

3-D PRINTING- AT A GLANCE

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Abstract: *The 3D PRINTING innovation has grabbed the eye of clinical gadgets industry and drug industry because of its applications on different stage in medical services industry. Despite the fact that this innovation exists for quite a while it is of public interest exceptionally now because of the endorsement of three dimensional printed tablet and other clinical gadgets and furthermore with the coming of USFDA's direction on specialized contemplations intended for gadgets utilizing added substance producing which includes 3-layered (3D) printing has set off numerous contemplations about this innovation which should be considered for effective conveyance of expected item. This paper presents administrative offices assumptions, constraints, issues in laying out such arrangements for creation of medication items, benefits, drawbacks, applications, techniques and related takes a chance with engaged with assembling. It likewise gives the far reaching audit of the flow status of innovative work on this stage.*

Keywords: *Three dimensional printing, personalized medicine*

1.INTRODUCTION

- Drug delivery is the technique of formulation development to efficiently transport a pharmacologically active compound in the body to achieve therapeutic efficiency in a safe manner. The efficiency and safety of a pharmaceutical product can be improved by controlling the release profile which in turn affects the pharmacokinetics of a drug. In clinical scenario, the interspecies variability is an obstacle which faced frequently. Personalized medicine and dosing receives increasing attention because of the high chances of undesirable side effects and proper medication. (1, 2)
- 3D printing technology play a significant role in multiple active ingredient dosage forms, where the formulation can be as a single blend or multilayer printed tablets with sustained release properties. This results in reduction of frequency and number of dosage form units consumed by the patient on a daily routine. 3D printing technology has high potential in personalized dosage form concept called the polypill concept. This brings about the possibility of all the drugs required for the therapy into a single dosage form unit. Three layered printing innovation is a clever fast prototyping procedure in which solid objects are developed by

sequencing multiple layers. The rapid prototyping involves the construction of physical models using computer-aided design in three dimension(3).

2. HISTORY

- 3D Printing acted like a potential stage for customized medication during the 1990s. There are significant accomplishments in 3D printed clinical gadget, FDA's Center for Device and Radiological Health (CDRH) has assessed and cleared 3DP clinical gadgets. The guideline of 3D "added substance processes" is in this interaction by laying out the progressive layer of material an article is created. Folio material is put layer by layer on powder bed in inkjet printer heads. This cycle permits to deliver complex shapes with the assistance of utilizing less material than conventional assembling strategies.
- The first 3D printing strategy utilized in quite a while was accomplished by inkjet printing a fastener arrangement onto a powder bed, restricting along these lines the particles together. The interaction was rehashed until the last wanted structure was gotten.
- This previously occurred in the mid 90's at the Massachusetts Institute Technology created and protected by Sachs et al . In 1989, Scott Crump, documented a patent on another 3D printing innovation: combined testimony displaying, where expelled polymer fibers warmed into a semi-fluid state were expelled through a warmed spout and saved onto a form stage layer by layer to solidify. Inkjet printing was the strategy used to produce Spritam (levetiracetam) tablets for oral use, the primary 3D printed drug endorsed by the Food and Drug Administration (FDA) in 2016 by Aprelia Pharmaceuticals . 3D printing is further developed in the fields of vehicle, aviation, biomedical and tissue designing than in the drug business where it is in its underlying stage. FDA energizes the improvement of cutting edge fabricating innovations, including 3Dprinting, utilizing risk-based approaches.

Table-1: Comparison between traditional manufacturing and 3-D printing .

	TRADITIONAL MANUFACTURING	3D PRINTING
COST	Higher cost of manufacturing and shipping.	Upto 70% savings due to prototyping costs.
DESIGN	Less innovative design due to cost constraints.	Allows for easy yet inexpensive innovation in design.
SPEED	More time to build final product.	Lesser time taken due to compressed design cycles.
QUALITY	Creates more waste; subtractive process will compromise on precision.	Lighter and smaller amount of waste; higher precision with layer by layer manufacturing.

