DOI 10.11603/1811-2471.2026.v.i1.16128
УДК 615.4:615.2:665.5

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ADDITIVE TECHNIQUES AND BIOPRINTERS IN PHARMACEUTICAL INDUSTRY: A REVIEW OF MODERN APPLICATIONS

SUMMARY. The aim – to search in informational-scientific and sciencemetric data bases such as Scopus, Web of Science and PubMed by the key words: additive techniques, 3D printing, medicines, cosmetics, manufacturing, personalized medicine, for systematizing of scientific professional literature data in regarding the implementation of additive techniques and bioprinting in the production of medicinal and cosmetic products, assessing the advantages and constraints of the techniques as well as to prognose the ways of future research directions in this field.

Material and Methods. The source material for the study was derived from scientific publications of domestic and foreign authors presented in professional peer-reviewed publications and electronic scientific databases dedicated to application of additive techniques in pharmaceutical and cosmetic industries. For our research we used the methods of systemic analysis, comparative and generalization of literary sources, as well as logical and structural processing of information.

Results. The modern healthcare system is undergoing a fundamental transformation shifting the focus on personalized medicine. The adaptation of therapy to the individual needs of patients in context of pharmacogenetics, metabolism and physiological characteristics has become the mainstream of the pharmaceutical industry.

The techniques are focused on layer-by-layer objects based on digital models for designing medicines with complex geometry, controlled active substance release, and the ability to combine several active ingredients in a single dose. Inkjet printing, fused deposition modeling (FDM), selective laser sintering (SLS), stereolithography (SLA) and pressure-assisted microsyringe (PAM) are the techniques currently being practically tested by pharmacists and cosmetologists for the above purposes.

Conclusions. We summarized current information on application of additive techniques in manufacture of medicines and cosmeceutical products. 3D printing has been shown to enable to create personalized medicinal and cosmetic formulations with controlled structure and release profile. Bioprinting has been proven to boost the potential of preclinical screening and alternative safety models, particularly in cosmetology and regenerative medicine. However, widespread adoption of these techniques is hampered by technological and regulatory constraints.

KEY WORDS: additive techniques; 3D printing; medicines and cosmetics products manufacture techniques; personalized medicine.

Introduction. The modern pharmaceutical industry is experiencing a period of rapid technological transformation driven by the need to personalize medical treatment, increase the efficiency of production processes, and respond to the challenges of personalized medicine as more than 90% of patients have at least one genetic variant that requires alteration of medication dosage or regimen in cases of prescribing certain medicinal products [1]. One of the most promising areas of innovations in the industry is incorporation of additive techniques that open up fundamentally new potential for development of novel medicinal and cosmetic products.

Additive techniques, including 3D printing based on layer-by-layer material deposition, make it possible to manufacture products of complex geometry with precisely controlled composition and individual characteristics. While traditional pharmaceutical manufacture methods are focused on mass production of standardized forms, additive techniques provide flexibility in creating personalized medicinal and cosmetic forms with targeted pharmacokinetic parameters that meet the specific needs of individual patients or certain groups [2, 3].

Additive techniques are used in the pharmaceutical sector for manufacture of modified-release tablets, combined medicines, transdermal systems, and for creation of innovative cosmetic products with personalized characteristics. Of particular importance is manufacturing pediatric and geriatric medicinal forms with optional correction of standard dosage [4-6].

The topicality of the study of application of additive techniques in pharmaceutical industry is preconditioned by a need to analyze their potential for optimizing manufacture processes, improving product quality and safety, and shaping new strategies for development of the industry in the context of personalized medicine and cosmetology.

Bioprinting (3-D bioprinting) is developing in parallel with classical 3D printing to utilize bioinks containing cells and biopolymers for creating tissue models. This aspect is especially important for cosmetics due to high ethical requirements in the industry and a need for safe informative alternative models. Bioprinters make it possible to reproduce complex skin compounds, including immune components, thus increasing the relevance of preclinical screening of ingredients and preparations [6, 7, 8].

