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FORMULATION STRATEGIES FOR SELECTIVE LASER SINTERING IN PHARMACEUTICAL 3D PRINTING

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Abstract
Selective Laser Sintering (SLS) is an advanced powder-based 3D printing technology that has gained significant attention in pharmaceutical formulation development. In SLS, a high-energy laser selectively sinters powdered materials layer by layer to form solid dosage forms without the need for solvents or binders. The formulation used in SLS printing plays a crucial role in determining the quality, mechanical strength, drug release behavior, and stability of the final product. Typically, SLS formulations consist of a drug, polymeric carriers such as polyvinyl alcohol (PVA), polyethylene glycol (PEG), or polycaprolactone (PCL), and suitable additives like fillers or absorbers to enhance laser energy absorption. The particle size, flow properties, and thermal characteristics of the powder blend are critical parameters affecting printability and sintering efficiency. SLS enables the production of personalized dosage forms with complex geometries, controlled porosity, and modified drug release profiles. Additionally, it allows the fabrication of immediate-release, sustained-release, and multi-drug dosage forms. Despite its advantages, challenges such as thermal degradation of drugs and limited availability of pharmaceutical-grade polymers remain. Overall, SLS 3D printing formulation represents a promising approach for personalized medicine and innovative drug delivery systems.

Keywords: *Selective Laser Sintering (SLS), Powder-based additive manufacturing, Polymer powder formulation, particle size distribution, Flowability of powders.*

1. INTRODUCTION

Using a computerized 3D design as a guide, three-dimensional printing, commonly referred to as additive manufacturing, is a revolutionary technology that builds things layer by layer [1]. Over the past ten years, three-dimensional printing (3DP) has been more and more popular in the healthcare industry because of its immense potential to address a number of the drawbacks of traditional drug delivery and therapeutic technologies. Over the years, the pharmaceutical and biomedical industries have developed and deployed a variety of printing processes, including binder jetting, fused deposition modeling (FDM), powder bed fusion (PBF), and vat polymerization. Hideo Kodama created a technique in 1981 that used UV light and photo-hardening polymers to create 3D sculptures. Stereolithography, the first 3D printing method developed by Chuck W. Hull a few years later, was sold by 3D systems [2]. At first, the applications of these technologies were restrictedtion because of high prices and poor innovations printing quality. In technology have led to the creation of affordable 3D printers with high print speeds and precision that have previously worked in a wide range of industries, including Over the past two decades, biomedical, space, education, automotive, and art decades [3].

Presently, 3D printing is being used extensively in many different industries to produce things like toys, food, fashion items, high-end art, models, and airplane parts. Anatomical prototypes for surgical planning, medical education, prosthetic device development, medical devices, and bioprinting using viable cells, biomaterials, and biological molecules have all been produced in the healthcare industry using 3D printing [4].

The process of creating three-dimensional (3D) objects layer by layer from a computer-aided design (CAD) is known as additive manufacturing or 3D printing. The information required for the spatial geometry of the object to be manufactured using CAD programs is contained in the stereolithography file (stlfile), which is created from the CAD file. Following the.stl file is split up into several segments, including the slice file (SLI segment), which is then sent to the 3D printer to be printed [5]. The pharmaceutical industry could shift from mass-producing tablets and capsules in a one-size-fits-all manner to creating customized dosage forms

that meet patient clinical requirements thanks to the majority of 3D printing technology. The most widely used 3D printing technology is by far extrusion-based technologies like FDM. The technology was created. Stratasy's co-founder Scott Crump created it, and it was patented in 1989 [6].

2. MATERIALS AND REQUIREMENT

2.1. SLS Printer and Process Parameters

It is noteworthy that all 14 reviewed studies employed selective laser sintering (SLS) printers equipped with a blue diode laser operating at 445–450 nm. Among these, 13 studies reported the use of the Sintratec kit (AG, Brugg, Switzerland). The printlet templates were designed using computer-aided design (CAD) software, saved as STL files, and subsequently transferred to the 3D printer software.

