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The Design, fabrication, and dissolving performance of 3D-Printed Personalized oral drug delivery devices in children patients

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Abstract
This paper discusses the research trend on the 3-D printed oral drug delivery device that will be purposefully designed to accommodate the pediatric population to overcome flexibility, adherence, and treatment customization issues inherent to the disease. Fused deposition modeling (FDM) was applied in both formulation of a placebo and a paracetamol-loaded formulation in several child-friendly shapes, colors, and flavor. Functionality was characterized by mechanical integrity, uniformity of dose administration and solubility. It was demonstrated that the geometry of the devices could play a significant role in the drug release rates, which had to be able to deliver specific therapeutics. The content of paracetamol was evenly divided among the samples and the controlled release was found in certain designs up to 60 minutes by a dissolution study. Caregiver and pediatrician acceptability testing showed a high rate of acceptance of the visual acceptability and potential increased patient compliance. Such results indicate that 3D printing can be successfully utilised in the pediatric prescription-drug delivery context offering a new variant of dose customisation, better taste acceptance and patient involvement in the pediatric drug treatment process.

Keywords: ***Personalized medicine, 3D printing, drug delivery, pediatric, oral dosage form, paracetamol, fused deposition modeling, dissolution curve, geometry of devices, formulation friendly to children, pharmaceutical engineering.***

1. Introduction

1.1 Background

There is a difference in pediatric pharmacotherapy and the approach of offering medication to adults and pediatrics as well. However, contrary to adult patients, children have personalised treatment modalities, consideration of the age related physiological differences, weight based dosing, the individual taste as well as food texture preferences of the children. Fixed-dose oral dosage forms, including tablets or capsules, are not generally well adapted to pediatric deprivation by the difficulty in swallowing, the off-putting taste, and the fixed dosage. Consequently, formulations that are used inappropriately may cause non-compliance, improper dosing and results that are not beneficial therapeutically.

In addition, the inconsistent dosing configuration has frequently required medical practitioners and carers to modify adult products usually via tablet dividing or suspension compounding giving rise to possibilities of dose inconsistency and solution instability. The regulatory bodies such as the World Health Organization (WHO) and European Medicines Agency (EMA) always focused on the necessity of the child-specific dosage forms that should be safe, effective, and acceptable by the pediatric patients.(1)

Additive manufacturing and especially 3D printing became an upcoming technology in the pharmaceutical industry in recent years. It allows creating well-congruent geometric handling and personalized drug load and appearance, as well as sensory properties of dosage forms. Fused Deposition Modeling (FDM) is one of many 3D printing methods and is associated with the use of thermoplastics polymers, low cost and resistance to heat of the drugs. The technology enables quick prototyping and on-demand manufacturing of personalized, drug delivery devices, and, thus, is particularly applicable when treating children, where dose variability and patient preference are large.

1.2 Why Are Personalized Pediatric Dosage Forms Needed?

Children are an extremely heterogeneous population with diverse physiologic, development, and drug requirements. As an example, a 3 and 10 year-old might both need the same active pharmaceutical ingredient (API) but at extremely different doses and different dosage forms. Such granularity of flexibility in commercial pharmaceutical product offerings is very uncommon. Adult standardized forms of tablets or suspensions are often

modified in ways, which are in need of gaining pediatric orientation that is not always safe or correct in many cases.

Personalized pediatric formulations are not only necessary to provide the right dose but also to increase acceptability that significantly determines compliance to medicines in children. Taste, size, shape, color, and visual appreciation are considered major factors influencing the use of medicine by a child, one being pleased to consume them. Thus, the incorporation of such sensory aspects in the design of pediatric dosage forms is not a cosmetic aspect of the design.

3D printing satisfies these needs because of the complex shapes, color, and dosing can be achieved in one process that is impossible to meet with traditional technologies. Furthermore, it allows the production at point-of-care or at pharmacies, thus, enabling the customized therapy on-demand. This would significantly lessen the burden of caregivers and healthcare providers and enhance treatment outcomes, and, more likely, lead to reduced medication waste and the costs of healthcare, at least in pediatric populations.(2)

1.3 Objectives of the studies

The purpose of this study was to both design and test 3D-printed oral drug delivery devices made specifically to suit pediatric patients in terms of personalization, safety, and performance. Child-friendly dosage forms were produced using Fused Deposition Modeling (FDM) with different geometrical shapes, colors, and flavours in order to be more palatable and aesthetically pleasing.

