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Development of a fast and flexible generic process for the reduction of nitro compounds

*K. Haas-Santo¹, B. Vankayala¹, R. Dittmeyer¹, R. Singh², K. V. Gernaey²,
R. Ganf², J. M. Woodley², R. Rozada-Sanchez³, F. Muller³,*

¹ IMVT, Karlsruhe Institute for Technology, Germany, ² Technical University of Denmark, Denmark, ³ AstraZeneca, United Kingdom

The hydrogenation of aromatic nitro substrates is a frequently used reaction in the multi-step fabrication of active pharmaceutical ingredients (APIs). Today most pharmaceutical production processes are performed in batch mode. In the frame of the C2-campaign speed is an important factor during the production of a multitude of possible API's. A generic reactor set-up able to be adapted for the transformation of a specific substrate would reduce the development time and thereby the campaign time significantly. In the frame of the EU-project F³-Factory such a flexible and continuous reaction system for this important reaction class able to produce 1-5 kg API is being developed. To allow for an easy and fast adaptation of this process for a range of nitro substrates a substrates adoption methodology (SAM) is also being developed.

A literature study of the nature of different reduction methods (H₂ gas, H-Donor, CO gas, etc.) led to the conclusion that the liquid phase reduction of aromatic nitro substrates by either hydrogen gas or an H-donor is the most selective method. Following the requirements of that reaction type a flexible and modular reactor for the liquid phase reduction with a heterogeneous slurry catalyst was designed that can be adapted for reduction of a range of nitro compounds. The generic process provides the possibilities of swapping out a reactor or work up technology as required. The equipments of the generic process should be also able to operate at wider range of operational variables making it suitable for a range of substrates. The SAM identifies the necessary changes to a generic process and plant in order to adapt it for a given substrate.

The objectives of this presentation is to highlight the design of a generic nitro reduction process and to demonstrate the application of this generic process on a pharmaceutical manufacturing case study involving the nitro reduction of 6-Nitroquinoline.