Summary of Batch Analyses for Clinical Studies for [Brand Name] ((S)(A)NDS, Control No. XXXXXX)

Reference: Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs) (Effective date: 2018/01/30)

Study Number	Is the study considered pivotal? *(Yes/No)*	Drug Product Description *(Strength/dosage form/formulation)*	Drug Product			Drug Substance *(repeat if necessary)*		
			Lot Number	Manufacturing site	Location of Tabulated Summary or CoA within submission	Lot Number	Manufacturing site	Location of CoA within submission