After each layer is sintered, the build platform is lowered along the Z axis, and a new layer of powder is spread over the previously fused layer. This layer-by-layer process continues until the object is fully formed. Once printing is complete, the dosage forms are removed from the build platform and brushed to eliminate excess powder. The unconsolidated powder remains in place during fabrication, acting as a natural support structure. This feature provides a significant advantage over other 3D printing techniques that require additional support structures to be constructed [7].

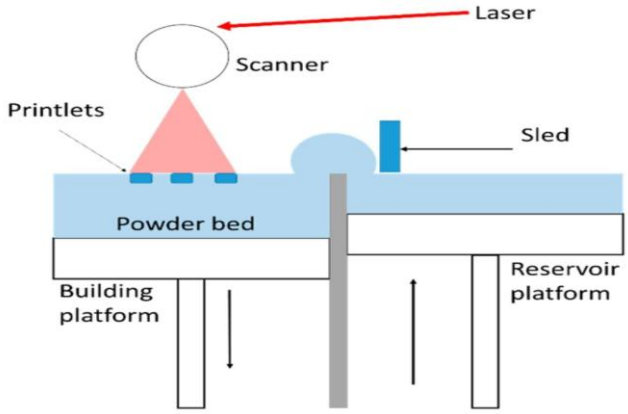

Figure 01: Schema of the SLS printer.

The blue diode laser (445 nm) used in the Sintratec kit operates at a relatively low power of (2.3 W), which is considerably lower than the power of conventional lasers employed in SLS systems, such as CO_2 and Nd:YAG lasers, whose output can reach up to 500 W. This lower energy output constitutes a key advantage, particularly for the fabrication of heat-sensitive pharmaceutical dosage forms SOFs; since the input energy is relatively low, the active ingredients are less susceptible to undergo thermal degradation. In SLS, the degree of sintering of an object is governed by multiple parameters, but mainly directed by the energy density (ED), which is the amount of energy transmitted per volume unit. This critical parameter depends on four process parameters as shown by the empirical equation:

$$ED\ J/mm3 = LP\ (SS \times HS \times LT)$$

In this context, LP, SS, HS, and LT refer to laser power, scanning speed, hatch spacing, and layer thickness, respectively.

In the Sintratec kit, the laser power is fixed and cannot be adjusted. Therefore, the amount of energy delivered to the powder bed can be modulated indirectly by altering the scanning speed or the hatch spacing. A slower scanning speed increases the interaction time between the laser and the powder particles, resulting in greater energy input. Hatch spacing represents the distance between two adjacent sintered lines within the same layer. Consequently, smaller hatch spacing enhances energy transfer due to increased overlap between laser passes [8].

2.2. Raw Materials

Selective laser sintering (SLS) utilizes powder-based feedstock, similar to materials commonly used in conventional pharmaceutical manufacturing processes such as tableting and granulation. Unlike other 3D printing techniques, such as fused deposition modeling (FDM), SLS does not require a preliminary pre-printing step.

2.2.1. Polymers

Similar to fused deposition modeling (FDM), selective laser sintering (SLS) requires thermoplastic polymers to serve as drug-carrying matrices. These polymers can be processed and reshaped upon heating and cooling due to their thermal responsiveness. Prior to sintering, the printer temperature is adjusted below the melting point of semi-crystalline polymers or below the glass transition temperature (Tg) of amorphous polymers. During printing, the laser provides additional localized energy which, depending on the scanning speed, promotes partial or complete fusion of the powder particles [9].

