OBSERVATION 1
Testing and release of drug products for distribution do not include appropriate laboratory determination of satisfactory conformance to final specifications and identity and strength of each active ingredient prior to release.

Specifically, the firm does not test batches of produced non-sterile drugs to ensure consistency and potency before products are released. The firm compounds (b) (4) drugs/week. day [day] [day].

OBSERVATION 2

Records of the calibration checks of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically, the firm does not have any documentation demonstrating the calibration and service for the (b) (4) balance, (b) (4) machines (b) (4) thermometer and (b) (4) . Further, there is no record of calibration of thermometers for the refrigerator, where compounded Lansoprazole 15 mg/5 ml for pediatric populations is stored.

OBSERVATION 3
Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component or establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at
appropriate intervals.

Specifically, the firm relies solely on the Certificate of Analysis provided with each raw ingredient as no additional tests are conducted upon receipt.

OBSERVATION 4

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, the firm does not consistently perform in-process checks on produced non-sterile drugs to reduce variability. The in-process checks is based on the confidential information.