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3-D Printing In Pharmaceutical Sector- An Overview

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ABSTRACT:
The pharmaceutical industry is moving forward at a rapid pace. Modern technology enabled the development of new dosage forms for targeted therapy. However, production of new dosage forms on an industrial scale is limited and the industry they still run on conventional drug delivery systems, especially modified tablets. The introduction of 3D printing technology in the pharmaceutical industry was opened new horizons in research and development of printed materials and devices. The main advantages of 3D printing technology lie in the production of small series drugs, each with tailored doses, shapes, sizes and release characteristics. The manufacturing drugs in this way may eventually lead to the concept of personalization cures become reality. This chapter provides an overview of how to 3D print technology has expanded from initial unit operations to developed final products.

KEY WORDS :3-D printing , manufacturing , 3D print technology, printed materials and devices

I. INTRODUCTION TO 3D PRINTING

The concept is gaining huge interest in both academia and industry three-dimensional (3D) printing (3DP) technology. Domains such as aviation, engineering, FMCG, architecture, military, fashion industry, chemical industry and medicine are by no means untouched by this technology . 3DP has a wide range applications such as tissue design, organ printing, diagnostics, biomedical device manufacturing, and drug and delivery system design in the medical field . From data obtained by various techniques such as computed tomography (CT). and magnetic resonance imaging (MRI), complex anatomical and medical structures can be made according to the patient's needs . Replacement and repair defective organs like kidney, heart, etc. or all of them together form a new organ that mimics the same features as the original are some other uses of this technology . In this technology, the concept is transformed into a prototype by taking help from 3D computer-aided design (CAD) files, i.e. digitally controlled and customized the product can be produced . This technology uses a bottom-up approach which layers of materials such as living cells, wood, alloys, thermoplastics, metals, etc. they are placed on top of each other to create the desired 3D object . Therefore, 3D printing is also known by other terminologies such as layered manufacturing, additive manufacturing, computer-automated manufacturing, rapid prototyping, or solid freeform technology (SFF) [1] [2] [3]

II. 3D PRINTING PROCEDURE

✓ First, virtual 3D design of the object using digital design software such as On shape, It is created by Solidworks, Creo parametric, Autocad, Autodesk, etc .

✓ This digital model is then converted into a digital file format (.STL) that is valid for standard tessellation language or stereolithography .

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✓ Triangulated faces provide information about the surface of the 3D model which is present in the file (.STL) .

✓ The (.STL) file is converted to a G file by dividing the design into series 2D horizontal slices using specialized slicer software that is installed in the 3D printer .

✓ Now the printhead is moved in the x-y axis to create the base of the 3D object.

✓ The printhead can now move in the z-axis, saving itlayers of the required material, creating a complete 3D object.

✓ The maximum number of 3D printing technologies is compatible with the (.STL) file.format. Some errors may occur during the conversion of the 3D model to .STLdigital file; therefore software like Magics (Materialise) can be used to fix it.errors during conversion. File formats other than .STL, such as Additive Manufacturing File Format (AMF) and 3D Manufacturing Format (3MF), are used in the same way as .STLthey do not have information about the type of material, its color, structure, properties, and other functions [3] [2]

III. YEAR- MAJOR DEVELOPMENT

1980- Dr. Hideo Kodama filed first patent for RP technology
1984 - Stereo lithography apparatus (SLA) was invented by Charles Hull
1986 - Carl Deckard invented apparatus for producing parts by selective sintering
1989 - Patent was granted to Carl Deckard for SLA
1990 - Fused deposition modeling (FDM)
1992 - First SLA machine was produced using 3D system
1993 - 3D printing patent was granted to E.M Sachs
1996 - Clinical application of biomaterials for tissue regeneration
1999 - Luke Massella received first 3D printed bladder which was an amalgamation of 3D printed biomaterials and his own cells
2000-MCP technologies introduced the SLM technology
2002 - Miniature functional kidney was fabricated
2003 - Term organ printing was coined
2004 - Dr. Bowyer conceived the RepRap concept of an open-source, self-replicating 3D printer
2005 - First color 3D printer was introduced by Z Corp
2007 - Selective layer customization and on-demand manufacturing of industrial parts
2009 - Organovo, Inc., announced the release of data on the first fully bioprinted blood vessels
2011 - 3D printing was applied in gold and silver World's first 3D printed car, robotic aircarft was introduced
2012- Extrusion-based bioprinting for an artificial liver 3D -printed prosthetic jaw was implanted
2013- SolidConcepts produced a 3D printed metal gun
2014- Implementation of multi-arm bioprinter to integrate tissue fabrication with printed vasculature
2015 - First 3D printed pill was approved by US FDA Organovo announced the release of data on the first fully bioprinted kidney [3]

IV. FUSED DEPOSISTION MODELLING :

3D printing has revolutionized various fields of human activity in the last few decades, which is one of the pillars of the fourth industrial revolution. In recent years, the use of this

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technology in the preparation of medicines has shown such potential. This is why experts from all over the world are pointing out that the pharmaceutical industry has finally been given, two at a time century an opportunity for a significant technological leap .

