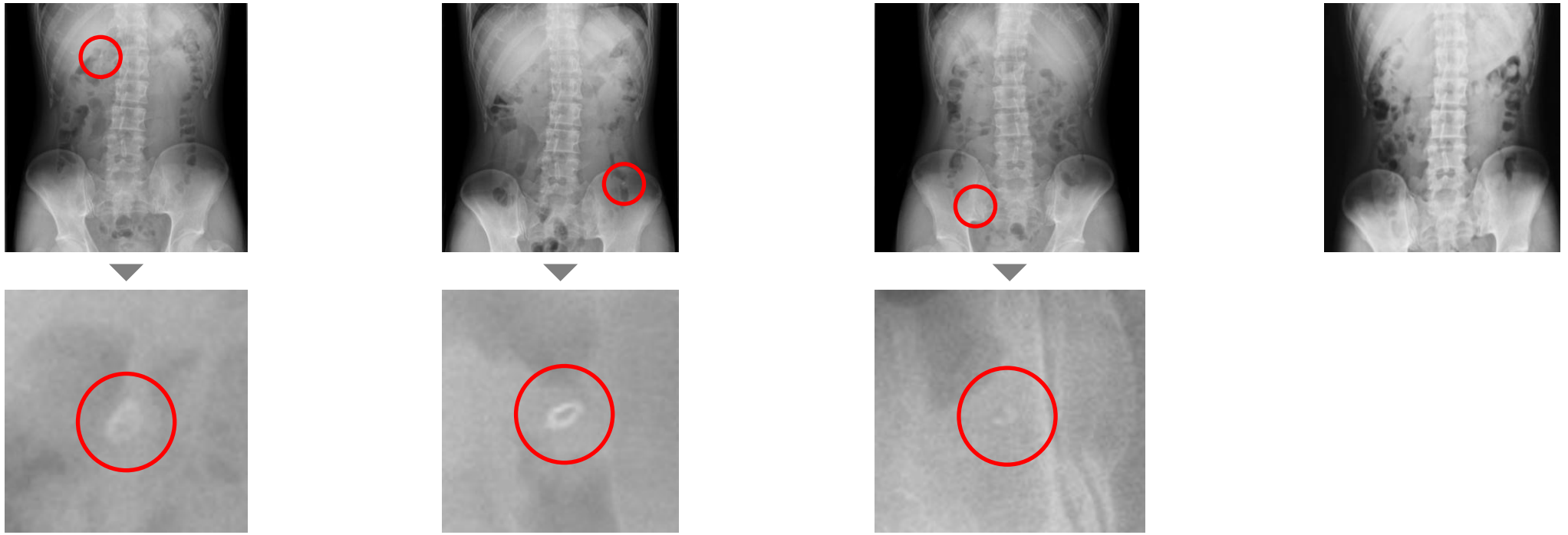
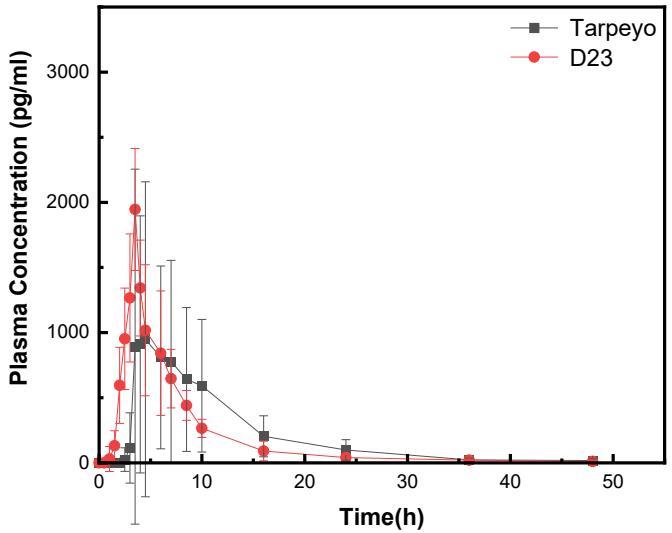
***In vivo* human tracing results (n=12)**

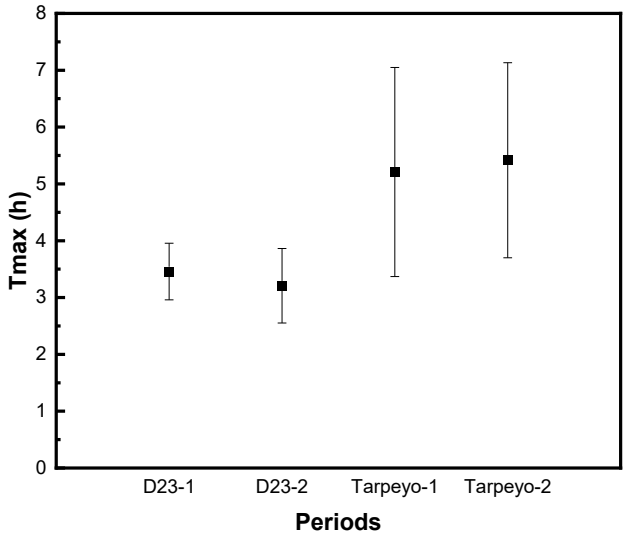
2h post-dose	2.5h post-dose	3h post-dose	4h post-dose
Tablet in duodenum X-ray tracer: intact	Tablet in jejunum X-ray tracer: intact	Tablet in ileum X-ray itracer: partially disappeared	X-ray tracer: disappeared



Human PK Study Results

In vivo human PK results (n=12)





	D23	Tarpeyo
Manufacturing Process	MED® 3D printing (simple)	Sugar sphere with three-layer coating filled in the capsules with two more coatings on capsule (complicated)
Drug loading	High	Low
Product Size	Small	Large
Variability in Human PK Study	Low	High

Summary

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1. MED® 3D printing technology has been successfully used to develop products with desired release profile to target specific GI location.

2. 3D printed budesonide delayed release tablets achieved more precise delivery of budesonide to the distal ileum region and reduced in-vivo variability.

Acknowledgements

Triastek Teams

- Engineering
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- Material Sciences
- Innovation Center
- Intellectual Properties

Investors & Collaborators