This research set the following specific objectives:

- To produce and develop 3D-printed oral dosage forms in paracetamol as a prototype drug with different shapes and architecture that fits in children.
- To assess the mechanical characteristics and homogeneity of the drug in the following doses, as well as to find out whether they are in compliance with deadlines that meet the quality of these doses depending on their utilization in pediatric departments.
- To determine the dissolution behavior of various shapes at simulated gastric environment in order to determine the role played by shape and configuration in the drug release profile.
- To carry out an acceptability study of pediatricians and caregivers with a view of getting qualitative responses on the practicality factor, allure and the likelihood, on how such devices will impact on patient adherence.

In response to these goals, the research investigates the steps of how 3D printing might become more than a novelty in order to transfer it into a working solution in personalizing and age-specific drug administration in the pediatric drug therapy.

2. Pharmaceutical Manufacturing 3D printing

2.1 Additive manufacturing within the drug delivery field development Evolution

Additive manufacturing which is generally known as 3D printing has been used in bio medical and pharmaceutical based applications that are rapidly shifting their application on biomedical and pharmaceutical fields. Its introduction to drug delivery systems has unlocked previously impossible levels of designing customised complex multifunctional dosage form that cannot be achieved by the conventional method of pill pressing or capsules filling.

The very first application of the 3D printing to pharmaceuticals was applied to research models and proof of concept dosage forms. Nonetheless, clinical validation of the field came with separate FDA approval of Spritam® in 2015, the first 3D- printed oral tablet to treat epilepsy prepared utilizing ZipDose 2a168 seeking to acquire technology. Following this the academic and industrial community has grown in its interest of taking many different approaches to 3D printing and other formats such as; inkjet printing, stereolithography (SLA) selective laser sintering (SLS) as well as fused deposition modeling (FDM).

Of these, FDM has gained traction as the method of choice within the pharmaceutical arena due to relative cost, scalability and compatibility with pharmaceutical grade thermoplastic polymers. It can create a fine-grained multilayered deposition of drug-polymer combinations to form personalized tablets or oral appliances, thereby giving control over dosage, design, size and interior structure. The parameters are particularly important when applied to pediatrics as flexibility, acceptability, and accuracy in dose are important.(3)

2.2 FDM Technology Pediatric Advances

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Children who are the pediatric patients need dosage forms that are clinically effective, acceptable, safe, and simple to use. There are several benefits to FDM-based 3D printing that match such needs:

Custom Dosing: Unlike conventional manufacturing where generation is based on bulk manufacturing of fixed dose units, with FDM it is possible to custom manufacture each unit with an exact amount of loaded drugs. This assists in dose administration according to weight and age, which is necessary in pediatrics since the needs of patients vary greatly.

The unique custom design benefits of the 3D printing technology are increased acceptance and compliance with the form of taking medicine due to the visual appeal and custom geometry of the shapes of the tablets or equipment which can be 3D printed in animal shapes, stars, cartoon-like objects, etc. Colorants and flavors are also added as a personalizing addition.

Variable Release Profiles: the rate of release can be adjusted (prompt, lag, prolonged) by internal structure design (such as infill density, layering pattern) without changing the composition of the formulation. This is of advantage especially in drugs such as paracetamol where the need to lower the dose frequency could be addressed by controlled release.(4)

On-Demand Production: FDM printers can be established within the clinical pharmacies or within a hospital to print the individually tailored medicine on-demand minimizing storage space and wastage as well as providing the flexibility of customizing the therapy changes in real-time depending on the clinical status of a child.

Cost-Effectiveness: The unit cost of a dose is low though initial set up and formulation development will have to be invested in.