In addition, personalized 3D printed medicines appear to be a missing part of the cycle of care trending telemedicine. Launched as the future of medicine, telemedicine has the capacity expand access to health, making it possible to contact patients from the most needy areas of the world with the most qualified doctors on the planet using the latest technological resources that they enable remote consultations and accurate diagnoses. 3D printed drugs offer pharmacotherapeutics treatment in response to a virtual prescription, paving the way for a digital pharmacy which completes the cycle of care that may definitively mark the 21st century [5] [12]

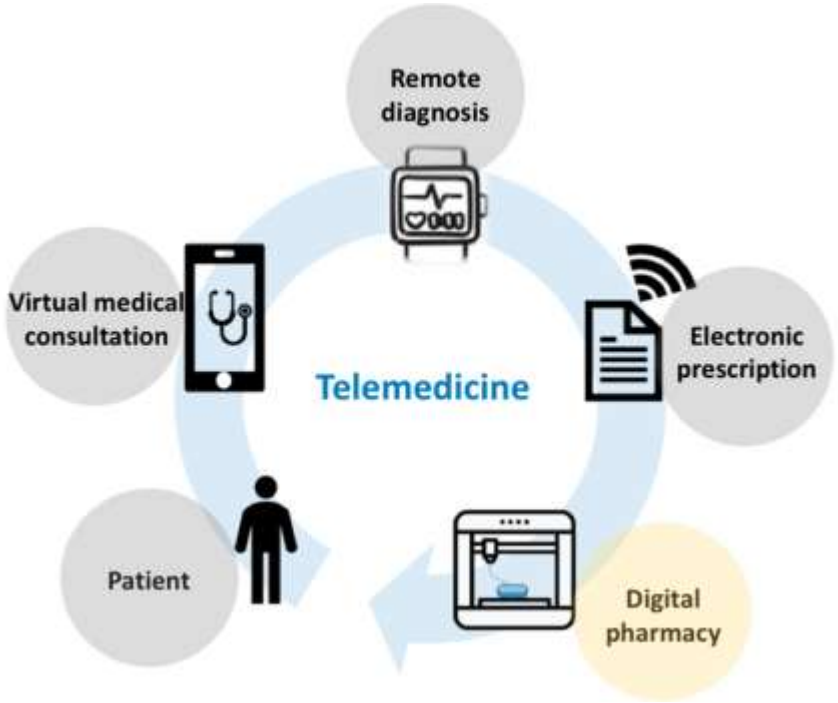

FIG 1 : FLOW CHART OF THE TELE MEDICINE [7]

V. THE VERSATILITY OF FDM 3D PRINTING FOR DRUG DELIVERY DEVICES

FDM 3D printers can produce a wide variety of different drug delivery devices, as evidenced recently published scientific reports on the subject. Searching for the combined terms "3D printing" "FDM" and "drug" in SciFinder® for the years 2014 to 2018 resulted in 54 papers on the topic. These works provide insight into the potential of the technology .

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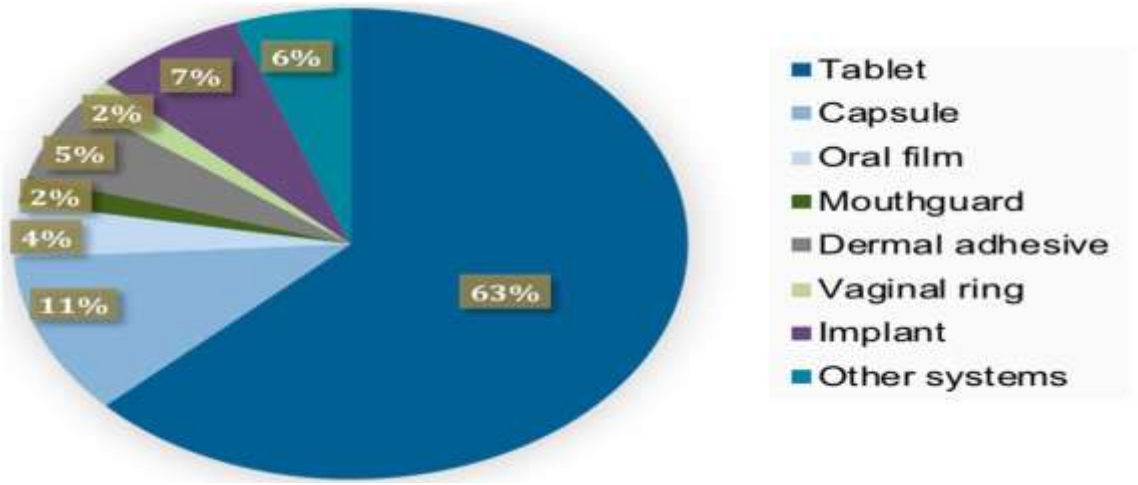

FIG 2:PROPORTION OFDRUG DELIVERY DEVICES (n = 54) THAT COULD BE PRINTEDUSING MELT DEPOSITION [13]

