Chapter 13  
Evaluation of Stability Data  

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Abstract This chapter discusses the evaluation of stability data. It follows the stability study information from the point that raw data is generated in the lab, calculations are performed to give test results, and test results are entered in the stability summary sheets, until data is finally entered into a stability report for submission purposes. This chapter also includes a summary of data evaluation addressed in ICH Q1E and a discussion of Out-of-Specification (OOS) and Out-of-Trend  

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13.1 Data Evaluation and Trending

ICH Q1A(R2), Stability Testing of New Drug Substances and Products [1], for drug substances and drug products intended for marketing in the ICH Tripartite region includes sections on the evaluation of stability data. ICH Q1E, Evaluation of Stability Data [2], provides further details for data evaluation and includes recommended procedures for statistical analysis. These ICH guidelines are applicable to New Chemical Entities (NCEs) and associated drug products but do not apply to generics, manufacturing variations, clinical trial batches or devices.

This chapter describes the data evaluation that is to be performed from the time that data are generated until they are reported in a regulatory submission. Figure 13.1 provides a flow diagram for stability data evaluation.

![Flow diagram of stability data evaluation](image.png)

**Fig. 13.1** Flow diagram of stability data evaluation

13.1.1 Evaluation of Raw Data

Stability data evaluation must begin when raw data is generated in the laboratory. cGMPs require that drug products and drug substances must meet their