

3.2.S.2.2. BATCH SCALE AND DEFINITION [ANDOVER]**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

The batch number system for drug substance consists of a material designation code followed by a unique number assigned by the material inventory system.

Each drug substance batch is assigned one batch number for the entire process. Batches are released under their drug substance batch number.