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2 Types of sterile product. The most obviously recognized sterile pharmaceutical preparations are injections. These vary from very small-volume antigenic products to large-volume, total parenteral nutrition products. Other sterile products include ophthalmic preparations, creams and dusting powders. This section describes their formulation and

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packaging and the constraints imposed by
sterilization on stability, formulation and
packaging of some of the more common sterile
products. 2.1 Injections

Sterile pharmaceutical products |

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Both formulations and processes are
challenged and optimized to ensure that the
Drug Product can be manufactured by a robust
and efficient process according to QbD
concepts. During scale-up critical parameters

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control strategies to ensure that quality
attributes are consistently met for
validation during routine manufacturing.

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