



# capri

## Press Release

November 2022

### Predicting the availability of API from the oral form of the drug using the OCT tool

In line with the CAPRI project assumptions, the OCT study of the tablet surface was implemented at AMS. An experiment was designed with two variable parameters and three selected values:

$$2^3 = 9 \text{ experiments}$$

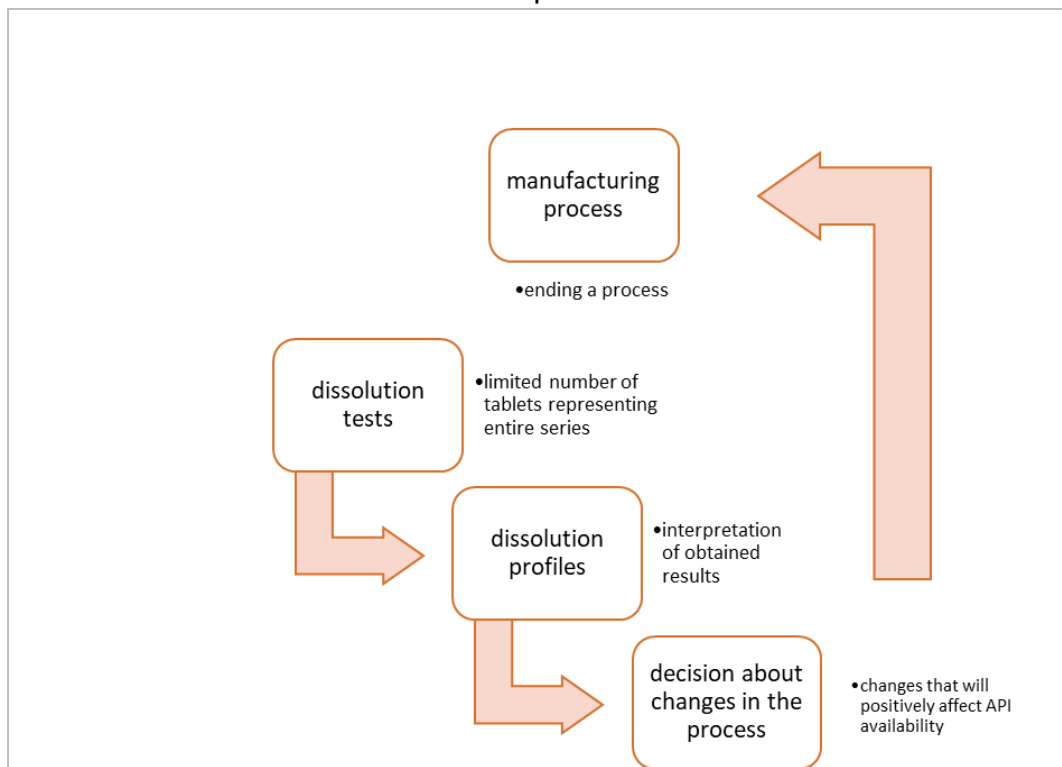


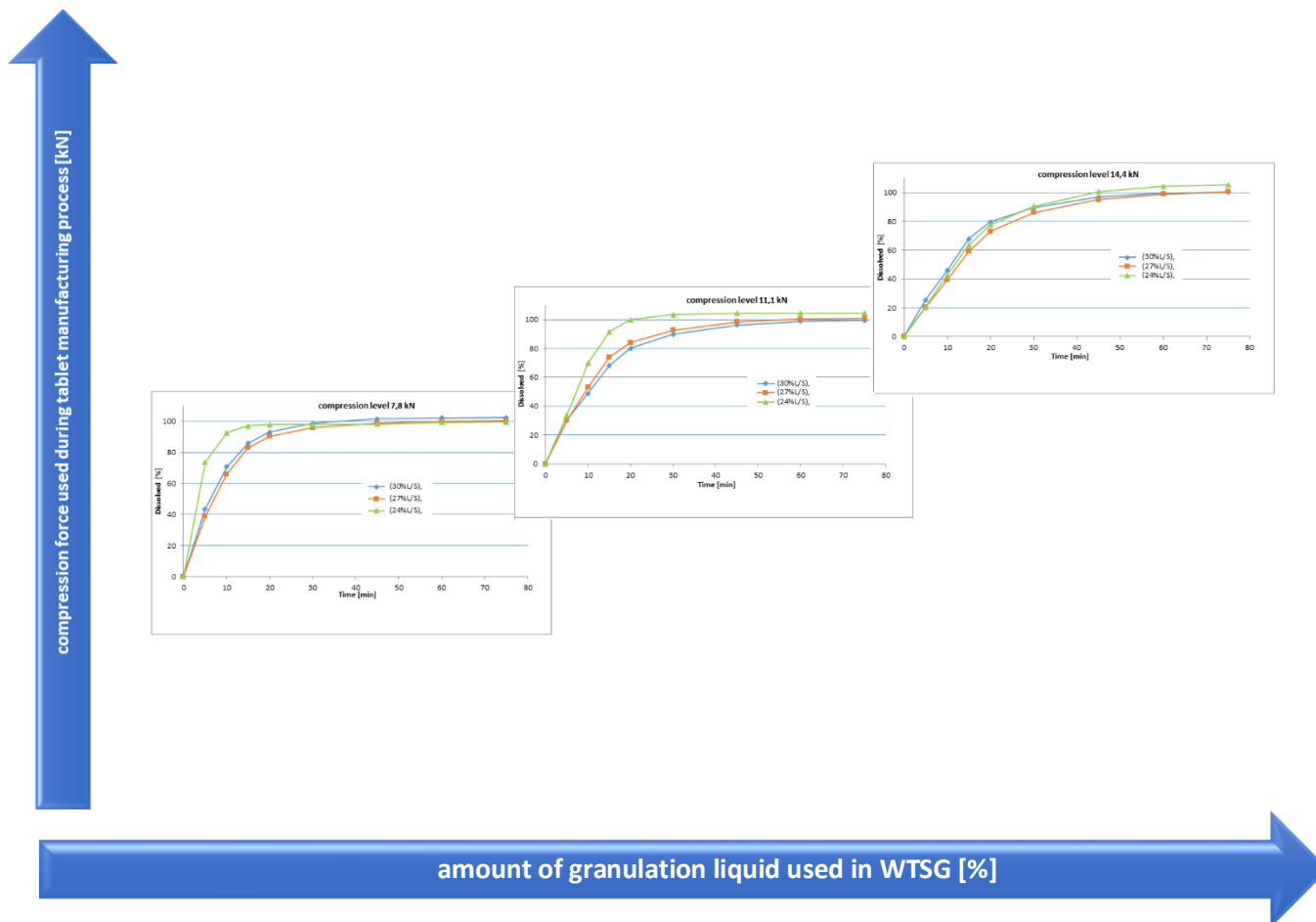
Figure 1 Conventional current approach



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 870062.

Three batches of low API uncoated tablets were produced at AMS by using 3 different granulation amounts (24% w/w, 27% w/w and 30% w/w) and the twin-screw wet granulation process. Each dried granulate batch was divided into 3 sub-batches which were compression to tablets by using three different compression forces (7.4kN, 11.1 kN and 14.4kN).

OCT measurements were made on the manufactured tablets - hundreds of images were obtained for detailed measurements of the tablet structure and its variability in relation to variable parameters. Moreover, all variants were tested in terms of API availability and a series of dissolution profiles were created, which were then used to define the correlation between the availability of small amounts of API over time and the structure of the tablet surface.



By using cognitive solutions, it was possible to use the corresponding dissolution data to fit a dissolution model of the form of function. The model allows predicting the availability of even small amounts of API from the tablet. Model dissolution profile designed on the basis of the results obtained from OCT measurements corresponds to a very large extent to the dissolution profile obtained at AMS with the currently used conventional method of direct testing in an appropriate buffer.

OCT measurements can be performed at many stages of the drug substance manufacturing process in tablet form. This is a major step towards making continuous processes in the pharmaceutical industry more common - the future of drug substance manufacturing. Continuous production creates opportunities to save time, energy, reduce research that requires interruptions in the process.

Using the OCT technique, it is possible to evaluate the manufacturing process in-line, which enables the optimization of process parameters immediately during the process. To have the



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predicted dissolution profile it is enough to perform in-line OCT measurements. It is a much better approach than the conventional one because it saves time, materials and human resources, generally improves efficiency significantly. Dissolution model of the form of function is a huge step forward in this approach.

OCT measurements - optical coherence tomography based on low coherence interferometry, is a non-contact, non-destructive high-resolution imaging technique. Thanks to the OCT technique, it is possible to show up close a wide picture of the tablet structure, for example its pores, cracks. The imperfections are visible in the OCT image as dark pixels - it is possible to dimension them precisely. The highlighted imperfections are a very useful indication in optimizing the compressing process.

