

The FDA Warning Letters Report

Version 01

Finished Pharmaceuticals Top Ten Citations in Fiscal Year 2003 – Abstracts of the original wording

Date of Issue:
1 October 2004

[211.100 \(cont.\)](#) *Written procedures; deviations*

Original Wording	Company / Date
<p>You failed to formally approve (sign and date) the <u>INSTRUCTIONS ON LOT NUMBERING FOR OXYGEN REFILLING</u> procedure as required by 21 C.F.R. § 211.100.</p>	<p>Classic Medical, Inc.; St. Clair Shores, MI; 03.12.02</p>
<p>Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality and purity they are represented to possess [21 CFR 211.100(a)]. For example, no written procedures are established for receipt and acceptance of incoming bulk compressed oxygen, prefill, fill and post fill cylinder inspections, calibration and maintenance of equipment, purity and identity testing of filled cylinders, completion and review of batch production records, labeling, quarantine procedures, and training of personnel.</p>	<p>Gulf Medical Services; Milton, Florida; 16.12.02</p>
Original Wording	Company / Date
<p>You failed to follow your written process control procedures in the execution of production and process control functions and in the testing of drug product containers [21 C.F.R. § 211.100(b)].</p> <p>Additionally, there was no documentation of the review and approval of your written procedures [21 C.F.R. § 211.100(a)].</p>	<p>Southwest Pharmacy/DBA Anchor Home Care; McComb, Mississippi; 19.12.02</p>