Injectables-related USP Documentary Standards

All currently available monoclonal antibody therapies are administered either subcutaneously or by intravenous infusion. Provided below are the USP Documentary Standards related to Injectables published in the *United States Pharmacopeia-National Formulary* (*USP–NF*).

***USP-NF* Documentary Standard**
<1> *Injections and Implanted Drug Products (Parenterals)—Product Quality Tests*
<61> *Microbial enumeration tests*
<71> *Sterility Tests*
<85> *Bacterial Endotoxins Test*
<221> *Chloride and sulfate*
<281> *Residue on ignition*
<381> *Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems*
<643> *Total organic carbon*
<645> *Water conductivity*
<697> *Container Content for Injections*
<729> *Globule Size Distribution in Lipid Injectable Emulsions*
<787> *Subvisible Particulate Matter in Therapeutic Protein Injections*
<788> *Particulate Matter in Injections*
<790> *Visible Particulates in Injections*
<791> *pH*
<921> *Water determination*
<1231> *Water for Pharmaceutical purposes*
<1381>> *Assessment of Elastomeric Component Used in Injectable Pharmaceutical Product Packaging/Delivery Systems*
<1787> *Measurement of Subvisible Particulate Matter in Therapeutic Protein Injections*
<1790> *Visual Inspection of Injections*

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