

5.2 Uniformity of mass for single dose preparations

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Question: What is the purpose of uniformity of mass testing for single dose preparations?

Answer: Uniformity of mass testing ensures that each single dose unit contains the correct amount of active pharmaceutical ingredient (API). This is crucial for patient safety and efficacy, as variations in API content can lead to under- or overdosing.

Question: What is the procedure for uniformity of mass testing?

Answer: Uniformity of mass testing involves randomly selecting a sample of 10 or 20 individual units from the production batch. Each unit is weighed and the results are analyzed statistically to determine if the variation in mass falls within acceptable limits.

Question: What are the acceptance criteria for uniformity of mass testing?

Answer: The acceptance criteria depend on the weight and intended dose of the preparation. Generally, for single dose preparations with weights up to 250 mg, the relative standard deviation (RSD) of the mass should not exceed 10%. For preparations over 250 mg, the RSD should not exceed 5%.

Question: What are the consequences of failing uniformity of mass testing?

Answer: Failure of uniformity of mass testing indicates potential issues with manufacturing processes or packaging. The batch may be rejected or further

investigation may be required to determine the cause of the variability.

Question: What measures can be taken to ensure uniformity of mass?

Answer: To ensure uniformity of mass, manufacturers can implement good manufacturing practices (GMP) and adhere to standardized procedures. These include careful weighing and dispensing, equipment maintenance, and appropriate environmental controls. Additionally, statistical process control (SPC) techniques can be used to monitor and adjust processes to maintain consistent mass uniformity.

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