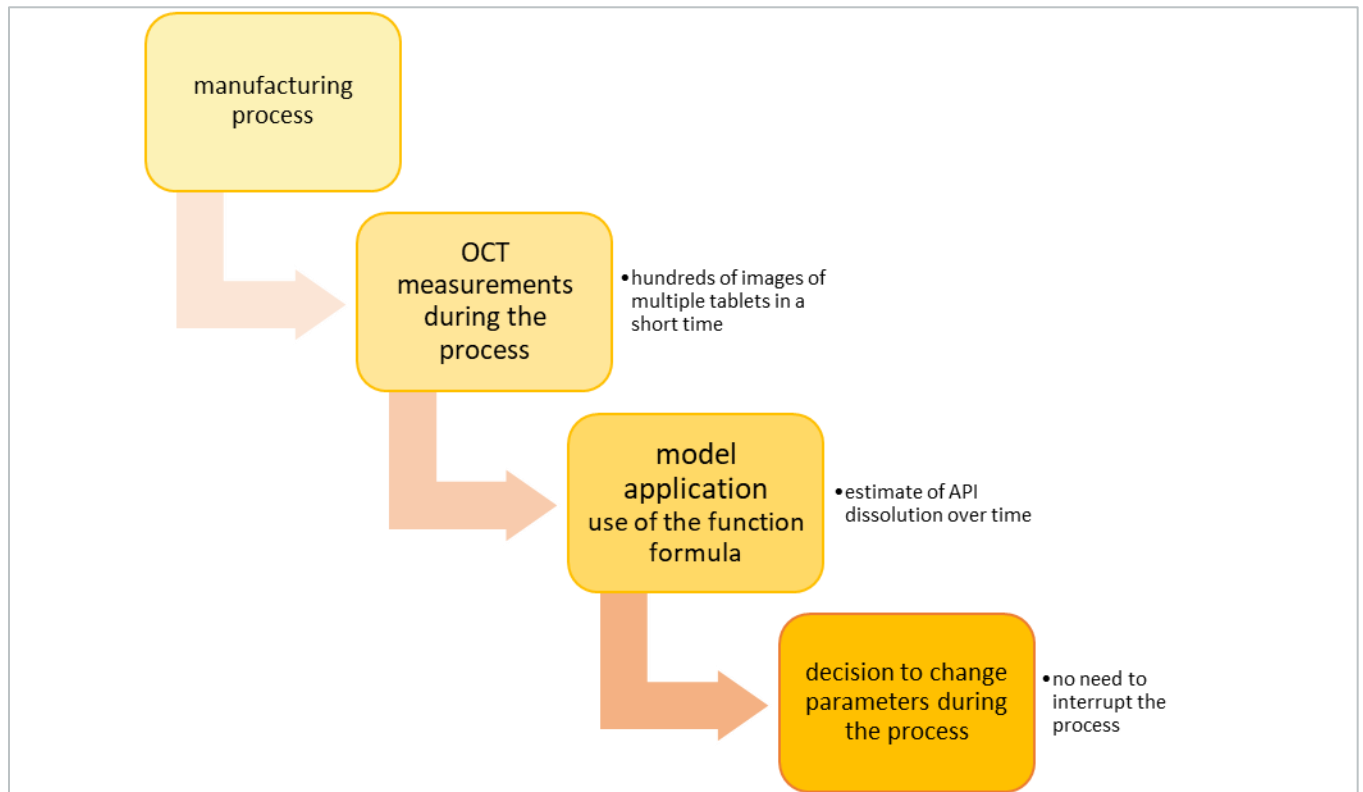


Figure 2 Future approach



## About the project

**Project Full Name:** Cognitive Automation Platform for European PRocess Industry digital transformation

**Project ID:** 870062

**Start Date:** 01/04/2020

CAPRI ([www.capri-project.com](http://www.capri-project.com)) is a 42-month H2020 project that brings cognitive solutions to the Process Industry by developing, testing, and experimenting an innovative Cognitive Automation Platform (CAP) towards the Digital Transformation. To achieve that, CAPRI enables cognitive tools that provide existing process industries flexibility of operation, improving the performance across different indicators (KPIs) and state of the art quality control of its products and intermediate flows.

Three main technical objectives enabled by the development, testing and experimentation of an innovative Cognitive Automation Platform (CAP) for three use cases from process industry (asphalt, pharmaceutical tablets and steel billets and bars manufacturing), are being pursued:

- **Process Industry Digital Transformation & Automation** through digital technologies like data collection, storage, and knowledge extraction to provide detailed insights into process control and resource availability.
- **Improved performance and flexibility in the process industry** via digitalisation of process industries to dramatically accelerate change in resource management, improve their performance and flexibility and in the design and the deployment of disruptive new business models.
- **Next generation process industry plans** for their autonomous operation of plants based on embedded cognitive reasoning, while relying on high-level supervisory control as well as providing support for optimised human-driven decision-making.

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## For additional information please contact

**Project Coordinator:** CARTIF  
Cristina Vega Martínez [criveg@cartif.es](mailto:criveg@cartif.es)

**Dissemination & Exploitation Manager:** Core-Innovation  
Nikos Kyriakoulis [nkyriakoulis@core-innovation.com](mailto:nkyriakoulis@core-innovation.com)



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