

3.2.S.2.4. HOLD TIMES [BNT MAINZ AND RENTSCHLER]

The validated hold times for manufacturing are described in Table 3.2.S.2.4-1. Pool hold times are not required for routine processing, but strategic holds in the process (≥ 24 h) to aid in manufacturing scheduling were validated as described in [Section 3.2.S.2.5 Hold Times \[BNT Mainz and Rentschler\]](#).

Table 3.2.S.2.4-1. Hold Times for mRNA Drug Substance (Routine Manufacturing)

4.2 1st ind

During the Proteinase K Pool hold time the transport at 4.2 1st ind to Rentschler, Laupheim for further processing is included ([Section 3.2.S.2.5. Shipping Performance Qualification \[BNT Mainz and Rentschler\]](#)).