

3.2.P.3.4. IN-PROCESS MONITORING AND CONTROL – OVERVIEW

This section provides a description of the controls of critical steps employed during manufacture of BNT162b2 drug product to ensure that product quality and integrity are maintained. Process parameters and in-process tests that are used to control the process and drug product quality are provided in this section.

Process parameters discussed in this section include all critical process parameters (CPP) as well as relevant non-CPPs. As described in [Section 3.2.P.2.3 Process Risk Assessment Strategy](#), CPPs and relevant non-CPPs were identified using Cause and Effect Risk Assessment based on product/process knowledge and available data. (b) (4)

(b) (4) see [Module 2.3 Introduction to Quality Overall Summary](#)).

In-process tests for control (IPT-Cs) and in-process tests for monitoring (IPT-Ms) were used throughout the process to ensure consistent manufacturing. IPT-Cs are in-process tests used to control a quality attribute/critical quality attribute within a specified range so that it meets the desired drug product quality. The IPT-Cs have an associated acceptance criterion. The IPT-Cs are tabulated with their associated acceptance criteria in Section 3.2.P.3.4 LNP Production and Bulk Drug Product Formulation and Section 3.2.P.3.4 Fill and Finish. The test methods for IPT-Cs are described in [Section 3.2.P.3.4 In-Process Test Methods](#).

In addition to IPT-Cs, IPT-Ms were implemented throughout the process to ensure consistency of the manufacturing process. IPT-Ms are used to monitor a quality attribute to either ensure it is consistent with previous process history or to enable forward processing. The IPT-Ms may have action limits. The IPT-Ms are described in Section 3.2.P.3.4 In-Process Test Methods.

(b) (4)

This section also provides information regarding process step (b) (4) as described in Section 3.2.P.3.4 Process Step (b) (4) – LNP Production and Bulk Drug Product Formulation and Section 3.2.P.3.4 Process Step (b) (4) – Fill and Finish.