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Development of 3D Printed Oral Disintegrating Tablets of Oxcarbazepine Using Co-Processed Excipient

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PURPOSE

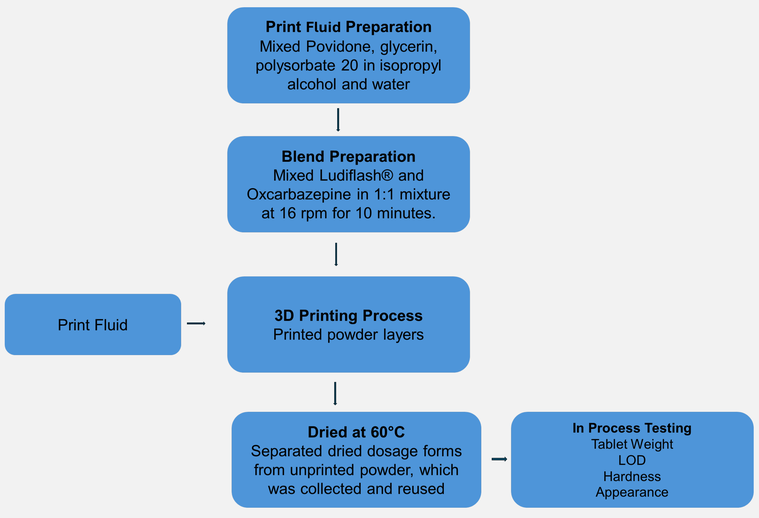
- Application of oral disintegrating tablets (ODTs) for central nervous system (CNS) diseases have gained significant attention to address patient compliance issues.
- Manufacturing of ODTs using the 3-dimensional printing (3DP) technology has the unique advantage of producing highly porous structures.
- We evaluated binder jetting technique for production of ODTs by spreading the powder blend in layer-by-layer manner followed by jetting of binder solution over the selected region.

OBJECTIVE

- In the current study we evaluated the manufacturing of a high dose ODTs of oxcarbazepine utilizing 3DP with Ludiflash® as co-processed excipient.

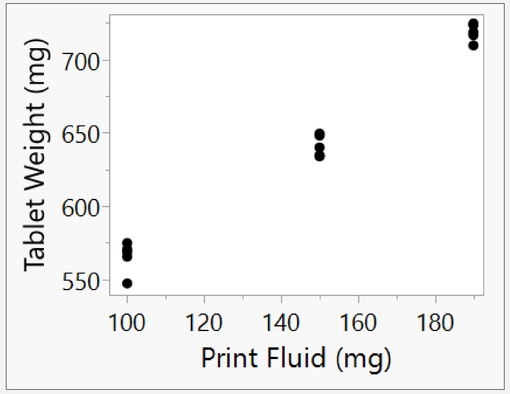
METHOD(S)

Process Flow Diagram

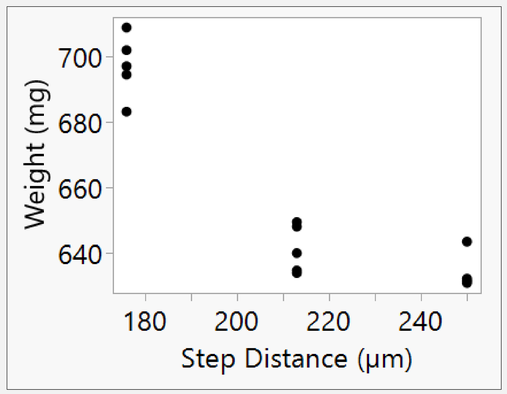


RESULT(S)

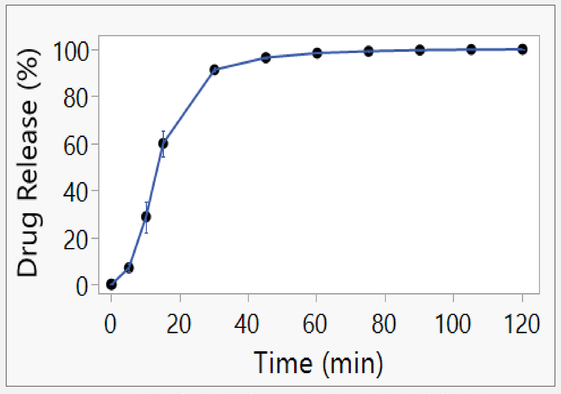
Effect of Print Fluid Quantity on Tablet Weight



Effect of Layer Thickness on Tablet Weight



Oxcarbazepine ODTs Dissolution Data



Dissolution Condition: 37 °C apparatus II at 75 rpm, in 900 mL 1.0% SLS, n=3.

Effect of Layer Thickness on Tablet hardness

Layer Thickness (µm)	Avg. Tablet Weight (mg)	Avg. Tablet Hardness (N)	Disintegration Time (s)
250	700.4 (SD 8.34)	2.8 (SD 0.45)	14
213	641.2 (SD 7.31)	9.4 (SD 0.55)	15

- 3DP process was optimized by adjusting the number of powder layers, print fluid quantity and roller speed.
- ODTs target weight was achieved by adjusting print fluid spray amount and adjusting the layer thickness.
- Powder bed layer height was adjusted to improve the tablet hardness from 3N to 9N.
- ODTs disintegration time was 15 seconds for the tablets produced through the optimized parameters.

Oxcarbazepine 3D printed ODTs

CONCLUSION(S)

- High dose ODTs were manufactured by 3DP using Ludiflash® as co-processed excipient.
- 3DP process parameters were optimized to manufacture oxcarbazepine ODTs with acceptable physical characteristics.
- 3DP of high dose formulations using co-processed ODT excipients will enable faster evaluation of blend compositions.
- Our research suggests that 3DP technology can be explored for the development of ODTs for other active pharmaceutical ingredients using co-processed excipients.

REFERENCES

- Jacob, J., & Caputo, K., & Guillot, M., & Sultzbaugh, K. J., & Thomas G, W. (2017). Rapidly dispersible dosage form of oxcarbazepine (Patent No. US9616018B2).
- Jacob, J., & Coyle, N., & West, T. G., & Monkhouse, D. C., & Surprenant, H. L., & Jain, N. B. (2023). Rapid disperse dosage form (Patent No. US20230069979A1).

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