3. METHODOLOGY

- Inkjet Printing
- Laser Based Writing System
- Powder Based 3D Printing
- Nozzle-Based Deposition Systems
- Extrusion based method

3.1 Inkjet Printing

Inkjet printing depicts frameworks which use design creating gadgets to carefully control and spot little fluid drops on a substrate. In pharmaceuticals, suitable combinations of medication, alongside reasonable excipients (known as ink) are kept as little drops in a layer wise style on a suitable substrate. Continuous inkjet printing (CIJ) and drop on demand (DoD) are the two fundamental inkjet printing stages(16,17)

3.1.1 Continuous Inkjet Printer

As the name recommends, continuous inkjet printers delivers stream of fluid beads on a substrate persistently, in any event, when the drops are excessive. Here, a tension wave is created into the ink stream, which separates the ink into uniform estimated beads through vibration of the nozzle and afterward delivers the drops out of the nozzle. Since it ejects beads consistently, this innovation prompts the wastage of ink. The benefits of this printing innovation incorporate high velocity consistent bead formation, because of which the nozzle doesn't get stopped up without any

problem. Burdens incorporate low-resolution and expensive maintenance(18)

3.1.3 Drop-on-Demand Inkjet Printer

In these printers, drops of fluid are ejected out from the printhead because of a trigger sign, just when it is vital and the drops are deposited onto a substrate. This sort of printer commonly contains numerous spouts (100-1000, yet particular printheads make out of only one). Differentiating the continuous inkjet printer where ejection of drops is because of the outside pressure, drop-on-demand inkjet printers have the drops kinetic energy obtained from sources near every spout and situated inside the printhead(19). This innovation is moderately basic, offers high accuracy and is minimal expense. It can possibly store little drops of controllable sizes and furthermore delivers them with great arrangement precision. It additionally limits the wastage of medications. Henceforth, it is preferred over continuous inkjet printing for printing applications(20,21), Drop-on-demand inkjet printer can be further classified, based on the type of printhead, into thermal inkjet and piezoelectric inkjet printer(22)

3.1.4 Thermal Inkjet Printer (TIJ)

Here, thermal energy is the trigger system used to release drops, which then leave the spout. The printheads have resistors inserted in them which are in prompt exposure with the liquid (ink) and endless supply of electric flow produce heat. This heat then outcomes in the development of an air pocket inside the unstable liquid, which then, at that point, grows and discharges a little volume of liquid out of the spout framing a bead (Fig. 1a). The limitation of this procedure is the utilization of high temperatures (200-300°C) of the resistor, which could prompt the degradation of thermo labile active ingredients(18,23)

3.1.5 Piezoelectric inkjet printer (PIJ)

This innovation makes out of a piezoelectric component or actuator which changes its shape because of an electric voltage. This produces a strain, which prompts the liquid (ink) being ejected out of the spout. After the component returns to its original shape, the spout is reloaded with the liquid and is fit to be initiated once more(21,24). The principle benefits of this procedure incorporate its operability at room temperatures utilizing less volatile and more biocompatible fluids(23)

3.2 Laser Based Writing System

It depends on the principle of photopolymerization, wherein free radicals are delivered after the interaction between the photoinitiator and UV light.

This strategy was the first industrially introduced SFF (strong freestyle creation) methods and created in 1986. In

the field of bioengineering, they are vigorously utilized and evaluated [24]. To make a model, models, examples, and creation parts utilizing a photochemical interaction with the assistance of printing innovation as Stereolithography [SLA] [31]. His research came during the 1970s, yet the term was coined by Chuck Hull in 1984 when he licensed his process, which was allowed in 1986.

