4. BATCH ANALYSES [{DRUG SUBSTANCE NAME}, {MANUFACTURER}]

Description of batches and results of batch analyses should be provided. These Batches include lots used in safety, efficacy, BA/BE, and primary stability studies. In the discussion for this section, describe any analytical procedures that are not included in section 3.2.S.4.2. as well as any changes that could impact the analysis results. Note that these results will be used in section 3.2.S.4.5 to justify release specifications for the drug substance.

Reference ICH guidances Q3A, Q3C, Q6A, and Q6B.

Note to the Author: Please replace the text contained within <<double angle brackets>> with actual Lot numbers.

3.2.S.4. Control of Drug Substance [{Drug Substance Name}, {Manufacturer}]

Table 1: Batch Analysis for Drug Substance

Lot No.		**<<Lot No.>>**	**<<Lot No.>>**	**<<Lot No.>>**	**<<Lot No.>>**	**<<Lot No.>>**	**<<Lot No.>>**
Batch Size							
Date of manufacture							
Site of Manufacture							
Use							
Test Method	**Proposed Specification**	**Result**	**Result**	**Result**	**Result**	**Result**	**Result**

Use - (Stability, Registration, Clinical Supply)

3.2.S.4. Control of Drug Substance [{Drug Substance Name}, {Manufacturer}]