As expected, most studies investigated the development of oral dosage forms with tablets the largest share of cakes (63%), followed by capsules (11%). Oral pharmaceutical preparation presentations represent more than 40% of medicinal products on the market . Simple control printing variables may offer interesting therapeutic benefits to 3D printed medicinal products. Accuracy personalization of dosage is undoubtedly one of the great advantages of FDM 3D printing technology, as has been conveniently explored in the case of Warfarin tablets. This active pharmaceutical ingredient was printed in tailored doses safely administered to rats, eliminating the need for division and facilitation dose progression and regression as typically used in treatment with this drug. Another major approach was to print domperidone discs with low fill, increasing the duration of administration of the drug in the stomach through flotation, thereby reducing the frequency of administration of tablets income . In addition, several drugs can easily be associated with the same pharmaceutical unit, e.g as in the case of a "polypill" imprinted with intercalated layers of paracetamol and caffeine, leading to simultaneous release of both drugs . [5] [3] [16]

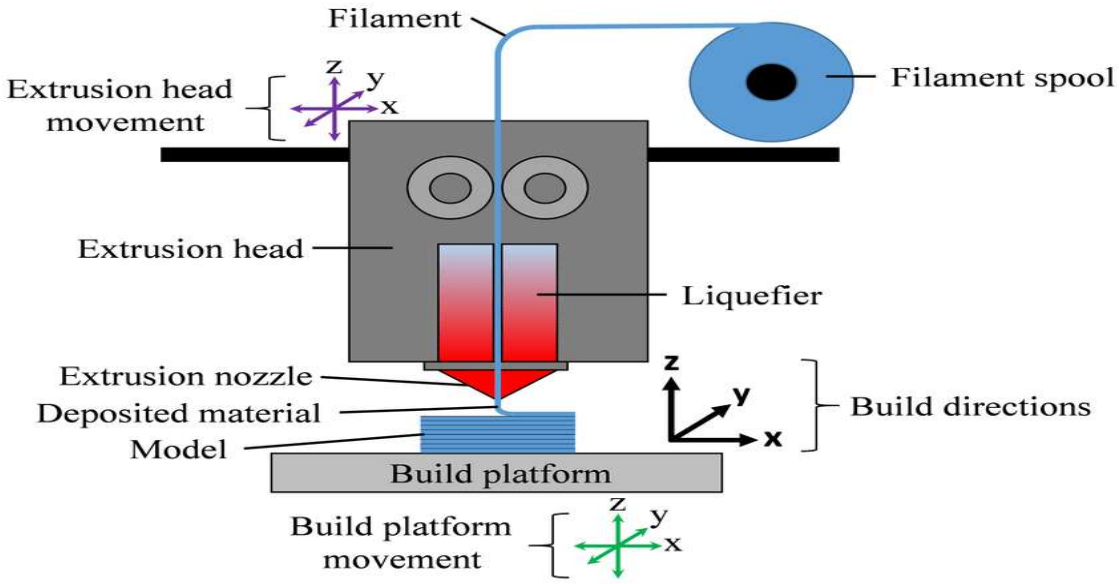

FIG 3: 3D PRINTING BY EXTRUSION NOZZLE METHOD [7]

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VI. THREE-DIMENSIONAL BIOPRINTING

Three-dimensional bioprinting includes a variety of 3DP modes and is used in various fieldspharmaceutical studies and tissue engineering. Contemporary treatment of bone fractures and bone defects include bone grafts or metal prosthetic implants that may be limiting for substantial reasons tissue loss from surgery, prolonged recovery periods and donor site morbidity. That's why there a new way of treating bone fractures and defects is needed. Kondiah et al., investigated 3D bio-printed drug-delivering pseudo-bones sca olds that were made of polypropylene fumarate (PPF), free radical polymerized polyethylene glycol-polycaprolactone (PEG-PCL-PEG) and Pluronic (PF127). Sca olds were optimized using MATLAB software and artificial neural networks (ANN) with ANN optimized sca olds showing controlled release of simvastatin for more than 20 days. Simvastatin has been incorporated into the sca sera due to its ability to promote bone healing and repair. The bioprinted samples were tested on fractured human clavicles. Matrix analysis showed that after the application of sca olds, the fractured bone had a similar matrix hardness and matrix resistance to healthy human clavicles. This highlights the potential for bioprinted pseudo bone scales to fill the fracture sites, resulting in great fracture bone adhesion and repair to the intended mechanical strength . Andriotis et al. developed a 3D bioprinted wound dressing using pectin-based bio-ink. The properties of pectin bioinks were optimized by adding chitosan and cyclodextrin inclusion complexes with propolis extract to improve antimicrobial properties and wound healing inks. The inks were able to form transparent films upon drying and showed rapid disintegration in contact with an aqueous medium. In vitro wound healing studies have shown that the add of cyclodextrin/propolis extract (CCP) inclusion complexes improved wound healing and also antimicrobial properties of patches with a 95% increase in the antimicrobial activity of films. The addition of CCP to a certain point also increased the bioadhesive properties of the dressing. However, at higher CCP concentrations, cell viability was reduced by >10% w/w. He can have that was due to the presence of insoluble film material at higher CPP concns., which could physically block the cells. Overall, this study was able to effectively show the potential for use biodegradable, 3D printable inks for the production of direct and indirect wound dressings[13] [1][14].