Despite brisk progress, broad integration of 3D printing and bioprinting into manufacture process is quite constrained for a number of technological, organizational and regulatory barriers [9, 10]. Therefore, technology-summarizing efforts demonstrating successful cases and problematic issues are an important tool for planning innovations in the industry.

The aim of the study was the search of informational-scientific and sciencemetric data bases such as Scopus, Web of Science and PubMed by such key words as additive techniques, 3D printing, medicines, cosmetics, manufacturing, personalized medicine, in order to systematize the scientific professional literature data in regarding the implementation of additive techniques and bioprinting in the production of medicinal and cosmetic products, assessing the advantages and constraints of the techniques as well as to prognose the ways of future reseach directions in this field.

Material and Methods. The source material for the study was derived from scientific publications of domestic and foreign authors presented in professional peer-reviewed publications and electronic scientific databases dedicated to application of additive techniques in pharmaceutical and cosmetic industries. The methods of systemic analysis, comparative and generalization of literary sources, as well as logical and structural processing of information were used in the study.

Results and Discussion. Application of 3D printing technologies in manufacture of medicinal products is characterized by a number of significant advantages. For example, additive methods deliver high productivity and accuracy, since individualized dosage forms of complex architecture can be manufactured in a short time with high reproducibility exceeding the potential of traditional techniques [11, 12]. At the same time, 3D printing creates conditions for personalization of pharmacotherapy through precise dosing and openness to individual patient characteristics, including pharmacogenetic profile, age and sex, which are especially important for medicines with a narrow therapeutic index [13]. Moreover, additive techniques contribute to lower production costs and higher economic feasibility of manufacturing complex medicinal forms, boasting adaptation of a release profile of active pharmaceutical ingredients by creating porous and multilayer structures or combining several active pharmaceutical ingredients (APIs) in a single medicinal product at the same time [14-19].

Transdermal delivery of active ingredients is inherent in both pharmaceutical and cosmetic products as the same carrier (patch, hydrogel, microneedle system) can be used as a dosage form (e.g., for wound or acne treatment) or as a cosmeceutical platform (moisturizing, anti-aging, lightening, barrier function enhancement). That is why this segment is considered one of the most promising for 3D printing [7, 20].

The specifics of additive techniques, including 3D printing, is the layer-by-layer formation of an object using a digital model, which is segmented and reproduced by printing machine. Rapid progress in this field has contributed to the emergence of numerous technological approaches that differ in types of materials, work mechanisms and characteristics of finished products. Given the above differences, the American Society for Testing and Materials has classified 3D printing techniques into seven groups: extrusion technique, binder jetting, powder layering, photopolymerization, material jetting, directional energy deposition, and sheet lamination [21-24]. 3D printing techniques are characterized by high efficiency, versatility and flexibility of pharmaceutical production process, as they facilitate creating a wide range of complex and individualized medicinal forms by varying the parameters of a digital model, such as dimensions, geometry and filling density of medicinal or cosmetic form [25]. For example, they are used for manufacturing a variety of medicinal forms, such as immediate-release tablets, controlled-release tablets, dispersible films, microneedles, implants, and transdermal patches [26].

In pediatric practice, 3D printing releases the potential of creating personalized low-dosage medicinal products adapted to age and improvement of organoleptic properties of medicines, thus contributing to better children's adherence to treatment [4, 27].

For elderly patients who often suffer from dysphagia, additive techniques open the way for production of light, porous and rapidly dissolving dosage forms that ease the swallowing process. For

patients prone to polypharmacy, different active pharmaceutical substances can be combined into one multilayer or combined tablet, thus reducing the risk of errors and missed doses and generally increasing the safety of pharmacotherapy. Moreover, the technique provides the possibility of applying special markings or formations on the surface of medicinal products, which is especially useful for patients with eye disorders [5, 28, 29].

