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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 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 | Basicmedical Key

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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 are established and verified with appropriate control strategies to ensure that quality attributes are consistently met for validation during routine manufacturing.