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## PRESENTATION ABSTRACT

Title: European Pharmacopeia Perspective on Functionality-Related Characteristics

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Abstract: In 2002 the European directorate for the quality of medicines and healthcare organised a symposium with manufacturers and regulators on the quality requirements and functionality related testing of excipients.

Functionality is based on:

- the properties of the molecule,
- the physical and chemical properties,
- in some cases, impurities (naturally occurring, degradation, added deliberately)

Functionality of an excipient is influenced by other constituents of the formulation and the manufacturing process. Because of that, the European Pharmacopeia chose to introduce functionality-related tests and not functionality testing.

In 2008, a general monograph on functionality-related characteristics of excipients was introduced in the European Pharmacopeia. The importance of functionality-related characteristics in the pharmaceutical development is explained therein.

The objectives in pharmaceutical development are to justify the qualitative and quantitative composition of the drug product:

- to justify the manufacturing process,
- to define the critical properties of the components and of the drug product, the critical steps of the manufacturing process,
- to define the pharmaceutical specifications for the drug substance and for the excipients in relation to the performance of the drug product.

According to the guideline ICH Q8 pharmaceutical development, the assessment of the criticality should be done preferably on a risk-based approach. The pharmaceutical development may establish the acceptable range of the critical characteristics including both the physical and chemical property variation and may define the design space. The knowledge of functionality related characteristics that are known to have an impact on the functionality of the excipient for the stated use is helpful. It may also facilitate the application of Process Analytical technology, one of the key elements of ICH Q8. This development should be seen in light of the desired regulatory flexibility based on establishing the acceptable range of material properties within the design space and in light of the real release time.

Most of the methods used to determine functionality-related characteristics are described in the general chapters of the European Pharmacopoeia. When monographs on excipients have a section entitled "Functionality-related characteristics," this section is included for the user and is not a mandatory part of the monograph. The author will explain the way of using functionality related characteristics described in the European Pharmacopoeia, the different ways of giving the information on the functionality related characteristics. Some examples of monographs of solid excipients, semi-solid excipients and liquid excipients are taken.