PC50040

3D-print of orally disintegrating tablets – how to get started

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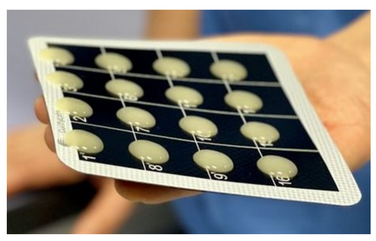
WHAT WAS DONE?

The initial steps necessary before implementing 3D-printing for manufacturing personalized tablets has been identified and completed. The clinical advantages and barriers of the personalized treatment has been discussed interdisciplinary, and the new dosage form has been risk evaluated in dialogue with the competent authority.
As a result, the best suited technology has been identified.



Picture from Curifylabs.com

WHY WAS IT DONE?

There is an interest in implementing more safe, affordable, and sustainable treatment methods for patients for whom a personalized approach is beneficial. These treatments can be expensive and associated with patient safety and compliance issues. For the pediatric population, many medications are not available in appropriate form or dose and is therefore being manipulated before administration. Extemporaneous oral solutions often have a limited shelf life and bad physical properties or undesirable excipients.

The use of 3D-printed tablets, would also help to eliminate the risk of adverse events, due to incorrect dosage.

Other patient groups with the need for accurate dose adjustments are also expected to benefit from 3D-printed tablets.

HOW WAS IT DONE?

The European marked has been searched for technologies suitable for extemporaneous personalized production in hospital pharmacies. 3D-printed tablets was identified as most easily implemented both concerning technology, GMP and patient acceptance.

A dialogue about risks and benefits regarding 3D-printed tablets was initiated with the hospital staff. Risks identified concerned the number of drugs available for 3D-printing, the need for stability testing and resistance from authorities. Benefits like flexibility, just-in-time preparation and patient safety was identified.

In collaboration with the competent authority, the necessary level of validation, documentation and analysis needed on the final product and starting materials, have been established.

This includes e.g.:

- Incoming controls of the used starting materials
- Validating the manufacturing process
- Establishing the level of quality control on the finished tablets

WHAT HAS BEEN ACHIEVED?

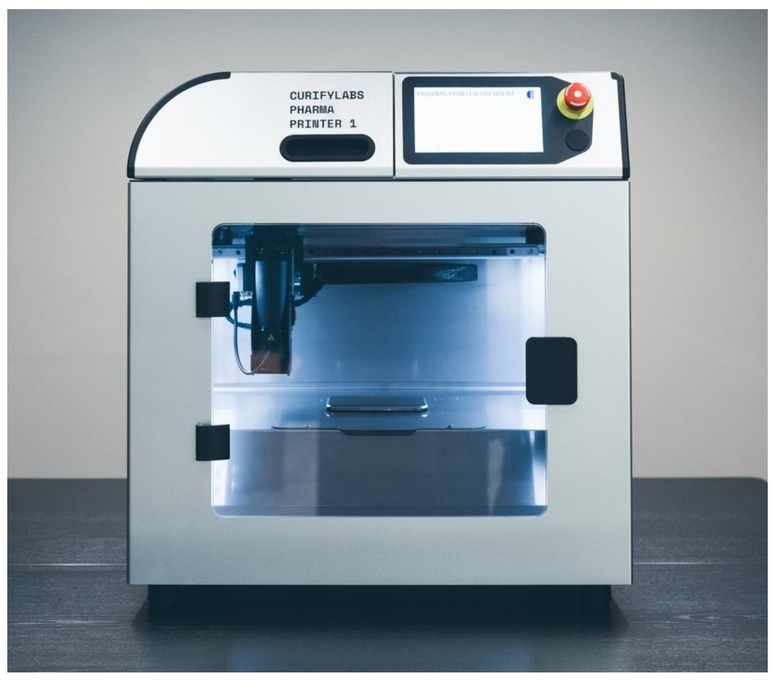
The necessary steps to get started have been identified and completed. Risks and benefits were assessed, and the decision about implementing 3D-printed tablets was made. An equipment that is reliable and automated has been sourced. A quality visit has been carried out at the equipment manufacture and a contract for the procurement of the equipment has been signed, and the equipment has been ordered.

An API for the initial manufacture was selected, combining clinical relevance and adequate physical properties.

Ink/matrix for the 3D-printer was evaluated and found safe for medicines for children. The matrix is manufactured according to GMP.

A regulatory framework has been agreed upon with the national competent authority.

Because of the new technology, a network with the Nordic countries have been establish, enabling the sharing of knowledge regarding manufacturing of 3D-tablets.



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WHAT NEXT?

- ❑ Validating the equipment
- ❑ Validating the methods of analysis in the QC lab
- ❑ Setting the specification for the starting materials
- ❑ Setting the specification for the finished product
- ❑ Printing of the first tablets to be used in the clinic

Hopefully the first patient can be treated by the end of 2025

Documents required before purchasing:

URS → Risk assessment → Contract

Documents required after purchasing:

SAT → Change control for the equipment → IQ/OQ/PQ → User manual

ACKNOWLEDGEMENTS
We wish to conclude with a word of thanks to all our colleagues in the hospitals, and the hospital pharmacy that have contributed with hard work in this project.
For more information regarding the clinical assessment, visit our colleague's poster CPS50106
Also a thanks to the innovative staff at CurifyLabs, for their collaboration in making 3D-printing a possibelity at our facility.
To learn more about CurifyLabs, visit them at booth #24.