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### 3.2.A.2. ADVENTITIOUS AGENTS SAFETY EVALUATION

Multiple mechanisms, procedures, and assays are used to minimize the entry of adventitious agents into the process stream and detect those agents that do enter the process stream. The adventitious agent control program includes the (b) (4)

#### 3.2.A.2.1. Introduction

The main theoretical risk associated with these ingredients is contamination of the product by Transmissible Spongiform Encephalopathy (TSE) agents. A multifaceted program exists to ensure the viral safety of the drug substance, including (b) (4)

Management of transmissible spongiform encephalopathy (TSE) / bovine spongiform encephalopathy (BSE) risks is part of the comprehensive adventitious agent control program for BNT162b2 drug substance.

All raw materials used in the production of drug substance are evaluated as part of a comprehensive program to identify and manage TSE/BSE risks. Under this program, the risk of transmission of TSE/BSE from animal-derived materials is managed by sourcing such materials in a manner consistent with the current industry guidelines including those from the European Medicines Agency (EMA), the Therapeutic Goods Administration (TGA), and the World Health Organization (WHO).

The conclusion from the TSE/BSE risk evaluations performed for raw materials in the BNT162b2 process is that the risk of transmitting TSE/BSE via drug substance has been minimized.

Details of any starting material, reagent or component containing material of animal origin including its source and preparation are discussed in the following sections. (b) (4)

Moreover, equipment and materials are (b) (4) according to validated procedures.

#### 3.2.A.2.2. Non-Viral Adventitious Agents

##### 3.2.A.2.2.1. Raw Material Sourcing and Testing

Raw material information is provided in Section 3.2.S.2.3 Control of Materials.

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Information for animal-derived materials is provided in [Table 3.2.A.2-1](#). All other materials are of synthetic and/or biological origin.

**Table 3.2.A.2-1. Materials of Animal Origin Used in the Manufacture of Drug Substance**

(b) (4)



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**Table 3.2.A.2-1. Materials of Animal Origin Used in the Manufacture of Drug Substance**

(b) (4)



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### 3.2.A.2.3. Conclusion

In summary, a comprehensive, multifaceted program is in place to ensure that the risk, with respect to potential viral and non-viral adventitious agent contamination of drug substance, is acceptable.