



3D printed medicines: ZipDose technology

While medical devices are subject to the German Medical Devices Act (MPG) and thus to a multitude of regulations, medicinal products are subject to the even stricter German Medicinal Products Act (AMG). The prerequisite for the manufacture of medicinal products is compliance with Good Manufacturing Practice, which is intended to ensure that only safe, effective and harmless medicinal products are placed on the market. These guidelines refer to all measures necessary for the quality assurance of a medicinal product or its active ingredients in connection with its manufacture, testing or storage. For this reason, the introduction of new manufacturing processes in the production of medicinal products that are not yet GMP-compliant is a testing-intensive and lengthy process.

FDA approval of a 3D-printed drug, as first occurred in 2015, opens up new opportunities for drug production. Direct 3D printing technology offers the opportunity for on-demand production of products with personalised dosing, drug combinations, geometries and release properties that were previously not possible with traditional production technologies.

With the so-called ZipDose production technology, it is possible to build individual dosage forms in tablet form within open powder beds. Using digitally controlled layering of multiple powder streams and pressurised fluids, it is possible to produce 3D printed medicines within a given spatial boundary. ZipDose technology can be used for a wide range of applications with both small and large molecules. Conventional 3D printing technologies produce products by depositing and assembling successive layers of a material, including the necessary active ingredients and excipients, in predefined geometries. The ZipDose technology offers more flexibility in the production of pharmaceutical products and can thus process significantly higher quantities of active ingredients than any rapid melting technology available on the market to date. In addition, it is confirmed that more than 150 substances are compatible for production. Another special feature is that more than one active ingredient can be used in the production process, which later also has an influence on the duration of the active ingredient release and the product differentiation can be adapted.

By using aqueous liquids to bind several powder layers together, several therapeutic challenges can be taken: Firstly, higher dosages up to a dosage load of 1,000mg are possible. In addition, medicinal products prepared in this way offer the advantage that the solution decomposes quickly on contact with liquid, as the bonds formed during the 3DP process are easily broken. Furthermore, it is possible to incorporate improved taste masking technologies during the manufacturing process, thus making it more pleasant for the patient to take.

INNOVATIVE TECHNOLOGICAL APPROACH

- ◇ **Company:**
Aprecia
Pharmaceuticals

- ◇ **Product:**
SPRITAM for epilepsy treatment

- ◇ **Advantages:**
Possibility of personalised medicine

Medicinal products with customised release profiles

Easy intake for patients due to fast-dissolving composition

Combination of several active ingredients in one pill

- ◇ **Website:**
<https://www.aprecia.com/>

What benefits does 3D printing of medicines bring to the health sector?

- ◇ Progress in personalised medicine
- ◇ Prescription of medicines with exact, individual doses for each patient

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