

3.2.S.2.2. BATCH SCALE AND DEFINITION [BNT MAINZ AND RENTSCHLER]

3.2.S.2.2.1. Definition of a Production Batch – BNT162b2 Drug Substance

Commercial scale drug substance batches are executed at a scale of 4.2 1st ind starting volume for in vitro transcription (IVT) to produce about 4.2 1st ind of drug substance at approximately 2.25 mg/mL. All material produced is purified by a single two-stage ultrafiltration/diafiltration (UFDF) to produce drug substance.

3.2.S.2.2.2. Batch Number System

Each drug substance batch is assigned a separate batch number for the IVT and the UFDF process.

The batch number for the IVT process is manually generated and consists of a product code followed by a sequential number.

For the UFDF a unique batch number is generated by a validated enterprise resource planning (ERP) system and is used to identify a single lot of drug substance. Individual drug substance processing steps for each lot are identified and traceable through an internal documented numbering system.

Batches are released under the drug substance batch number generated for the IVT process with cross reference to the UFDF batch number.