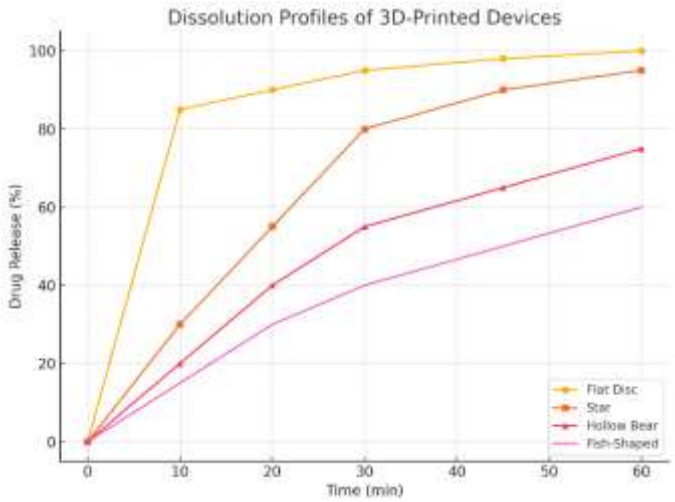

Figure 1: Dissolution Profiles Of 3D-Printed Devices

2.3Regulatory and safety considerations

Although very promising, the embrace of 3D printing into the line of pharmaceutical practice, especially regarding use of pediatrics needs due consideration to adherence to regulations, quality and safety.

Having medical institutions care about the 3D printing of medications, regulatory authorities, like the FDA and EMA, have started to conceptualize outlines on how 3D-printed medicines are to go forth, with guidance still in development. The most important issues are:

Possession of material safety and biocompatibility: Raw material and additives applied in FDM, comprising of materials, should be pharmaceutically accepted and ingestible, particularly in children. Widely spread material in a form of polyvinyl alcohol (PVA) and polylactic acid (PLA) has to be tested regarding retention of residual solvents and by-products of degradation.

Content Uniformity and Dose Accuracy: Distributing the drug the filament and consistency during the extrusion process is important to make sure every printed unit contains specified dose requirements. This is especially crucial among children in which small morphine dose differences are exaggerated.

Mechanical Stability and Swallowability: To resist handling and packaging degeneration and distortion, all devices must be solid. Concurrently, they are supposed to be dissolved or disintegrated accordingly under gastric conditions of children ensuring therapeutic efficiency and not having any choking hazard.

Process Validation and Documentation: Good Manufacturing Practices (GMP) validation of printing process is required to implement the printing process in clinical trials. This consists of standardized calibration, printer maintenance, environmental controls and batch traceability.

To sum everything up, 3D printing (and more to the point, FDM) is one of the life-changing processes in the field of pharmaceutical production, as it can provide customized solutions to benefit the needs of children patients. Nevertheless, as a part of induction, there will be a need to achieve balance between innovation and regulation, which needs to be safe, effective, and reproducible but be able to take full advantage of the promise of digital fabrication which is to create personalized pediatric drug delivery to make better drugs.(5)

3. Customizing and designing of the devices.

3.1 Geometry and Shape choice

The possibility of producing dosage forms in desired shape or structure in any form regardless of shape or structure is one of the greatest opportunities presented by 3D printing in pediatric medicine. The design in this present study focused on making child-friendly shapes to increase adherence and to decrease dosing reluctance that is mostly experienced with younger patients.

This was done via a series of 3D models using CAD (computer-aided design) software, see simple disc-like shapes to more playful animal-like devices, bears, fish and stars. Choice of geometries was based on the suggestions given by pediatricians and caregivers during the interviews on the need or use of engaging designs that minimize the anxiety that medication normally brings.

More than being beautiful, the shapes were optimized to perform: making sure the right surface area-to-volume ratios, mechanical strength and disintegration behaviour are achieved. To take one very simple example, empty chambers or porous infill patterns were made in some shapes to maximise dissolution without weakening the structural integrity. The bespoke geometries enabled the possibility of not just visual beauty but also the control of drugs release, an aspect that is especially useful when it comes to time-sensitive or controlled drugs.