2.2.2 Intrinsic Properties

Absorbance at the Laser Wavelength

Because the thermal energy source in SLS is a laser beam, powder particles must be capable of absorbing light at the same wavelength as the printer's laser to enable sintering and the formation of interparticle bonds. In the case of the blue diode laser (445 nm), the polymers investigated do not exhibit sufficient absorbance at this wavelength. Therefore, an absorbance enhancer is systematically incorporated to facilitate the sintering process, with Candurin® being the most commonly used additive. Two metallic-effect grades of Candurin®-Gold Sheen and NXT Ruby Red have been employed in SLS formulations. Regarding concentration, the available studies consistently report that the inclusion of 3% Candurin® ensures optimal sintering performance. Investigations evaluating the absorbance of various materials across different SLS laser wavelengths have demonstrated that metals, such as titanium and aluminum exhibit higher absorbance at lower wavelengths within the UV–visible region, whereas polymers tend to show increased absorbance at higher wavelengths in the infrared region. This phenomenon explains the effectiveness of metallic

colorants in compensating for the limited absorbance of polymers at 445 nm more recently, alternative colorants have been explored. Notably, Tartrazine Lake at a concentration of 0.2% has been shown to effectively promote the sintering of pharmaceutical polymers when using a blue diode laser [10].

2.3 Active Phrmaceutical Ingredients (API)

Active pharmaceutical ingredients (APIs) have primarily been incorporated as model compounds to evaluate the impact of SLS on drug properties, including thermal degradation, physical state, and drug release behavior. Although APIs are typically present in lower proportions relative to the polymeric matrix, Yang et al. recently demonstrated the successful sintering of two-dimensional structures composed solely of API, without the use of a polymeric carrier. In addition, studies involving high-dose drug formulations indicate that SLS is more accommodating to low polymer content compared to FDM. In FDM, filaments containing 30% or fewer polymers were found to be too brittle and therefore unsuitable for printing. Moreover, the sintering of APIs has previously been investigated in the context of drug delivery devices (DDDs). These studies revealed that certain APIs, such as progesterone and ibuprofen [11], can absorb energy at the CO_2 laser wavelength (10.6 μm), attributed to the presence of carbonyl functional groups. This absorption enhances the sintering process and promotes effective particle fusion.

2.4. Operational Principles of Selective Laser Sintering

Selective laser sintering (SLS) is a widely used powder-based fabrication technology with numerous applications in the biomedical and pharmaceutical fields, and it is suitable for large-scale manufacturing. The technique was first developed by Carl Deckard in 1984 at the University of Texas and was patented in 1990.The original system employed a 100 W neodymium-doped yttrium aluminum garnet (Nd:YAG) laser and utilized acrylonitrile butadiene styrene (ABS) powder as the thermoplastic material. SLS has since been extensively applied in the design and production of physical models through the selective solidification of different types of powders. Its applications include oral and maxillofacial prosthetics, implants, tissue engineering scaffolds, and the fabrication of surgical tools, including those used in neurological procedures. Additionally, SLS has been employed in disease diagnosis planning, personalized patient treatment, and rapid prototyping. This technology is classified as a powder bed fusion (PBF) additive manufacturing (AM) technique. In SLS, a high-powered, directed energy source-typically a laser-is used to selectively sinter or melt a bed of powder composed of resin, metal, or polymer. The localized energy input fuses the powder particles together, resulting in the formation of a solid structure [12].

2.5 Manufacturing Challenges of SLS

Selective laser sintering (SLS) has been widely applied in the fabrication of metals, ceramics, and pharmaceutical products. However, its use in the development of oral solid dosage forms remains relatively limited, with few published reports addressing critical process parameters (CPPs), critical material attributes (CMAs) of the powder, and critical quality attributes (CQAs) of the final product. Numerous variables can influence the quality of SLS-fabricated dosage forms, posing significant challenges in achieving comprehensive process understanding and establishing a robust control strategy. These SLS parameters are generally categorized into four main groups [13]:

a) Laser and scanning parameters, which include laser power, spot size, pulse duration, pulse frequency, scan speed, scan spacing, and scan pattern.

b) Powder material parameters, such as particle shape, particle size and size distribution, morphology, melting temperature, and surface roughness.

c) Powder-bed and recoater parameters, including powder bed density, layer thickness, and powder bed temperature.

d) Build environment parameters, which encompass factors such as shielding gas, thermal conductivity, ambient temperature, oxygen concentration, and surface free energy.

