To Evaluate the Delivery of Generic Lansoprazole Delayed-Release Capsules through Nasogastric Tube via In Vitro Testing
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Purpose
Lansoprazole Delayed-release (DR) Capsules can be administered via nasogastric (NG) tube per the product labeling. FDA had previously received adverse events reports indicating that the formulation can clog and block the tube. In some cases, patients have had to seek emergency medical assistance to unclog or replace their feeding tubes. Therefore, it is critical that generic products have similar delivery through the NG tube as does the reference product. The purpose of this study was to compare the transit of generic and reference listed drug lansoprazole granules through the NG tube.

Methods
Based on the FDA lab study results and extensive regulatory and literature research, the FDA developed in vitro NG tube study recommendations including sedimentation testing, particle size distribution study, recovery testing and comparative acid resistance stability testing. The FDA requested Abbreviated New Drug Application applicants to conduct in vitro NG tube studies comparing the transit of lansoprazole granules through 16 French NG tube of the test product to that of the reference product.

Results
We retrospectively collected the in vitro NG tube data from five approved ANDAs for Lansoprazole DR Capsules. The results of sedimentation testing showed that sedimentation volume was similar between the test and reference. In addition, the sedimentation testing provided the initial visual observation for granule performance in the dilution solvent. Differences in particle size distribution between the test and reference in all five applications were not statistically significant. It should be noted that no clogging or obstruction was observed. The recovery was greater than 90% recovery in all five studies and the generic drug products showed comparable recovery to the reference product. The results of acid resistance testing showed that the % release for both test and reference was much less than 10% in all five applications.

Conclusion
The results of in vitro NG tube studies demonstrated that the process of dispersing lansoprazole granules and delivery through the combination of oral syringe and NG tube did not impact the integrity of the enteric coating for generic drug products and that the generic products had a similar performance profile to the reference product during NG tube administration.