

# Implementation of a Ph. Eur. compliant recombinant method for testing of bacterial endotoxins in sterile pharmaceuticals

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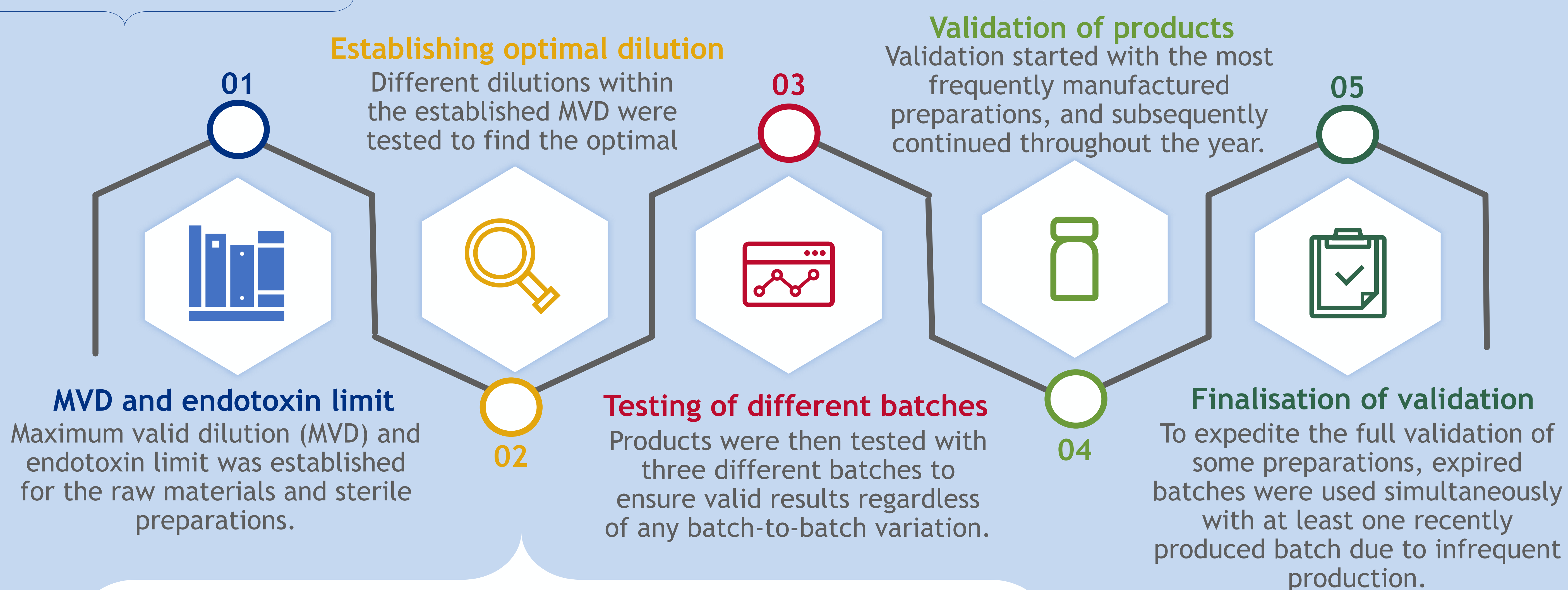
## What was done?

The hospital pharmacy implemented a modern system for testing for bacterial endotoxins as a part of the quality control of raw materials (i.e. water for injection (WFI)) and sterile pharmaceuticals manufactured at the pharmacy, replacing the old gel-clot test.

## Why was it done?

- Endotoxin testing by the gel-clot method is a limit test, and relies on the operator's subjective evaluation of the results. The procedure itself contains several steps and dilutions, and it is time and resource consuming.
- The availability of the amoebocyte lysate reagent can also vary since it's harvested from the endangered horseshoe crab.
- The recombinant factor C method (rFC) is a fluorimetric method based on the gene sequence of the horseshoe crab, providing quantitative results with no interpretation by an operator.
- The rFC method consists of less handling and is less susceptible to human error.

## How was it done?



## What has been achieved?

- 25 sterile pharmaceuticals and raw materials were successfully validated for endotoxin testing by rFC during 2021 and 2022.
- The gel-clot method is no longer in use at the hospital pharmacy, reducing the negative impact on the horseshoe crab population.
- The rFC method streamlined the testing for endotoxins, reducing the time spent on performing the analysis by 50% due to less handling and increased capacity.
- Results are quantitative and objective, not relying on observations by the operator, thereby improving the quality.

## What next?

The rFC method increases both quality and capacity of testing, opening up for expanded testing in the pharmacy, and including samples from other departments or hospitals.

### Keywords:

- Preparation and compounding> Sterile production
- QC/QA> Microbiological testing
- QC/QA> Quality control

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