3. METHODS

3.1.Materials

Isoniazid (≥99% TLC purity, analytical standard) was obtained from Sigma-Aldrich, USA, and used as the model drug. Kollidon® VA 64, a vinylpyrrolidone–vinyl acetate copolymer, was kindly provided by BASF, USA. Carbonyl iron (≥97% Fe basis; particle size 5–50 μm) waspurchased from Sigma-Aldrich, USA. Candurin® Gold Sheen was procured from Merck Group, Germany.

3.2 Selective Laser Sintering Process

A desktop selective laser sintering (SLS) printer, Sintratec Kit (Sintratec AG, Brugg, Switzerland), was used to fabricate the oral dosage forms. The tablet templates were designed using 3D Builder (version 18.0.1931.0, Microsoft Corporation). Cylindrical tablets with a diameter of 11.15 mm and a height of 3.75 mm were modeled for printing. For th13e preparation of the physical drug mixture, 5% (w/w) isoniazid (≥99% TLC purity, analytical standard; molecular weight 137.14 g/mol; melting point 171–173 °C) obtained from Sigma-Aldrich, USA, was used as the model drug. Kollidon® VA 64 (BASF, USA), a vinylpyrrolidone–vinyl acetate copolymer with a glass transition temperature (Tg) of approximately 105 °C, was selected as the polymeric carrier. Kollidon® VA 64 has previously been reported in pharmaceutical SLS studies.For all formulations, 200 g of the model drug–excipient blend was prepared using a mortar and pestle to ensure uniform mixing. The blended powder was then transferred into the powder reservoir compartment (110 × 110 × 110 mm) of the SLS printer. The compositions of the formulations used in this study are presented [13].

4. SINTERING PROCESS AND POWDER COALSCENCE (IN – SITU OBSERVATION)

The sintering process is challenging to observe directly due to the high speed of laser scanning and the involvement of multiple interacting factors. The reasons why certain polymers exhibit better sintering behavior than others remain incompletely understood. As highlighted by Peyre et al [14], there is still limited understanding of the SLS process, particularly regarding laser irradiation effects, the actual temperature profiles within the powder bed during printing, and the influence of powder properties on densification behavior.

5. D PRINTED ORAL DOSAGES

Selective laser sintering (SLS) is a rapid prototyping 3D printing technology that utilizes single-component powders or powder blends as feed materials. The properties of the fabricated structures are strongly influenced by processing parameters, including laser power, scanning speed, powder bed temperature, and laser beam spot size, as well as by the intrinsic properties of the powder itself. SLS has attracted considerable attention for the development of oral solid dosage forms, particularly following the commercialization of Spritam®, manufactured using ZipDose® technology by Aprecia Pharmaceuticals [15]. One of the earliest investigations was carried out by Leong et al., who explored the feasibility of fabricating structures with controlled porosity for sustained drug release using blends of polylactic acid (PLA) and polycaprolactone (PCL). Their study demonstrated that laser power, scan speed, and powder bed temperature play critical roles in the SLS printing process. However, at an intermediate scan speed of 5080 mm/s, mechanically robust tablets with approximately 50% porosity were successfully fabricated [16].

6. SLS FOR DRUG DELIVERY SYSTEM MANUFACTURING

Selective laser sintering (SLS), initially developed for manufacturing engineering and technical components, is increasingly being explored for the fabrication of drug delivery systems, including orodispersible tablets, modified-release oral dosage forms, and immediate-release formulations. This compatibility makes SLS particularly attractive for small-scale or on-demand manufacturing of oral solid dosage forms (often referred to as printlets), such as in hospital pharmacy settings [17].

Although these methods are well established, some are associated with high production costs, process complexity, and limitations in achievable drug loading. Rather than replacing conventional manufacturing approaches, selective laser sintering (SLS) offers a complementary and versatile platform for the fabrication of oral dosage forms, particularly orodispersible tablets. Its adaptability and design flexibility represent a significant advancement and position SLS as a promising technology for the pharmaceutical industry [18].

