PRODUCTION SYSTEM
1.) Blending of in-specification with out-of-specification (OOS) intermediate batches is performed.

Specifically, intermediate batch tested OOS for impurity. The batch was manufactured starting on 03/05/2018. QC testing of this batch yielded a result of % for the impurity against a specification of less than or equal to %. Deviation investigation DV/1801, written for this incident, calls for this batch to be blended with other batches that have an in-specification result for manufacturing. The OOS batch was blended with in-specification material as follows:

A.) kg of batch blended with kg of batch to manufacture batch

B.) kg of batch blended with kg of batch and kg of batch to manufacture batch

C.) kg of batch blended with kg of batch to manufacture batch

D.) kg of batch blended with kg of batch and kg of batch to manufacture batch

The manufactured batches were used in the production of packaged lots of...

LABORATORY CONTROL SYSTEM
2.) Laboratory investigations for OOS intermediate batches are not conducted.

Specifically, according to SOP BDQC-311 for OOS investigations (effective 07/16/2018), OOS is to be conducted on "...all quantitative and qualitative tests of...intermediates..." An investigation of an OOS impurity result in the intermediate, batch was not conducted.