

3.2.P.4. Control of Excipients [{Drug Product Name}, {Dosage Form}]

5. EXCIPIENTS OF HUMAN OR ANIMAL ORIGIN [{DRUG PRODUCT NAME}, {DOSAGE FORM}]

For excipients of human or animal origin, information should be provided regarding adventitious agents (eg, sources, specifications, description of the testing performed, viral safety data). (Provide details in Appendix 3.2.A.2).

If an excipient of human or animal origin is used, the use of this excipient should be discussed with the FDA to get additional information about the requirements for this section.

Reference ICH guidances Q5A, Q5D, and Q6B.