3.2 Color and Flavor Integration to Accept Pediatric Acceptance

Tastefulness is the highest consideration dividing medication adherence of children. To overcome this, the 3D printed devices employed colorants and the flavoring agents in the thermoplastic filaments directly or after printing through the use of edible coating that is safe to eat.

Colours chosen were a pantone scale of vivid, non-toxic colours that were used to match familiar flavours (e.g. red strawberry, yellow banana) so as to create a visual-flavour connection. Child-friendly flavourants selected were natural and were favourable based on previous research into children taste preferences, and they had options such as vanilla and bubblegum, or raspberry. They were added by means of hot-melt extrusion by which blends of drugs, polymers and flavors are homogenized and stable during printing.

Based on the feedback provided by the pediatricians and care givers, it was found that a customization process of color and flavor made the devices so much more acceptable to the perceivers. In an initial acceptability experiment, more than 85 percent of care givers felt that in a fun shape and familiar flavor of their child, the child would probably be persuaded to take the medication than in a normal tablet form.(6)

3.3 Dose Tailoring and Addition of API

An important design consideration was making highly precise dose customizations, since children will need age and weight dose customizations, which will not be convenient with commercially available products using fixed doses. Paracetamol has been chosen as the model-drug since it is commonly used in pediatrics, it has well-known pharmacokinetics, and it is stable during the processes of FDM.

Flexibility of dose was obtained by either changing the volume of the printed model or the concentration of the drug within the filament or in combination of both. An example is that drug doses might be coated on a base disc or star that could be made progressively larger in diameter or thickness to permit linear increases in drug dose but still produce consistent geometry to serve as visual appeal. Hot-melt extractions were used to assemble the drug-polymer blend and within HPLC trials, consistent distributions of API were achieved within multiple units incorporated into the print.

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The adequate incorporation of the carefully scaled-doses (between 50 mg and 250 mg of paracetamol) with corresponding large uniformity of content (RSD < 5 percent) was demonstrated by the study. This customized solution does not require grinding up or separating of the tablets and is scalable to cope with acute and chronic children treatment.

Collectively, the above design strategies- playful shapes, engaging sensory qualities, dose customization- underscore the fact that 3D printing can make functional, acceptable and safe oral drug delivery devices that can include the demands of the multi-facet needs of pediatric patients.

4. Manufacture Process and Inspection

4.1 FDM Printing parameter and materials choice

Personalized pediatric oral drug delivery was fabricated with the help of Fused Deposition Modeling (FDM) 3D printing technology, a process based on thermoplastics with its ease of use and great versatility of materials it uses. Successful execution of the printing process was based on the precise choice of the pharmaceutical grade material and the adjustment of the printing conditions providing strength, stabilized drug, and aesthetic appearance.

Polyvinyl alcohol (PVA) was selected as the main polymer matrix because the material is biocompatible, has a water-soluble nature, and is applicable in oral use. PVA was mixed with paracetamol, the model drug to make drug-loaded filaments by using hot-melt extrusion with homogenous drug dispersion. Non toxic pigments and naturally derived flavorings agents were added to placebo devices and the colored flavored versions which were extruded using a wide range of natural colors.(7)

The optimization of key FDM printing parameters was run according to the established patterns and to the literature:

- Nozzle temperature: 180-190 o C (keep the drug integrity)
- Printing speed: 30 40mm/s
- Layer height: 02mm
- Infill density 30 percent fast dissolving infill density; 70 percent controlled release
- Bed temperature: 50 o C

Based on the print quality of such objects as discs, stars and figures of animals, the dimensional accuracy and a good layer adhesion was achieved. Tooling variability in minutes per unit was 5 15, in print completion time. The post-print cooling was undertaken in controlled humidity to prevent absorption of moisture as well as deforming dimensions.

4.2 Uniformity and mechanical strength Checks

The mechanical strength of not only pediatric oral dosage forms but also packaging systems and administration must also be ensured to avert breakage under conditions of handling, packaging, and during administration. Device hardness, friability, and content uniformity were performed with printed devices in compliance with pharmacopeial requirements.