7. ADVANTAGES OF SLS

7.1. Printing Features

A major advantage of selective laser sintering (SLS) is that it does not require additional support structures during printing. The unsintered powder surrounding the printed object serves as a natural support material for the tablet. Consequently, post-processing is simplified and the risk of damaging the printed design is minimized [19].

7.2. Control of Surface Properties

One of the principal advantages of selective laser sintering (SLS) is its ability to fabricate diverse structures by fusing powder particles through sintering, without the use of solvents or prior preprocessing of the powder blends. The controlled sintering or partial melting of powders enables precise regulation of key morphological and mechanical surface characteristics, particularly porosity. In many pharmaceutical applications, the ability to tailor porosity is highly beneficial, as it allows modulation of surface properties and dimensional attributes, ultimately influencing drug release behavior and mechanical performance.[20]

8. APPLICATIONS OF SLS IN PERSONALIZED MEDICINE

Three-dimensional (3D) printing is anticipated to significantly advance personalized medicine because of its flexibility in manufacturing printlets with varied geometries, compositions, and drug release characteristics. At present, fused deposition modeling (FDM) is the most widely established additive manufacturing technique in pharmaceutical research, providing multiple strategies to tailor drug dosage and release profiles according to individual patient needs. This is reflected in the substantial increase in scientific publications utilizing this technology in recent years. Selective laser sintering (SLS) also shows considerable potential in the field of personalized medicine. Its capability to modulate porosity and drug dissolution behavior through careful adjustment of processing parameters and formulation properties further supports its application in patient-specific drug delivery systems [21].

9. TECHNICAL CHALLENGES OF SLS

9.1. PRINTABILITY OF PHARMACEUTICAL MATERIALS

In selective laser sintering (SLS), the printability of a powder-defined as its ability to successfully form coherent printed structures-must be evaluated before targeting specific functional characteristics of the final product. Both printability and the performance attributes of the printed parts are influenced by the intrinsic properties of the powder as well as the selected processing parameters [22].

9.2. Drug Stsbility

High-performance liquid chromatography (HPLC) has generally been employed to confirm that the measured drug content corresponds to the theoretical drug loading of the analyzed formulations. These studies have also verified that no significant drug degradation occurred during the sintering process when a blue diode laser (445 nm) was used [23].

10. REGULATORY REQUIREMENT FOR THE IMPLEMENTATION OF SLS

Despite the significant advances achieved in the 3D printing of pharmaceuticals, several regulatory challenges remain unresolved. In 2017, the U.S. Food and Drug Administration (FDA) issued guidance on additive manufacturing for medical devices [37]; however, no specific regulatory framework has yet been established for 3D-printed dosage forms. Likewise, current pharmacopeias do not provide dedicated quality control tests tailored to 3D-printed medicines. Consequently, most research studies evaluating pharmaceutical 3D printing technologies have relied on conventional quality control assays originally developed for traditionally manufactured products [24].

11. FUTURE DIRECTIONS

11.1. Expansion of Printable Pharmaceutical Materials

Future research should focus on the development and validation of additional pharmaceutical-grade polymers and excipients compatible with SLS. Expanding the range of printable active pharmaceutical ingredients (APIs), particularly thermosensitive and biologically derived compounds, will also be critical. Material optimization strategies aimed at improving flowability, thermal stability, and sintering performance are expected to enhance formulation versatility.

12. CONCLUSION

Selective laser sintering (SLS) represents an emerging advancement in the 3D printing of solid oral dosage forms, particularly in the context of individualized therapy. Although the number of publications in this field remains limited, existing studies provide valuable insight into the technology and its potential benefits for personalized medicine. Nevertheless, further research is strongly encouraged-especially regarding the printability of pharmaceutical-grade polymers, an area that remains insufficiently explored. Additionally, limited information is available on how variations in laser wavelength may influence the sintering process, as most reported studies have employed the same wavelength.

13. AUTHOR CONTRIBUTIONS

All authors are contributed equally.

14. FINANCIAL SUPPORT

None

15. DECLARATION COMPETING INTEREST

The authors have no conflicts of interest to declare.

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