

## 2.3.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 (b) (4)

[REDACTED]

### 2.3.A.2.1. Adventitious Agents Safety Evaluation [Andover]

#### 2.3.A.2.1.1. 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)

[REDACTED]

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. 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 [3.2.A.2. Adventitious Agents Safety Evaluation \[Andover\]](#).

#### 2.3.A.2.1.2. Non Viral Adventitious Agents

##### 2.3.A.2.1.2.1. Raw Material Sourcing and Testing

Raw material vendors are qualified to sourcing materials from them for use in the manufacturing process. Raw material information is provided in [3.2.S.2.3 Control of Materials used in Manufacturing](#). In particular, the human or animal-derived materials are provided in [3.2.A.2. Adventitious Agents Safety Evaluation \[Andover\]](#). All other materials are of synthetic and/or biological origin.

##### 2.3.A.2.1.2.2. 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.

### **2.3.A.2.2. Adventitious Agents Safety Evaluation [Kalamazoo]**

#### **2.3.A.2.2.1. Introduction**

The main theoretical risk associated with these ingredients is a contamination of the product by Transmissible Spongiform Encephalopathy (TSE) agents. A multifaceted program has been established to ensure the viral safety of the drug product, including development of a formulation process that is devoid of human or animal proteins

All raw materials used in the production of BNT162b2 are evaluated as part of a comprehensive program to identify and manage TSE/BSE risks. 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 BNT162b2 has been minimized.

Details of any material, reagent, or component containing material of animal origin including its source and preparation are discussed in [3.2.A.2. Adventitious Agents Safety Evaluation \[Kalamazoo\]](#). These products are (b) (4)

#### **2.3.A.2.3. Non-Viral Adventitious Agents**

##### **2.3.A.2.3.1. Raw Material Sourcing and Testing**

Raw material vendors are qualified to sourcing materials from them for use in the manufacturing process. Raw material information is provided in [3.2.S.2.3 Control of Materials used in Manufacturing](#).

In particular, the human or animal-derived materials are provided in [3.2.A.2. Adventitious Agents Safety Evaluation \[Kalamazoo\]](#). All other materials are of synthetic and/or biological origin.

##### **2.3.A.2.3.2. Conclusion**

In summary, a comprehensive, multifaceted program is in place to ensure that the risk, with respect to potential viral and non-viral adventitious agents contamination of drug product, is acceptable. Equipment is cleaned by validated cleaning procedures described in [3.2.A.1 Facility and Equipment – Kalamazoo](#). In addition, sterility testing is performed on the final product, as described in [3.2.P.5.1 Specifications](#).

#### **2.3.A.2.4. Adventitious Agents Safety Evaluation [Puurs]**

##### **2.3.A.2.4.1. Introduction**

The main theoretical risk associated with these ingredients is a contamination of the product by Transmissible Spongiform Encephalopathy (TSE) agents. A multifaceted program has been established to ensure the viral safety of the drug product, including development of a formulation process that is devoid of human or animal proteins

All raw materials used in the production of BNT162b2 are evaluated as part of a comprehensive program to identify and manage TSE/BSE risks. 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 BNT162b2 has been minimized.

Details of any material, reagent, or component containing material of animal origin including its source and preparation are discussed in [3.2.A.2. Adventitious Agents Safety Evaluation \[Puurs\]](#). (b) (4)

##### **2.3.A.2.5. Non-Viral Adventitious Agents**

###### **2.3.A.2.5.1. Raw Material Sourcing and Testing**

Raw material vendors are qualified to sourcing materials from them for use in the manufacturing process. Raw material information is provided in [3.2.S.2.3 Control of Materials used in Manufacturing](#).

In particular, the human or animal-derived materials are provided in [3.2.A.2. Adventitious Agents Safety Evaluation \[Puurs\]](#). All other materials are of synthetic and/or biological origin.

###### **2.3.A.2.5.2. Conclusion**

In summary, a comprehensive, multifaceted program is in place to ensure that the risk, with respect to potential viral and non-viral adventitious agents contamination of drug product, is acceptable. Equipment is cleaned by validated cleaning procedures described in [3.2.A.1 Facility and Equipment – Puurs](#). In addition, sterility testing is performed on the final product, as described in [3.2.P.5.1 Specifications](#).