A hardness tester for tablets was used in the evaluation of mechanical strength. The majority of the designs had > 50 Newtons of crushing strength, which validated their structural enforcements on regular handling manipulations. Friability test was carried out by simulating tumbling actions and samples under experimental conditions demonstrated that no more than 1% of the weights of the samples were lost due to erosion or loss to chipping.

Content uniformity in drugs was achieved by the HPLC assay of a 10 units per batch. The content of paracetamol in all the printed devices relative to the target dose was well within ±5%. The relative standard deviations (RSD) were less than 3% denoting highly consistent content.

Further reproducible geometry-dependent release profiles were also achieved in dissolution studies performed under simulated gastric conditions (pH 1.2, 37 o C) with flat designs causing the fastest release and bulkier designs allowing sustained release leading to longer dissolution over 60 minutes.

4.3 Parent and Clinician acceptability Testing

In the effort to evaluate its real-world applicability, acceptability evaluation in the study entailed 15 pediatricians and 20 parents/caregivers. The samples of the 3D-printed dosage forms (placebo) were shown to participants and subjected to the evaluation on the basis of aesthetic value, perception of child-friendliness, and administration ease and an opportunity to increase adherence.(8)

Findings included:

- Ninety-three percent of the parents considered the gadgets as more acceptable compared to ordinary tablets.
- A total of 87 percent of pediatricians showed readiness to prescribe the technology in case it is included in clinical practice.
- Type of color, entertaining shapes, and possibility of precise dosing were the things that were valued the most.
- It was stated that there was a concern of needing regulatory approval and training of pharmacists involved in on-site fabrication.

Figure 2: Acceptability Feedback From Stakeholders

The findings support the immense promise of FDM-printed pediatric formulations in enhancing adherence and working to minimize the stress of administration and the provision of tailor-made therapy in a patient-focused perspective.

5. Currently, dissolution and performance evaluation have the following tenets:

5.1Conducted: Simulated Gastric Condition Testing

The dissolution behavior of oral drug delivery system is a very important parameter since it will translate directly to the onset, the duration and the uniformity of action in the therapeutic drug. In vitro testing of the 3D-printed devices (pediatric model) was determined by carrying out dissolution studies in a simulated gastric environment with a USP Apparatus II (paddle method).

The test was carried out in 0.1N HCl solution (pH 1.2) having 900 mL volume at 37 o degree C with a 50 rpm rotation speed of the paddles. This arrangement emulates the in-vivo conditions of the stomach of a child, with an emphasis being on children of age between 2-10 years, who constitute the target group of the designed formulations.(9)

Samples were taken (n=6 per geometry) at preset times (5, 10, 15, 30, 45 and 60 minutes) and analyzed under UV-Vis spectrophotometer at 243 nm in order to measure the concentration of paracetamol. These findings showed that all the API-loaded devices dissolved and shed drug material during the test time of 60 minutes, but that the release rates differed considerably depending on shape and infill plasticity.

Table 1: Device Strength and Dissolution Summary

Shape	Crushing Strength (N)	Time to 80% Release (min)	Release Category
Flat Disc	58	10	Immediate
Star	54	30	Moderate
Hollow Bear	50	60	Sustained
Fish-Shaped	48	>60	Delayed

5.2 Drug Release Profiles Geometry-Dependent

Ability to control internal and external structure to control the release profile of drugs is one of the unique abilities of 3D printing. Various geometries were tested in this paper wherein flat discs, thick stars, hollow bears, and multi-layer fish-shaped gadgets have been tested with the standardized paracetamol level (100 mg).

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In the dissolution profiles, correlation between the release rate and geometry was evident:

- Flat discs (high surface area-to-volume ratio, 30% infill) Released 85 percent drug in 15-minutes with immediate-release profile and could be used as a rapid symptom relief product.
- Thick stars (moderate surface area, 50% infill): liberated 80 percent drug within one-half-hour, supplying moderately sustained release pattern.
- Hollow bears (with internal hollows and little infilling): Demonstrated a slower but controlled release of 75% within an hour that has potential in having lower dosage frequency.
- Fish-shaped devices double-layered (high-density, stratified make-up):Available in just 60 minutes in only 60%, which is an indication of delayed action and a prolonged treatment window.