3D printing techniques can contribute to manufacturing of sustained-release medicinal forms designed for coherent action in line with daily fluctuations of disease manifestations. In particular, the T19 by Triastek manufactured using 3D printing technique was approved by the US Food and Drug Administration (FDA) for clinical trials in January 2021. Being administered before bed, it delivers maximum blood API concentration in the morning, when the most pronounced manifestations of pain and joint stiffness are usually observed. Maintaining therapeutic concentration of medicines throughout a day contributes to better disease control and higher efficacy of therapy [30].

3D printing technology at the stage of developing new medicinal products is particularly effective for small-scale prototype production, as it allows for rapid changes in design and form at minimal cost. The integrated nature of the manufacture process and low cost of small batches boost the demand for this technique to be used in conditions of limited time and resources. Studies have shown that utilization of a modified FDM (fused deposition modeling technique, where an active substance is dispersed in a polymer matrix) with "zoning" delivers a possibility of manufacturing reliable 3D-printed capsule shells for encapsulation of dry or liquid formulas and controlled release of active substances [31].

Advances in 3D printing have also contributed to its introduction into the development of cosmeceuticals, opening up possibilities for precise application of active substances in predefined layers or spatial patterns. For this purpose, additive techniques provide flexible customized formulation based on individual skin characteristics and needs. This level of personalization represents a new stage in the development of cosmeceuticals and is in line with current trends towards personalized skin care [32, 33].

The most common 3D printing technologies used in the pharmaceutical industry for manufacture of various medicinal dosage forms (MDF) are jetting, extrusion, and laser printing systems [18, 34, 35].

The Fused Deposition Modeling (FDM) technique is extruding thermoplastic polymer filament consisting of an active pharmaceutical ingredient (API) through a heated printing head for further layering and solidification of the material applied. Being initially heavily constrained by a lack of appropriate pharmaceutical polymers, the FDM technique is now widely using polyvinyl alcohol (PVA), polyvinylpyrrolidone (PVP), ethyl cellulose (EC), hydroxypropylcellulose (HPC), hydroxypropylmethylcellulose (HPMC), hydroxypropylmethylcellulose acetate succinate (HPMCAS), ethylated acrylate copolymer (Eudragit®RL and RS), polyethylene oxide (PEO), polylactic acid (PLA) and other synthetic materials. The method works under temperatures within the range of 150–230 °C, which increases the risk of thermal destruction of thermolabile APIs and forming porous structure when heated excessively. The effort to minimize the above disadvantages consists in using polymers with low melting and vitrescence temperature of the powder mixture. The FDM method allows producing a wide range of LFs, including implants and modified-release tablets [34, 36-38]. Fused Deposition Modeling is also promising method for creation of cosmetic products in the form of skin patches consisting of hydrophilic and hydrophobic components, namely polylactic acid (PLA) and polyvinyl alcohol (PVA). The PVA layer serves as a carrier for cosmetic formula, ensuring controlled release of active ingredients and reliable adhesion to the contours of the face, while the PLA liner gives the whole structure mechanical strength and durability. This design and combination of components allows the product to be precisely adapted to various anatomical areas of the face [38].

The semi-solid extrusion (SSE) method is based on the extrusion of a solvent-containing paste or gel from a syringe-like system for layer-by-layer formation of the object under low temperature conditions, which makes this technique suitable for working with thermolabile active pharmaceutical ingredients [34]. SSE is widely used for manufacture of immediate and controlled-release tablets, orodispersible dosage forms, flotation systems and other pharmaceutical products. At the same time, the effectiveness of the method largely depends on the optimal selection of excipients to ensure proper rheological properties, and normally requires post-processing, such as drying or cooling of finished products. The technique is limited by relatively low printing resolution due to large diameters of process nozzles [3, 39].

