PHARMSOL NEWS

THREE-DIMENSIONAL PRINTING (3DP): AN INNOVATIVE AND PROMISING TECHNOLOGY IN PHARMACEUTICAL INDUSTRY

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Three-dimensional printing (3DP) or additive manufacturing is an innovative and promising technology that has the future potential to revolutionize and cause a paradigm shift in pharmaceutical industry by moving away from conventional mass production of medicine towards tailor made pharmaceutical products that are personalized to each individual.

It also provides a unique platform that can produce medicines in response to changing situations and patient needs in a rapid, digital and decentralized manner which can be utilized for development of complex products with modified drug release profiles which requires highest precision and quality with the reduction in the manufacturing process time.

This technology is used to describe 3D products manufactured on a digital design platform in a layer-by-layer fashion.

Advantages

- Increases efficacy and preciseness
- Chance for personalized medication
- Flexibility in customized release profiles
- Multiple active drug pharmaceutical ingredients (API) into one dosage form.
- Quicker pre-medical assessment of new drugs
- Non-contact processing
- Single-step process with low manufacturing cost
- Decreases wastage compared to conventional manufacturing process.

Basic steps involved in 3D technology:

Designing a digital model of the desired 3D product by a special Computer Aided Design (CAD)

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Digital design is exported to a readable format for a system which is mainly a stereolithography (STL) file

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A slicer (3D printing software) transfers the STL file into a series of thin layers with the instruction tailored to generate the 3D object

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Preparing pharmaceutical formulation ink such as filament, binder solution, granulation, paste etc., based on the technology used

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While printing, the printer head moves and the formulation ink decomposes onto successive layers on a built tray which will be

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3D product may require movement of solvent residues, excess powder, polishing, and sintering which occur in the post-printing step

3D technology methods in pharmaceutical formulation:
Based on the energy source, material source and other mechanical characteristics various 3DP methods have been designed.

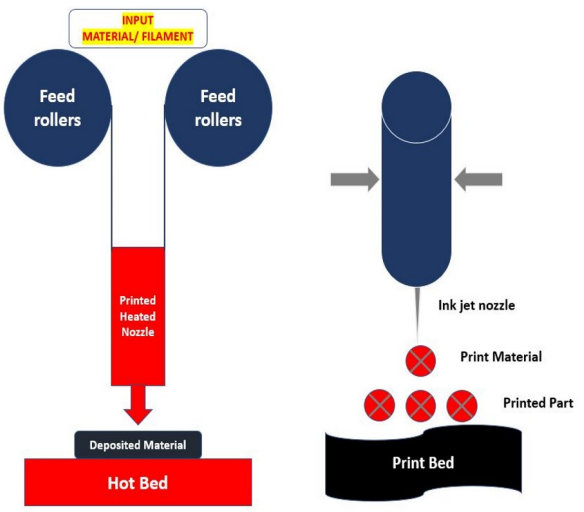
1) **Extrusion based**
   a) Fused deposition modelling (FDM)
   b) Direct Ink writing (DIW)
2) **Powder based**
   a) Selective laser sintering (SLS)
3) **Droplet based**
   a) Inkjet
   b) Binder jetting (BJ)
4) **Vat photopolymerization based**
   a) Stereolithography
   b) Digital light processing (DLP)

These methods vary in their function and productivity based on the way, a layer deposits on another layer.
In extrusion-based printing, the ink, i.e., the printable material in the form of a viscous melt or liquid (or slurry), is extruded through a nozzle forming individual struts (or lines) that solidify onto the build substrate. The nozzle follows a custom-designed line path determined by the g-code (computer-aided design) to form a 3D object in a layer-by-layer manner.

In Powder-based printing technology a laser beam moves over the powder bath raising the temperature of the powder particles on its path to sinter or fuse the particles spatially. Once a single layer is formed, the build platform moves down and a fresh layer of powder is applied from the top, and the process is repeated.

In Droplet-based printing technologies the ink is a low viscosity solution (below 10cps, which is ejected as an individual droplet (25–100 µm in diameter; 1–100 picolitres). In inkjet printing, the droplet is required to be placed on the print substrate and coalesce with the adjacent droplets to form a solid line.

In vat photopolymerization-based printing, the ink is a photocurable viscous liquid (i.e., a prepolymer, macromer, or a monomer). In traditional SLA printing, a beam of light (e.g., UV or laser) moves over the vat and cures ink spatially. In DLP printing, rather than using a single beam of light, a whole print layer is directly projected, leading to curing of a print layer at each exposure.



Basic Mechanism of 3D printing technologies commonly used:

(a) Extrusion based 3D printing and

(b) Droplet based ink & binder jetting,

3 DP Application in pharmaceutical industry:
Various formulations including oral solid dosage forms, implants, microneedle and hydrogel etc., can be developed using this technology using commonly used polymers, diluents, binding agents, disintegrants, lubricants, additives, plasticizers.

Challenges of 3D printing on formulation development:

- Availability of Non-toxic, biodegradable, biocompatible and stable excipients
- Development of printing software, operating procedures, control system and instruments
- Optimizing the mechanical and physicochemical properties of products, such as the viscosity and surface tension of the adhesives, fineness of the nozzle etc.,
- Regulatory landscape as no regulations or guidelines regarding 3D-printed medicines are currently available.

First commercial pharmaceutical product approved using 3DP technology is SPRITAM® levetiracetam by Zipdose® technology (by Apracia) for oral use in 2015 by USFDA. Zipdose technology engages both formulation science and critical 3 DP technology in product manufacturing.

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