

## GMP Yield—Considerations Beyond Percent Theoretical Yield

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US Food and Drug Administration good manufacturing practice (GMP) requirements regarding yield require that product be formulated to provide 100% of the labeled amount and that actual yields and percentages of theoretical yield be determined at the conclusion of each appropriate phase of manufacturing. Any unexplained discrepancy must be investigated. Percent of theoretical yield means that all materials assigned to the batch must be quantitatively reconciled. Meeting GMP requirements—acceptable percent of theoretical yield—is an extremely important attribute but is not necessarily indicative...

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