Title 21 —Food and Drugs
Chapter I —Food and Drug Administration, Department of Health and Human Services
Subchapter C —Drugs: General
Part 211 —Current Good Manufacturing Practice for Finished Pharmaceuticals
Subpart F —Production and Process Controls

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§ 211.100 Written procedures; deviations.

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.