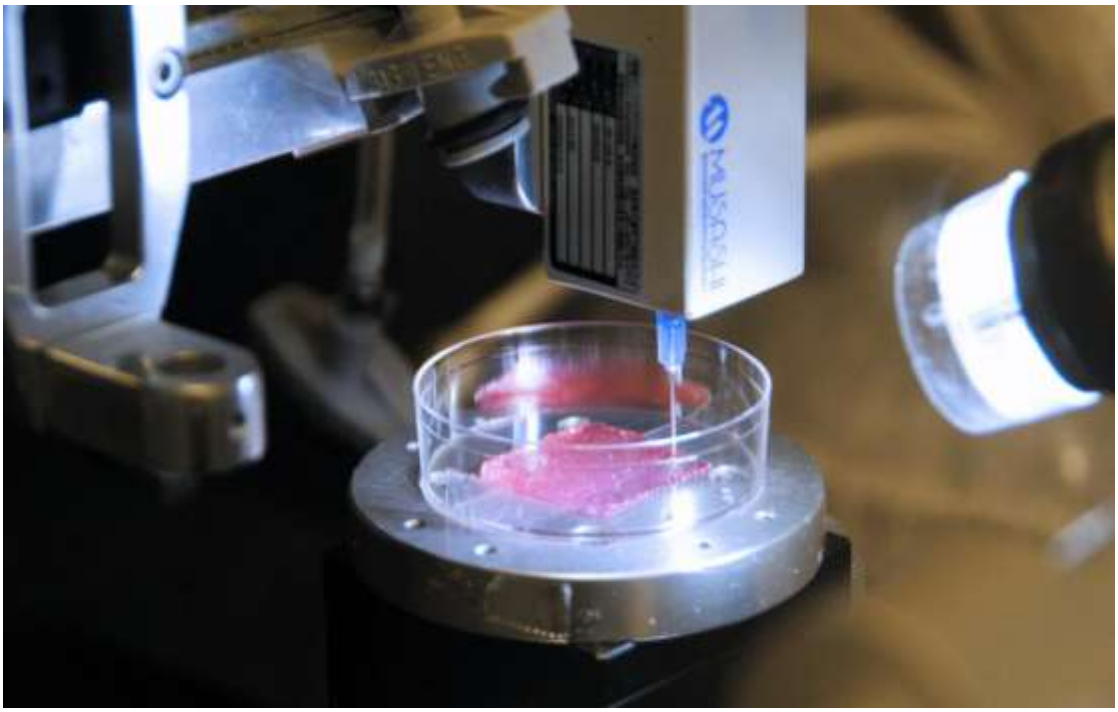

FIG 4: 3D PRINTING OF THREE-DIMENSIONAL BIO-PRINTING

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VII. STEREOLITHOGRAPHY (SLA)

Healy et al., used SLA as an AM process to create 2.5% and 5% oral dosage forms aspirin and paracetamol. A new photopolymerizable resin was used and drugs were printed with it SLA 3D printer. Healy et al. were able to produce 28 drug dosage forms in one press run potential for mass production of oral dosage forms through SLA. This study also highlighted effect of drug addition on the dimensions of printed dosage forms with printed form dimensions vary by design. This highlights an area that requires future research, about how adding materials can affect the printed product. The results of the release studies showed this highlights that there was an increased release of the active drug when the drug content increased the potential for patient-specific drugs to be created with the ability to modulate drug release. Overall, this study effectively highlighted the potential for creating solid dosage forms using SLA printing, with research leading to the ability to create personalized medicine and abilities modulate drug release from printed products . Robles-Martinez et al. were able to construct a new SLA printing method that allowed production of multilayer tablets (polypills) that had flexible drug content and shape. Drugs paracetamol, caein, naproxen, chloramphenicol, prednisolone and aspirin were chosen for the work. Three different tablet shapes were printed: a cylinder, a ring, and a ring with soluble filler. Raman microscopy confirmed the spatial separation of drugs but also showed the ability of certain drugs (naproxen, aspirin and paracetamol) for use between layers due to their solid phase properties. Dissolution tests showed that polypill geometry and excipient type influence drug release allowing distinct release profiles for each of the six drugs. This study showed the possibility of use SLA 3DP for the production of multi-drug tablets to improve personalization for patients .[8] [1][17]