3.2 Stereolithographic 3D Printing

Stereolithography depends on the solidifying of liquid resin by photo polymerization utilizing UV light. The set up of the printer can either be bottom up, where the UV source is situated underneath the printer and the moving stage above, or top-down, where the UV source is above and the stage is beneath. The main layer, subsequent to being followed by the laser in the x and y-axis coordinated by examining mirrors, gets photograph relieved and connects to the structure stage. The stage then, at that point, gets across the z-axis to a degree which relies upon the width of each layer (dropped down if there should be an occurrence of bottom-up approach and raised in the event of top-down methodology). Following this, the liquid resin is rearranged over the recently solidified layer for its solidifying and the cycle is kept on building the 3D article. The item is then purged with liquor to dispose of the abundance resin. Post-restoring can be employed utilizing an UV broiler to strengthen the article (22,99)

3.3 Selective Laser Sintering (SLS)

SLS, a laser-based innovation, as the name recommends works by causing combination in the powder bed by a controlled examining laser beam[19]. During the printing system, the laser is coordinated to draw a particular pattern onto the outer layer of the powder bed. When the primary layer is finished, a roller appropriates another layer of powder on top of the previous one. The item is constructed layer-by-layer, which is then recovered from under the powder bed. SLS has for the most part been utilized in the arrangement of frameworks in bioengineering with proper biocompatible materials. There are not many definitions concentrated on involving SLS as 3D printing innovation.

In 2017, quick delivery and changed discharge details of paracetamol as a model medication and Kollicoat® IR or Eudragit® L100-55 as polymers were printed utilizing SLS innovation [20]. SLS utilizes lasers to solidify the polymers by expanding the temperature of the polymer above dissolving temperature. In any case, there should be interaction between the laser beam and the powder particles for the process to occur. As of late, in 2018, orally deteriorating tablets (ODTs) with paracetamol as a model medication and hydroxypropylmethylcellulose (HPMC) and kollidon® VA 64 as polymers alongside Candurin® gold sheen was effectively planned utilizing SLS innovation [21].

SLS has advantages of high-resolution printing and printing of medicine without the need of the solvent. In any case, high energy lasers might cause degradation of medications and polymers utilized. With appropriate investigation of this innovation for the different dosage form and the accessibility of polymers ready to assimilate laser-light might give an alternative technique of printing medications utilizing 3D innovation. This strategy utilizes powder streaming or powder bed to extended far layers of powder and all the while applying fluid cover drops with the assistance of inkjet printers (35). The ink (covers and APIs or folio arrangements) is sprinkled over a powder bed in two layered style to make the eventual outcome in a layer by layer design. The adaption of this procedure into drug fabricating is simpler than different strategies as powder and cover arrangements are generally utilized in the pharmaceutical industry. This strategy has its own drawbacks too. Extra drying is expected to eliminate dissolvable buildups. Overabundance powder gathers during printing prompting wastage. Additionally the mechanical strength of the medication conveyance framework is poor because of the permeable design of the powder (4, 35).

3.4 Nozzle-Based Deposition Systems

New innovations have been created to overcome the limitations of the past innovation. Nozzle based system comprise the blending of medications, polymers and other strong components before 3D printing. The blend is gone through a spout that certainly begins, layer by layer, the three-layered product. There are two sorts of printings as indicated by the kind of material utilized: FDM (Fused Deposition Modeling), which utilizes dissolved parts, and, PAM (Pressure-Assisted Microsyringes), which doesn't need the utilization of liquefied materials [4].

3.5 Fused Deposition Modelling 3D Printing

This is the expelling a thermoplastic fiber through high temperature spout into semi-solid fused state fiber in layer by layer style. The article is framed by layers of dissolved thermoplastic fiber expelled from the printer's head at specific directions as directed by PC programming. The material is warmed to simply over its conditioning point which is then expelled through a spout, and deposited layer by layer, solidifying in a moment. To this end it is likewise called Fused Filament Fabrication Drug stacking in the fiber is typically accomplished through incubation in natural solvents and poor drug loading may restrict its utilization to low dosed drugs (36)

Xuyu Chai et al (37) utilized combination statement demonstrating 3D printing to get ready intragastric floating sustained release tablets of domperidone. The medication was stacked into hydroxypropyl cellulose fiber utilizing hot soften expulsion. The fibers were then printed into empty organized tablets through changing the shell numbers and the infill rates.