3D jetting has been implemented at account of using jet printers. There are several types of 3D jetting. Continuous ink jet printing (CIJ) and drop-on-demand (DoD) jetting are characterized by using both thermal and piezoelectric print heads, controlled particle formation and liquid viscosity rates. The use of printers with thermal heads is limited for liquids with a content of volatile components. Printers with piezoelectric heads can work with much larger volumes of source liquids [18].

Binder Jetting (BJ) is a 3D jet printing technique that involves applying a binder solution on a powder liner using a printer nozzle and further sintering the resulted layer. The process is repeated in the required numbers [34, 40]. Based on this approach, the ZipDose® technology was developed which was used for manufacture of Spritam®, one of the first FDA-approved 3D-printed tablets. The method can work at room temperature, supports a wide range of materials, is suitable for manufacture of highly porous LFs, but requires a multi-step process with subsequent drying, and often delivers insufficient mechanical strength of finished medicinal forms. The quality of a binder jetting product depends significantly on the behavior of a binder during printing, that is the ability to form stable droplets/particles, penetrate the free space between the powder particles, and to ensure sufficient strength before drying [3, 41, 42].

Laser printing techniques are widely used among the methods of 3D printing of medicinal products. Such methods include the Selective Laser Sintering (SLS) method, which uses sintering of API powder mixture and excipients. After sintering the first layer, a subsequent thin powder layer is applied onto its surface, after which the process is repeated until the finished medicinal form is ready. The method enables to manufacture complex structures and regulate the porosity by changing laser scanning rate [43]. High temperature and intensity of laser radiation may cause degradation of heat-sensitive APIs, thus substantially limiting the use of the method. The properties of the powder (particle size and distribution, bulk density, flowability, and humidity) and layer forming parameters are also very sensitive for powder techniques (SLS) [18].

The effect of ultraviolet (UV) radiation on curing of various polymer resins has been reflected in stereolithography (SLA), another 3D laser printing method. The method is based on layer-by-layer photopolymer curing of polymer resins under the influence of UV laser radiation. The method provides the highest resolution among 3D techniques and minimizes heating effect, making it suitable for temperature-sensitive APIs. The SLA effectiveness for the work with such substances has been confirmed when printing tablets containing 4-aminosalicylic acid [44].

A summary of the literature sources shows that 3D printing methods enable to create medicinal forms of various structures and purposes, ranging from microcapsules and mesoporous bioactive scaffolds to nanosuspensions and synthetic matrices based on hyaluronate [3, 23, 45].

Unlike "classical" 3D printing with source materials such as powders, polymers or API pastes, 3D bioprinting works with biological components, such as cells, extracellular matrix and biopolymers, which form so-called bioinks. Bioink is considered one of the key components of 3D bioprinting technique. It is defined as a special material consisting of cells suitable for processing by automated biomanufacturing techniques, which can also contain biologically active components and biomaterials. The fundamental difference between bioinks and biomaterial inks is the cells content; they are an obligatory component of bioinks and can be represented by individual cells or cell aggregates encapsulated in hydrogels, microcarriers, microgels, nanoparticles or nanofibers. In contrast, biomaterial inks do not contain cells during printing as they are added after formation of the structure [46]. In the most general term, bioprinting is an extrusion (or other controlled deposition) of organic and biological materials layer by layer, thus enabling the geometry and structure of tissue layers to be reproduced [7].

In pharmacy, bioprinters are subdivided into two main branches by application method. The first one is creation of informative skin models for preclinical screening of ingredients and preparations, including assessment of irritation, sensitization, inflammatory responses and action mechanisms. The second is the development of tissue engineering and potential regenerative solutions (scaffolds, cell constructs), which may be further used as medical products for treatment of complex skin lesions [9, 47]

From a methodological point of view, bioprinting presumes special demands on reproducibility, as it is necessary to control cell viability during printing, maintain standard composition of bioink, ensure sterility, and validate the functional characteristics of the model (barrier properties, marker expression, response to inflammatory stimuli, etc.). An additional driver for the cosmetic industry is a need for standardized alternative methods in response to growing ethical and regulatory restrictions on animal testing, therefore bioprinted models may become one of the most "physiological" tools of the kind [47].