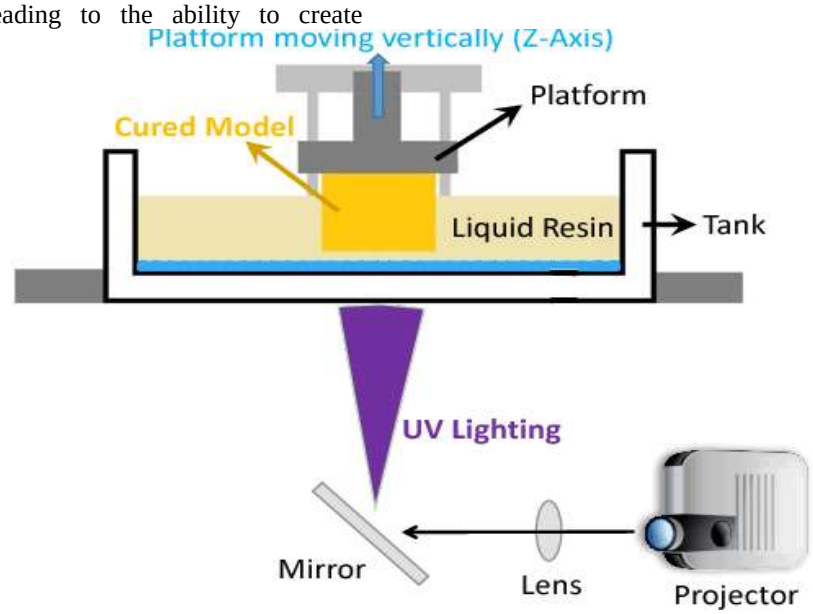

FIG 5: 3D PRINTING BY METHOD OF STREOLITHOGRAPHY

VIII. OTHER FORMS OF ADDITIVE MANUFACTURING

Selective Laser Sintering (SLS)

Similar to SLA, this AM method works with lasers, but the powder materials are bonded together, while SLA works with resin. Awad et al., first used SLS 3DP to fabricate small orals dosage forms with modified release properties. They made individual mini prints using paracetamol as a model drug and dual miniprints where paracetamol is combined with ibuprofen. For of individual miniprintlets, ethyl cellulose (EC) was used as the main polymer matrix. When dual miniprintlets one layer contained EC for sustained release while the other layer contained Kollicoat IR (graft copolymer containing PEG:PVA, 1:3) for immediate release. In order to assess The fancy size has dissolution properties, mini prints of two different diameters, 1 mm and 2 mm, were developed. Individual miniprints showed a slow release of paracetamol, which was reduced while increasing the diameter. For dual miniprints, the diameter has no effect on paracetamol release profile. This work demonstrates the possibility of using SLS 3D printing to combine more Active Pharmaceutical

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Ingredients (API) with different release properties in a single dosage form .

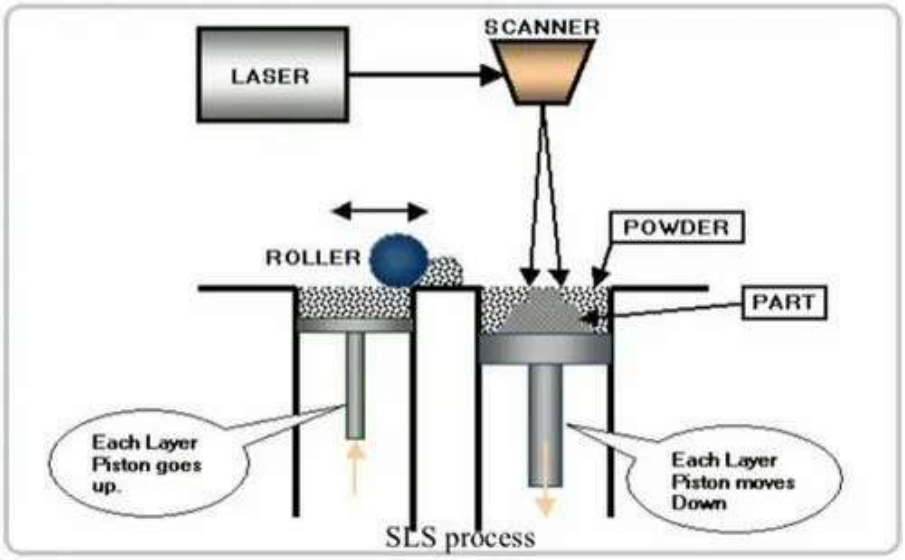

FIG 6 : SELECTIVE LASER SINTERING [2]

Digital Light Processing (DLP)

DLP is another 3DP method that is similar to SLA. However, it is a resin-based method rather than using a laser-focused UV beam, DLP uses UV light from a projector to cure each layer of 3D printed product. Madzarevic et al. prepared ibuprofen tablets using DLP 3DP technology. Eleven the formulations were prepared according to the D-optimal mix design from the Design Expert software. It has been found that increasing the water content results in an increase in print time. Two artificial one's neural networks (STATISTICA 7.0 and MATLAB R2014b) were used to evaluate how ingredients and printing parameters affect Ibuprofen release. Data obtained from these two softwares were compared with that obtained experimentally. Drug release was predicted with STATISTICA 7.0 was very similar to that obtained experimentally. [2] [9]

