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# Application of QbD Principles for the Evaluation of Empty Hard Capsules

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## Abstract

Understanding the product and process variable on the final product performance is an essential part of the quality-by-design (QbD) principles in pharmaceutical development. The hard capsule is an established pharmaceutical dosage form used worldwide in development and manufacturing. The empty hard capsules are supplied as an excipient that is filled by pharmaceutical manufacturers with a variety of different formulations and products. To understand the potential variations of the empty hard capsules as an input parameter and its potential impact on the finished product quality, a study was performed investigating the critical quality parameters within and in between different batches of empty hard gelatin capsules. The variability of the hard capsules showed high consistency within the specification of the critical quality parameters. This also accounts for the disintegration times, when automatic endpoint detection was used. Based on these data, hard capsules can be considered as a suitable excipient for product development using QbD principles.

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