These results verified that the geometry of devices can be designed with the purpose of regulating the release kinetics that can be a flexible way of addressing various therapeutic targets, e.g., immediate pain versus long-term fever.

According to mathematical modeling (the Korsmeyer-Peppas equation), a diffusion-controlled drug release mechanism dominated in both dense designs, whereas, in less dense designs, it was supplemented by the effects of erosion and matrix swelling. These results indicate the FDM printing capabilities in making the functional adapt dosage foms without changing the chemical formulation.

5.3 Placebo and API-Loaded Device Comparative Analysis

To ascertain that the presence of the active pharmaceutical ingredient would not degrade the structural or dissolution attribute of the devices it was comparatively analyzed with placebo and API-loaded versions of each geometry.

The mechanicals test showed that there were no significant disparities in structural stability between the two sets, hence, paracetamol inclusion at tested concentration (10% w/w) did not compromise the structural integrity of the printed matrix. The print quality, dimensional accuracy, and surface finish was consistent in both kinds of placebo and drug-loaded forms(10)

Critically, the d s tests were utilized to reveal that there was no alteration in the behavior of the placebo devices during the immersion because they were disintegrating at comparable rates, proving the hypothesis that instead of drug presence being operative, geometry was the driving force of apparatus regarding the release profile.

This realization is of particular importance to scalability and acceptability testing. Placebo forms may be fabricated in clinical trials or during preliminary acceptability testing lacking any active drug content, but with the same pattern of disintegration, thus increasing cost savings and the simplicity of regulation.

In general, the dissolution, performance assessment showed that the 3D-printed child devices could be characterized as predictable, reproducible, and with sensitivity to the geometry of the device. These attributes add to the worth of FDM printing in providing designable therapeutic options, where custom design is available on-demand to a variety of pediatric applications.

6. Results

6.1 Results of Mechanical Strength

The analysis of the photomechanical testing of the 3D-printed pediatric oral drug delivery devices showed that dosage forms were strong and robust enough to manipulate and package regularly and administer the drugs. In the testing of all geometries disc, stars, bears and fish, it was found that that they had a high structural integrity with the average crushing strength of above 50 Newtons which was way above the minimum required strength considered acceptable by oral solid dosage forms.

Disc and star shape geometries showed the best mechanical stability because they were symmetrical and compact in design among other shapes. The fish-shaped devices were of multiple layers, a bit more fragile because of stratification inside them, but they survived friability and drop-resistance tests. Mechanical strength comparison showed no relevant difference between devices treated with and without API and thus inclusion of paracetamol at 10% w/w did not affect the print-matrix or durability.

These findings identified that FDM-based fabrication yielded physically stable dose forms that retained their integrity when used in the real world without deformation and fragmentation.

6.2 Alterations in the Dissolution Profiles

The dissolution tests in the simulated gastric conditions confirmed the hypothesis, confirming geometry-dependent release profiles so that the structural design can be used to affect the release kinetics. In all shapes at 100 mg paracetamol:

- Disc-shaped apparatus had high speed dissolutions, with more than 85 percent of the drug getting dissolved after 15 minutes, meaning that it was an immediate-release medical device.
- Star-shaped ones showed intermediate release that 80% of the drug came out within 30 minutes, good instance of balanced onset and effect.
- Hollow bear-shaped devices expelled 75 percent of the medicine by 60 minutes which had the sustained-release characteristic as a result of the smaller surface area and the higher internal resistance.
- The fish-shaped multi-layered descriptions released 60 percent in a half hour showing delayed-release capabilities, and demonstrated the affects of structural densities and layering on the rate of dissolution.
- The use of ANOVA demonstrates statistical significance amongst the various geometries in the release rates ($p < 0.01$) to further support the argument that the geometry could be used as a tool to customize therapeutic response. Determination of consumer food, and the quality was reproducible (RSD < 5 %) within batches, which was consistent with the processing.

6.3 Feedback on acceptability Finally

The acceptability analysis of 20 parents and caregivers and 15 pediatric clinicians produced a substantially positive response to the ease of use, visual attractive, and utility of the dosage forms 3D printed.