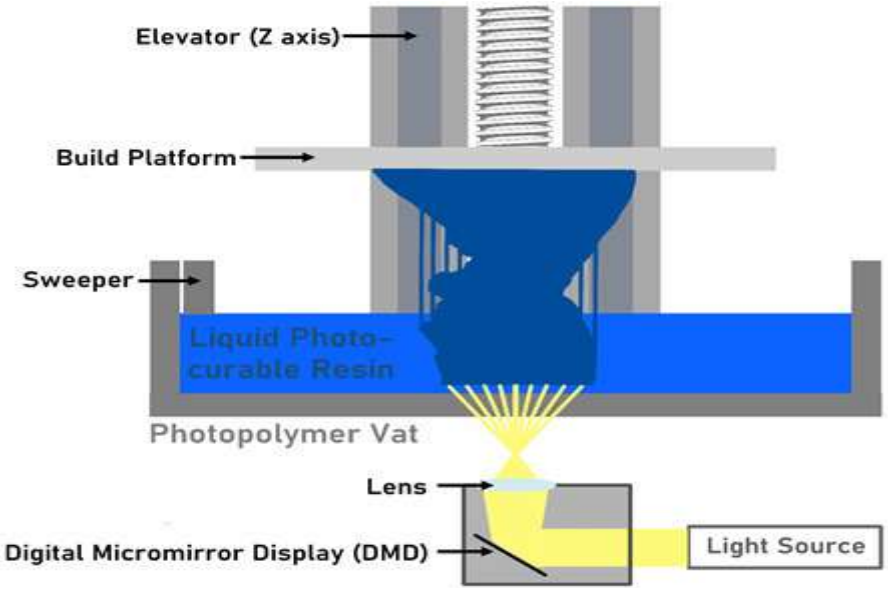

FIG 7 : DIGITAL LASER PROCESSING

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IX. MANUFACTURING TRENDS FOR FABRICATION OF 3D PRINTED MEDICAL PRODUCTS:

A 3D printing medical product can be generated using a kit of various processes that replace the ink with the desired one drug formulation and then spray it on the appropriate substrate in an additive process. The substrate can be an edible leaf with a functionalized structure of specific hydrophobicity/hydrophilicity, porosity and permeability. The main challenge of 3D printing technology isconvert starting materials (drug and excipients) into "curable ink" or printable material .The first step of producing a 3D object includes design of a digital model of the required 3D product a special CAD (software comes in many forms and license). Next, the digital design is exported into a readable form format for a system that is predominantly stereo lithography (STL) file. Then, slicer (3D printing software) converts the STL file into a series of thin layers with instructions adapted to generate a 3D object.

During printing, then the print head moves and the formulation ink is spread over the next layers on a built tray that will form the base for object. The process continues until the desired 3D

the product is constructed. Finally, a 3D product may require movement solvent residues, excess powder, polishing and sintering which occur in the step after printing .

3D printing has the potential to process versatile materials such as polymers, waxes, metals and hydrogels. The technique is even used to craft items made of a single material or a combination of materials, where each material can be stored separately print head or other application steps . While 3D printing is widely used for products which were created layer by layer, other terms like[10] [11] [7]

such as rapid prototyping, free-form manufacturing and additive manufacturing has also emerged as another names and can be labeled as 3D printing. These the terms were introduced by the manufacturing companies reflect special design for 3D products . AND a summary of the 3D printing process is shown

