|  |  |
| --- | --- |
| **Material Type** | **Document** |
| Excipient | * CoA (Certificate of Analysis)/ CoC (Certificate of Conformance) * Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy Certificate; Certificate of Origin * Back size/ bundle size information * ICH Q3D, Q3C and Nitrosamines * Stability statement (shipping and storage conditions, and shelf life) * MSDS (Material Safety Data Sheet) * GMO (Genetically modified organism) statement |
| Raw Materials | * CoA (Certificate of Analysis)/ CoC (Certificate of Conformance) * Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy Certificate; Certificate of Origin * Stability statement (shipping and storage conditions, and shelf life) * MSDS (Material Safety Data Sheet) |
| Primary Packaging Material | * CoA (Certificate of Analysis)/ CoC (Certificate of Conformance) * Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE) Certificate; Certificate of Origin * Irradiation Certificate * Material Specification (Technical drawing, design etc.) * Usage of sterile processing * Leachable and Extractable Information * Stability statement (shipping and storage conditions, and shelf life) |
| Secondary Packaging | * CoA (Certificate of Analysis)/ CoC (Certificate of Conformance) * Material Specification (Technical drawing, design etc.) * Stability statement (shipping and storage conditions, and shelf life) |
| GMP-Consumables | * CoA (Certificate of Analysis)/ CoC (Certificate of Conformance) * Material Specification (Technical drawing, design etc.) * Stability statement (shipping and storage conditions, and shelf life) |