A benefit of FDM over powder-bed printing is its higher resolution, which permits it to create more complicated platforms, and to accomplish a superior dosing precision. Other than this, FDM additionally offers great mechanical strength and the choice to acquire different delivery profiles of the printed dose structures by adjusting the infill rate, the model plan, or the surface region of the detailing.

Some drawbacks are the limited thermophiles materials options with good melt viscosity properties for extrusion, and the inability to use some APIs due to the high temperatures of the process [5].

Overall it is the most commonly used 3D printing technique under research because of its ability to create complex drugs with difficult geometrics, but the quality and speed of manufacture should be improved to make it effective in clinical practice.

3.6 Pressure-Assisted Microsyringe technology

This innovation depends on the utilization of a needle extruder that stores a viscous and semi-liquid material, through a compressed air cylinder, layer by layer, as per the designed geometry. Consistency, viscoelasticity, and the evident flexible limit are the key boundaries that decide the reproducibility of this strategy. It has advantages over other processes, as it has the possibility to work with a constant stream and at room temperature. It has additional impediments, similar to the utilization of solvents, which are frequently harmful to wellbeing and cause a loss of stability in specific APIs. Its most helpful applications are connected with tissue printing substitutes or frameworks of delicate tissues, as well as manufacture of complex drug delivery systems[4,22]

3.7 Extrusion based method

In the drug innovation region, hot-melt extrusion (HME) and expulsion of semisolid materials are well known processes [55]. This specialized technique is connected with progress probability of somewhat reasonable hardware and compact size, and expanding fame of printing strategy. Two different ways of printing strategy are notable [56]. 1. Extrusion cycle of semi-liquid materials or semi-solid (gels, glues) at room temperature or raised temperature.

2. Extrusion cycle of liquid celluloid or thermoplastic rod shape (fiber) materials.

In the two strategies, the materials are extruded from the nozzle and are spread in resulting layers on the form stage surface [57]. The distance of print head to fabricate plate is made on a characterized printing way and it is affected by the nozzle orifice diameter. The nature of the printed object is impacted by two-boundary nozzle hole measurement and print speed [58]. Another layer is applied when the print head or print plate moves along z-axis at the distance of

layer level [59]. Three-dimensional printers and the mechanical arrangement depend on printing materials. For the most part overall extrusion based strategy is utilized in 3D printing method.

4. ADVANTAGES

- High drug loading ability when compared to conventional dosage forms
- Accurate and precise dosing of potent drugs which are administered at small doses
- Reduces cost of production due to lesser material wastage
- Reasonable medication for challenging to formulate dynamic fixings like unfortunate water dissolvability, drugs With thin therapeutic window
- Medication can be prescribed to a patient in particular based on genetic variations, ethnic differences, age, gender and environment.
- In the event of multi drug treatment with numerous dosing routine, treatment can be altered to work on understanding adherence.
- As prompt and controlled discharge layers can be incorporated because of the adaptable plan and production of this measurement structure, it helps in picking the best remedial system for a person
- Avoids batch to batch varieties found in mass assembling of ordinary measurements structures.
- 3D printers occupy minimal space and are affordable.
- The ability to create tablets of any shape and size.
- The ability to set the dosage individually for each patient.
- The ability to regulate the number of active substances in the composition of the tablet, remove or replace individual components. This will assist many individuals with taking medication regardless of whether there are contraindications to an individual substance.
- The capacity to supplant countless medications with one tablet, which likewise decreases the recurrence of drug.
- The ability to control the process of release of active substances allows to slow down or accelerate the

effect of the drug, which will increase the effectiveness of tablets.