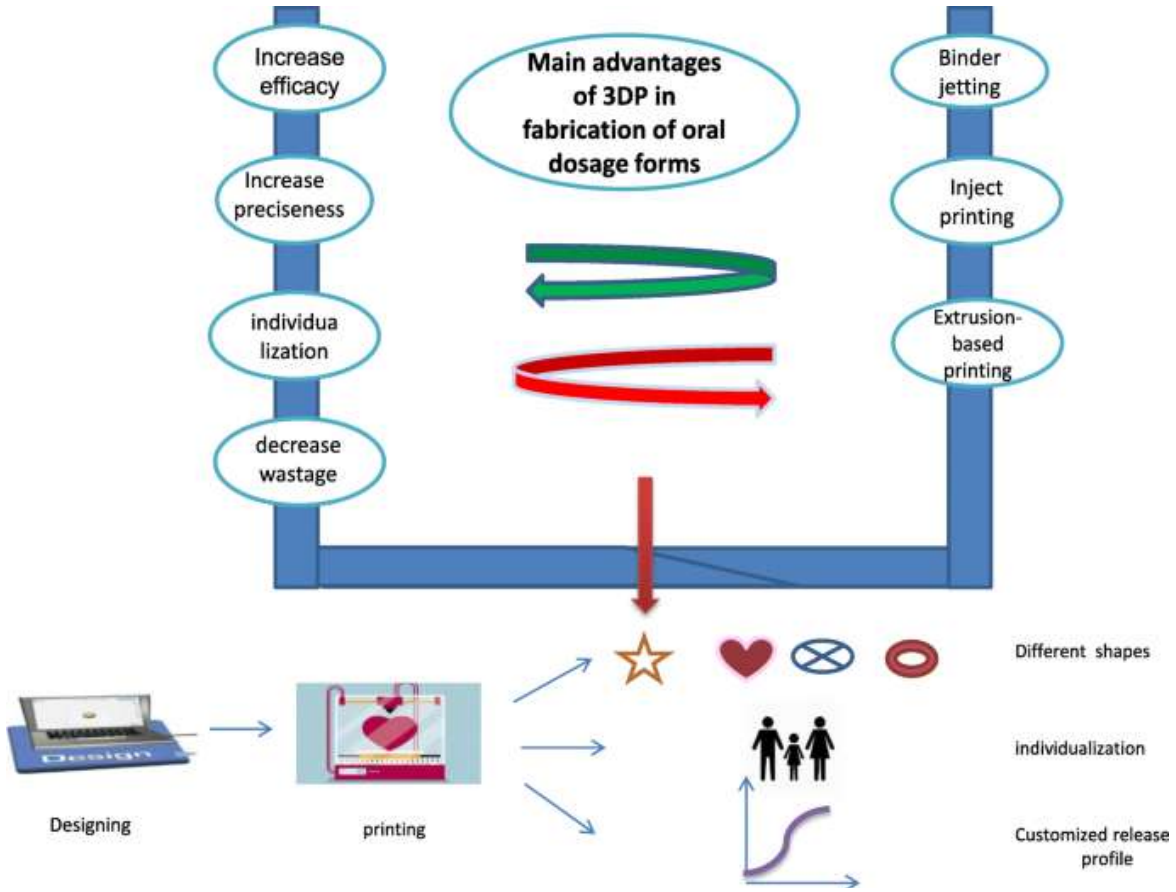

FIG 8 : FABRICATION OF LASER PRINTING

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X. INKJET PRINTING :

The 3D inkjet printing process is similar to other 3D printing processes in that it proceeds through layer-by-layer deposition. Printing instructions in each layer are generated from a 3D mechanical model for your product, just as is done with popular fused deposition modeling (FDM) systems[3] [9]

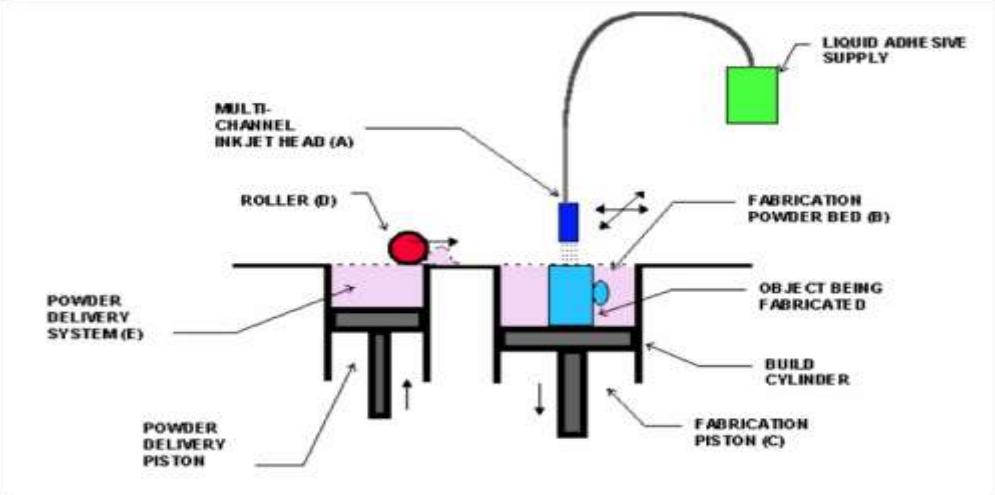

FIG 9: INKJET PRINTING [3]

An inkjet print head moves across a bed of powder, selectively depositing a liquid binding material. A thin layer of powder is spread across the completed section and the process is repeated with each layer adhering to the last.

XI. THERMAL INKJET (TIJ)

Thermal Inkjet (TIJ) printers use standard ink cartridge systems and do not require any bottles of inks or solvent, making thermal inkjet printers clean and simple to use.

Thermal inkjet printers use a drop ejection process, storing ink in a cartridge that regulates the pressure of the fluid. Inks are then delivered to the firing chamber and heated to more than 1,000,000 °C/second by an electric resistor. A 0.1 micrometer thick film of ink is heated to around 340°C, from which a bubble is formed to expel the ink. A droplet breaks away from this bubble causing it to collapse, the firing chamber then refills as the whole process repeats.

Our TIJ printers can help reduce production costs by removing labels and reducing SKUs on pre-printed packaging. While error-free coding will maximise uptime and reduce wastage.[13]

