

RUO vs RMF vs CTS™ - Standard Catalog Offering Attributes

Attributes	Standard Offering*		
	RUO	RMF	CTS™
Manufacturing per Quality Standard:			
ISO 9001 QMS	P	P	
ISO 13485 (Different classes) QMS	P	P	P
EP 5.2.12			P
USP <1043>			P
ISO 20399			P
Intended Use			
For Research Use Only. Not for use in diagnostic procedures.	P		
For Research Use or Further Manufacturing. Not for diagnostic use or direct administration in to humans or animals.		P	
For Research Use or Manufacturing of Cell, Gene, or Tissue-based products. CAUTION: Not intended for direct administration into humans or animals.			P
Testing			
General Product Testing performed (ex. Performance, pH, Osmolality)	P	P	P
Sterility Tests, product dependent	P	P	P
Bioburden Testing, product dependent			P
Endotoxin Testing			P
Mycoplasma Testing			P
Enhanced Raw Material Testing /Evaluations			P
Viral testing/clearance or reduction validation of raw materials			P
Product Specific Shelf-life Data (Catalog only)	P	P	P
Purity/Impurity Profile - Finished Goods, product dependent			P
Documentation			
Standard Documentation (i.e. COA, COO, SDS, ISO Certificates, User Guide)	P	P	P
TSE/BSE certificate for Bovine Source	P	P	P
Supportive Statements: Melamine, Beta-lactam	P	P	P
Pharmaceutical Environment- Required Statements: Nitrosamine, Elemental Impurities, Residual Solvent			P
Pharmaceutical Environment - Traceability to Master Cell Banks			P
Pharmaceutical Environment - Traceability to Raw Materials			P
Change notification available as an opt-in for individual products. Notifiable events differ between offerings.	P	P	P
Drug Master Files, upon request		P	P
Regulatory Support Files, upon request			P
Catalog vs Custom			
Catalog products: All products developed per Thermo Fisher Scientific Process/Specifications. Specifications/testing supports reported offering and COA claims including stability.	P	P	P
Custom products: Quality processes and noted above attributes are the same related as Catalog Product. Any customer specific product customizations outside of the Catalog's validated parameters, <u>may result in naming label change (specifically CTS.)</u> as some items may require additional testing to support such customizations (i.e real-time stability and additional performance testing).			P

*This is standard offering. Dependent on product type, this may vary.