4. BATCH ANALYSES [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

A description of batches and results of batch analyses should be provided. A discussion of analytical procedure changes should be described as well as detailed information on Analytical procedures that are not included in Section 3.2.P.5.2.

The batches should include all clinical safety/efficacy, bioavailability, bioequivalence, and primary stability studies.

Typically this is submitted in a tabular format as in the following example:

Table 1: Batch Analysis for Drug Product

Lot No.							
Dosage Strength							
Site of Manufacture							
Date of manufacture							
Batch Size							
Drug Substance Lot number							
Use							
Test Method	Proposed Specification	Result	Result	Result	Result	Result	Result

Reference ICH guidances Q3B, Q3C, Q6A, and Q6B.