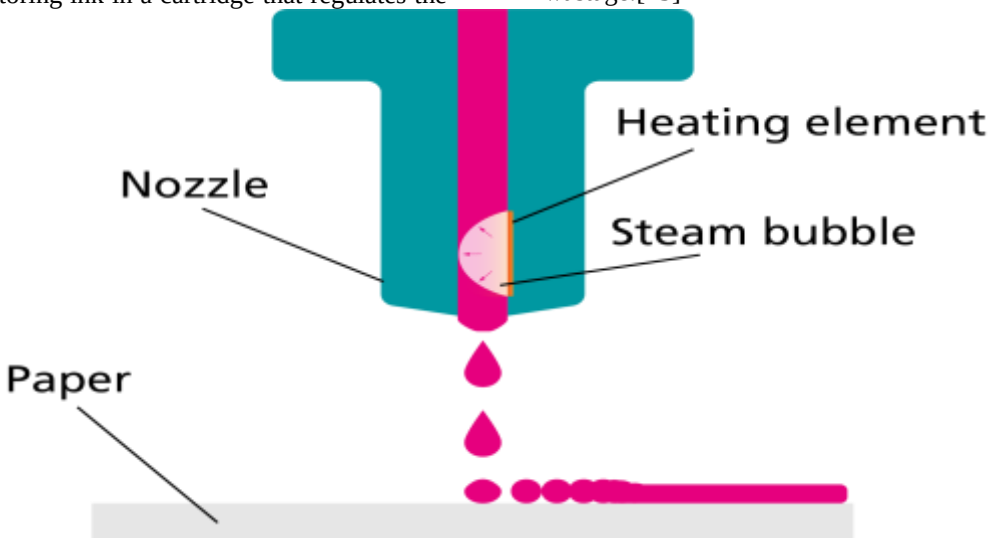

FIG 10 : THERMAL INKJET PRINTING

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XII. ANATOMICAL MODELS FOR SURGICAL PREPARATIONS

To have successful medical procedures, patient knowledge specific anatomy prior to medical surgery is necessary due to individual differences and complex human anatomy. 3D printed models helped a lot with this respect, which makes them a vital tool for surgical methods . One of the most complex structures of the human body is the head, whose 3D printed neuroanatomical models are a great help to neurosurgeons.

Sometimes, it is very difficult to get detailed information about the relationships between the skulls architecture, cerebral structure, cranial nerves and vessels from radiographic 2Dand even a slight error in a medical procedure can be fatal. Here comes the role of 3D models that are more realistic and provide a detailed comparison and contrast between normal brain structure and brain with deformation or lesions that suggest safer procedures to surgeons.

• Japan's Kobe University Hospital used 3D printing for a liver transplant model using replicas of the patient's own organs to find out exactly howto produce a donor liver with the least loss of tissue .

• 3D printed model of calcified aorta for surgical planning of plaque removalwas used by surgeons.

• Used to study the aerosol delivery of medicine to the lungs and airways of premature babies reconstructed using 3D printing technology [5] [1][14]

Direct

It includes a pattern generating device that moves according to instructions a computer-controlled translation stage so that the layers are put on top of each other to achieve a 3D microstructure. [3] [16] [1]

Dose on zip

This technology provides a personalized dose in addition to delivering a high drug content with high levels of disintegration and dissolution during manufacture highly porous material . [10] [1]

Bath photopolymerization

It is a light-induced polymerization where materials such as photopolymers, radiation-curable resins, and liquid are collected in vats that are gradually cured. into layers, one layer at a time by irradiation with a light source, thereby ensuring 2D patterned layer. This includes techniques such as stereolithography (SLA), digital light processing (DLP) and continuous direct light processing (CDLP).

Depending on the orientation of the light source and the surface where the photoactive resin is polymerized, SLA can be divided into two differentconfigurations:

1. Bath configuration (free surface zoom)
2. Bat configuration (restricted surface approach) [11] [14]

Advantages of 3D printing in the pharmaceutical field:

1. Increased productivity: 3D printing works faster than traditional methods, especially when it comes to manufacturing items such as prosthetics and implants, with the added benefit of better resolution, repeatability, greater accuracy and reliability
2. Customization and Personalization: One of the pioneering advantages of this technology is the freedom to produce customized medical equipment and products. Custom implants, prosthetics, surgical instruments, preparations can be a great benefit for patients and doctors
3. Increased cost effectiveness: Objects produced by 3D printing have low costs. It is an advantage for small production units or for companies that produce highly complex products or parts because almost all ingredients are cheap. Eliminating the use of unnecessary resources can also be a cost of production reduced. For example, 20mg tablets could potentially be formulated as 1mg tabletsas needed. 3DP enables controlled droplet size, complex drug release profiles, potencydosing and multiple dosing [4] [1] [7]

Disadvantages of 3D printing:

1. In inkjet printing, the correct ink flow can only be achieved with the ink which has exact viscosity.
2. The material for the composition of the ink should have the property of self-bonding, but it shouldnot bind to other elements of the printer. In some formulations, when the ink does not have sufficient self-binding property or binds with other elementsprinter, the resulting formulation does not have the required hardness
3. Drug release rate may be affected by ink binding with other printer materials [8] [1] [5]

XIII. CONCLUSION :

- We think in the future this 3Dprinting technology will really help the economy and benefit it tremendously. We will have results

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like never before. The advancement in the technology will help our society in many ways 3D printing is evolving from its infantile manufacturing roots into the realm of medicine. While its uses are still experimental and many challenges still exist before implementation, the technology exhibits enormous promise to the humanity.

- 3D printing is a layer-by-layer, automated process capable of producing complex personalized products on demand. In recent years researchers proposed dozens of 3Dprinting innovations to improve the safety efficacy, and tolerability of medicines The commercialfeasibility of this technology has been shown through the FDA approval of a 3Dprinted drug production. We can hope for further improvements in this field in future.

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