Conclusions. We have summarized current inputs on the use of additive techniques in medicines and cosmetics industries. 3D printing has been shown to enable the development of personalized medicinal and cosmeceutical formulations with controlled structure and release profile. Bioprinting has been shown expanding the capabilities of preclinical screening and alternative safety models, particularly in cosmetology and regenerative medicine. However, widespread adoption of these techniques is hampered by technological and regulatory constraints.

Sources of funding: authors' own funds.

Each author`s contribution:

O. V. Kryvoviaz – development of a research and publication idea, literature review and text writing;

Yu. O. Tomashevska – development of a research and publication idea, literature review and text writing;

V. V. Hutsol – literature review, information analysis and interpretation, text writing;

V. M. Koval – development of a research concept, reviewing literature, text writing;

T. I. Voitenko – analysis, discussion of results, generalization of conclusions;

O. Yu. Toziuk – literature review;

H. I. Kramar – analysis and discussion of results.

Conflict of interest: none.

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ВИКОРИСТАННЯ АДИТИВНИХ ТЕХНОЛОГІЙ ТА БІОПРИНТЕРІВ У ФАРМАЦЕВТИЧНОМУ ВИРОБНИЦТВІ: ОГЛЯД СУЧАСНИХ ПРАКТИК

РЕЗЮМЕ. Мета роботи – проведення пошуку в інформаційно-наукових та наукометричних базах даних Scopus, Web of Science та PubMed за ключовими словами: additive techniques, 3D printing, medicines, cosmetics, manufacturing, personalized medicine, з метою узагальнення та систематизації даних наукової фахової літератури щодо застосування адитивних технологій і біопринтингу у виробництві лікарських та косметичних засобів, визначення сучасних тенденцій, переваг і обмежень цих технологій, а також прогнозування перспективних напрямів подальших досліджень у даній галузі.

Матеріал і методи. Матеріалами дослідження були наукові публікації вітчизняних і зарубіжних авторів, представлені у фахових рецензованих виданнях та електронних наукових базах даних, присвячені застосуванню адитивних технологій у фармацевтичному та косметичному виробництві. У роботі використано методи систематичного аналізу, порівняльного та узагальнювального аналізу літературних джерел, а також логічного й структурного опрацювання інформації.

Результати. Сучасна система охорони здоров'я переживає фундаментальну трансформацію, зміщуючи фокус на персоніфіковану медицину. Головним завданням стає адаптація терапії під індивідуальні потреби пацієнта з урахуванням його фармакогенетики, метаболізму та фізіологічних особливостей.

Технологія базується на пошаровому створенні об'єктів за цифровими моделями, що дозволяє проектувати препарати зі складною геометрією, контрольованою кінетикою вивільнення активних речовин та можливістю поєднання кількох діючих компонентів в одній дозі. Серед основних технологічних платформ, що сьогодні досліджуються для потреб фармації та косметології, виділяють: струменевий друк (Inkjet printing), моделювання методом наплавлення (FDM), селективне лазерне спікання (SLS), стереолітографію (SLA) та екструзію напівтвердих матеріалів (PAM).

Висновки. Узагальнено сучасні дані щодо застосування адитивних технологій у виробництві лікарських та косметичних засобів. Показано, що 3D-друк забезпечує створення персоналізованих лікарських і космецевтичних форм із керованою структурою та профілем вивільнення. Встановлено, що біопринтинг розширює можливості доклінічного скринінгу й альтернативних моделей безпеки, зокрема в косметології та регенеративній медицині. Водночас широке впровадження цих технологій стримується технологічними та регуляторними обмеженнями.

КЛЮЧОВІ СЛОВА: адитивні технології; 3D-друк; технологія ліків та косметичних засобів; персоналізована медицина.

Отримано 17.01.2026

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