- The larger availability of drugs that can be obtained at any pharmacy with a 3D printer if a patient has a doctor's prescription.
- Eco-friendly production – in the process of manufacturing tablets with a 3D printer, no waste pollutes the environment.
- The ability to print small batches of drugs, saving money on the production and testing of drugs in comparison with the traditional method
- The manufacture of tablets on a 3D printer eliminates the possibility to mix up drugs or take other patient's tablets by mistake.

For the manufacture of drugs, a 3D printer is the only piece of required equipment. Therefore, mini-factories for the production of tablets can be in each local region. Such printers can even be installed in military hospitals and taken on space expeditions. This could help patients to get appropriate medications even during a pandemic, natural disaster or other events.

5. DISADVANTAGES

Minimum job opportunity

- Large structure is challenging for production.
- Limited number of ingredients are compatible with this technology
- The misuse of this technology is easily done.
- The copyright is another problem rising in printing replica from original product.
- Product liability.

6. LIMITATIONS AND CHALLENGES

- The excipients for 3D printing dosage form is limited as of conventional manufacturing process in case of process that uses heat. Biodegradable, biocompatible and stable excipients are required.
- As the complexity of structure of dosage form is increases, the software used for production is should be continuously required to updated. The mechanical equipment, working strategies and control framework should likewise be refreshed and streamlined to address the issues of the

different cycles, whether to prevent obstructing or advance item consistency.

- 3D printers used in pharmaceutical formulation preparation do not meet good manufacturing practice (GMP) standard and thus need to be validated to ensure they meet the required safety standards.
- There are different elements that can impact item properties with 3D assembling, from nozzle fineness and glue thickness to drying techniques and temperature. To ensure the mechanical properties are suitable, the equipment and control programmes must be enhanced, adhesive nozzles refined and printing process parameters optimised.
- There are some regulatory challenges in the quality of 3D printed drug delivery

7. APPLICATIONS

- The use of 3D printing in drug delivery is to compound and print personalized dosage forms.
- Personalized medicines are generally required for paediatric populations, geriatrics or patients exhibiting allergy to certain formulation components.
- SLS can be utilized in manufacturing particular measurements structures, for example, orally disintegrating (ODT), supported, broadened discharge, double delivery profiles, misuse obstacle details and undefined strong scattering.
- The 3DP innovation can deliver exceptionally permeable designs which can disintegrate shortly and meet breaking down time prerequisites of under 30 sec.
- Customary assembling includes different advances, for example, planning ASD by spray drying or hot liquefy expulsion followed by container filling or tablet pressure. SLS can create ASD measurement structures in a solitary advance with extremely low crystalline part, which can be additionally constrained by formulation parameters. The compliance to dosing regimen can be increased and accordingly unfavorable impacts might be reduced.
- The 3D printing is used for both mono and multidrug formulations.
- The innovation offers one of a kind capacities which are challenging to conventional manufacturing

8. CONCLUSION

- 3D Printing technology is emerging as a new field for advanced drug delivery with development of personalized medication. 3D Printing technology will revolutionize the pharmaceutical manufacturing style and formulation techniques and has become a useful and potential tool for the pharmaceutical sector, leading to personalized medicine focused on the patients' needs
- However, there is still a significant barrier to ensure that 3D printed medicines have the same efficacy, safety, and stability as the pharmaceuticals which conventionally manufactured by the Pharmaceutical Industry. Regarding the establishment of guidelines, laws, quality systems and safety of use and consumption of 3D printed medicines, it is a great challenge for the regulatory authorities involving various obstructions, given the conventional prerequisites by the drug area.
- In future 3D printing approach will be utilized to fabricate and engineer various novel dosage forms. As the commercial production of novel dosage forms is still difficult to formulate; creating customized medicine, enhanced drug discharge from measurements structure, compacting or keeping away from drug incompatibility, insurance of biomolecules during manufacture, construction of multiple drug dosage form and multiple release dosage forms will be taken to a new era through 3D printing technology.

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