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| **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 Nitrosamine
* Stability statement (shipping and storage conditions, and shelf life)
* MSDS (Material Safety Data Sheet)
* GMO (Genetically modified organism) statement
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| 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)
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| 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)
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| 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)
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| 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)
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