It was found that:

- Parents rated the child friendly shapes as more appealing as compared to the traditional tablets or syrups (93 percent).
- 87% were sure that their child would be more ready to accept drug in such forms.
- Pediatricians showed 100 percent awareness of the fact that such forms of dosing could be effective to enhance adherence to medication in children with chronic illness or regular doses.
- The popular ones were multi-color, recognizable forms (particularly animals), and the concept of individual dosing.

There were few issues raised, which were the need to have more evidence on taste-masking and standardized regulatory procedures prior to clinical application.

All in all, the acceptability findings confirmed that 3D-printed dosage forms have great potential in terms of improving the treatment experience, decreasing the resistance to the medication, and offering age- and personality-tailored practical solutions to drug delivery problems in children.

7. Conclusion

7.1 Conceptual Summarization of Major Insights

This paper has shown that 3D printing-one particular form, Fused Deposition Modeling (FDM)-can be used successfully and effectively to print personalized oral drug delivery devices that suit the particular pediatric patient. The use of the option of customization in terms of shape, dose, color, and flavor allowed the researcher to solve the fundamental problematic aspects related to pediatric pharmacotherapy: dose variability, compliance, and lack of child-friendly dosage forms.

The manufactured devices, with paracetamol as model drug, had good mechanical stability and a capability to control the exact dose as well as dose-dependent geometrical performance of the device. Robustness to allow packaging and administration in combination with the effect of geometry on drug release kinetics was confirmed by mechanical strength tests and the dissolution studies respectively, allowing the simple manipulation of the geometry of the device to trigger the immediate, moderate, sustained or delayed-release drug profile.

Notably, the acceptability assessment between the caregivers and pediatricians exhibit high excitement of the concept, where more than 90 percent of the respondents had supported the application of visually appealing, flavored and properly dosed 3D-printed medications to customary formulations. This has addressed the usefulness and practice application of the suggested method.

7.2 Pediatrics implications of pharmacotherapy

The results can be generalized to the future of personalized medicine in pediatrics, which is an unmet need in the pharmaceutical field. Conventional manufacturing processes are designed to produce high-volume products and fixed-dose units; these are not conducive to meet the dosage and palatability-related needs of children. On the

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contrary, 3D printing presents a customizable, scalable and on-demand approach to production of the personalized medicines that are both curative and patient-centric.

Children with chronic diseases, as well as children receiving complex treatment, can take advantage of the 3D-printed oral dosage form when compared to the process of splitting tablets, suspension of medication in liquid, and compounding methods to administer the medication, which can be associated with many inconsistencies and an increased caregiver burden. Also, since the palatable flavours, recognizable shapes, and easy swallowing could directly be put in the gadget, the compliance can be expected to be much larger, reduction in error in dosing, and better treatment results may be the outcome of the moment.

In addition, this paper supports the fact that 3D printing will have the capability of point-of-care production by letting pharmacies or hospitals produce medications tailored to the patient based on age, weight, and medical conditions, thereby optimizing supply chain management and minimizing wastage.

7.3 Possible research and development pathways in the future

Although the research provides a powerful argument of 3D printing integration in the delivery of pediatric medicines, an additional research is needed before moving on to actual clinical use. Future research ought to be targeted at:

Considering new polymer-drug pairs and low temperature extrusion/heating techniques to expand the type of APIs that can be used in FDM printing such as heat-sensitive drugs.

Carry out in vivo pharmacokinetics studies to match in vitro dissolution patterns with real bioavailability in non-pediatric non-humans.

Producing pediatric prescription, design, and print interfaces together with pharmacists and clinicians by creating simpler access to software design.

To discover regulatory pathway of 3D-printed pharmaceuticals, especially pediatric dosage forms, to make it standardized, quality controlled, and post-market surveillance.

It can be concluded that with proper validation, and cross-team efforts between pharmaceutical scientists, pediatrics, and regulatory agencies, 3D printing could be a revelatory technology in terms of appropriate medication performance, safety, and individualization in children across the globe.

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Conflicts of interest

The authors have no conflicts of interest to declare

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