Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Data Sheet

Validation Services

Test Parameters by Service Level

We understand that selecting the appropriate validation package can be a complex decision. As your trusted partner, we can guide and support you in making the right choice.

Choose the Classic or Advanced Package

We have streamlined our service offerings to ensure finding the right solution for you. Our Classic and Advanced services are both supported by our experienced technical team, and differ only in the extent of support offered. The table below outlines the framework of these two service levels.

	Classic	Advanced
Satisfies Applicable Global Regulatory Expectations	✔	✔
Regulatory Query/Inquiry Assistance	✔	✔
Online Support	✔	✔
Call-in Support from Project Management Team	✔	✔
Test Customization[1]	-	✔
Bacterial Retention and Compatibility Study Conditions	Process duration 48 hr max Room temp range[2]	Maximum process duration Maximum process temp
Extractables Study Conditions	Model solvent(s) selected based on risk level Extraction temp 40 °C & duration 24 h, 7d or 21d	Customizable
Integrity Testing	1 product lot	Up to 3 product lots
Documentation	Templated	Customizable
Documentation Revision	1 on specific sections[3]	Up to 3 on full document

[1] Classic testing covers predetermined range of process conditions with defined study parameters. Advanced testing provides higher level of customization, including process conditions, additional test equipment/resources, and more complex study requirements

[2] as per Pharmacopoeias

[3] Drug product and process information sections

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

MERCK

Bacterial Retention Test Parameters - For filters with sterilizing grade claim

	Classic	Advanced
Viability study	1 product/1 control	1 product/1 control
	+2 modified solutions max	+4 modified solutions max
	Up to 5 time points + 1 additional/day	Up to 6 time points + 2 additional/day
Recovery study	1 recovery study included	Up to 2 recovery studies included
	1 solution/1 control	1 solution/1 control
	0.45 µm Mixed cellulose esters recovery filter	Customizable flush scheme
		On demand recovery filter
Low Bubble Point (BP) membrane	3 test filters & 1 control	3 test filters & 1 control
	Inc. at least one low BP	Inc. at least one low BP
Test parameters		
Duration	≤48 h	Customizable
Temperature	within RT range[4]	
Bacteria	*Brevundimonas diminuta*	
#batch	1	
#solution	1 fluid filtered	
Sterilization	Predefined by Validation Services	
Filtration Intermittency	Predefined by Validation Services	
#PUPSIT[5]	≤2	

[4] Room Temperature range as per Pharmacopoeias

[5] Pre-use post sterilization integrity test

Extractables Test Parameters

		Classic	Advanced
Stream & Test Analytics → Selection Based on Risk Level[6]			
HIGH	Solvent	EtOH 50%, pH3, pH10	Same & customizable
	Test Analytics	LC-UV, MS pos/neg mode & GC-MS	Same
	# of Device replicates tested[7]	2 replicates	Up to 3 replicates
MEDIUM	Solvent	EtOH 50%	Same & customizable
	Test Analytics	LC-UV, MS pos/neg mode & GC-MS	Same
	# of Device replicates tested[7]	2 replicates	Up to 3 replicates
LOW	Solvent	EtOH 50%	Same & customizable
	Test Analytics	NVR, LC-UV	Same
	# of Device replicates tested[7]	2 replicates	Up to 3 replicates
Process sterilization parameters (Autoclave, Steam in Place)		Within device recommendations	Outside of device recommendations
Process parameters (temperature, duration) aligned with USP <665> recommendations		Extraction temperature 40 °C & Duration 24 h, 7d or 21d	Customizable
Pretreatment		None	Available
Gamma irradiation		Standard range 25–40 kGy	Customizable (e.g. >45 kGy)

[6] as per USP <665>

[7] Each replicate from different lots upon availability

Leachables Test Parameters

	Classic	Advanced
Feasibility	Product Up to 1 or 2 modified solutions	Neat product Includes 2 modified solutions
Process parameters (temperature, duration)	-20 °C, 2–8 °C, room temp, 40 °C Maximum duration 21 days	Process conditions & customizable
Pretreatment	Available	Available
Soaking study (orbital shaking/static soak)	2 replicates[8]	Up to 3 replicates[8]
Flush study design (point of use filtration)	2 replicates[8] + up to 8 sampling points	2 replicates[8] + >8 sampling points
Test Analytics	LC-UV, MS pos/neg mode & GC-MS	Same

[8] Each replicate from different lots upon availability

Chemical Compatibility Test Parameters – Filters

	Classic	Advanced
Test filter	3 membranes discs from 1 lot + 1 filter device	3 membranes discs up to 3 lots + 1 filter device
# filter lot	Single lot	Single to 3 lots
Evaluation parameters	Flow rate, mass variation, macroscopic examination, bubble point test[9]	Flow rate, mass variation, macroscopic examination, bubble point test[9]
Temperature	within RT range[4]	Maximum process temperature
Process sterilization simulation	-	Available
Contact time	Up to 48 hrs process	Maximum process

[9] As per the Certificate of Quality

Chemical Compatibility Test Parameters – Bags

Mobius® System / NovaSeptum® System

	Classic	Advanced
Test bag	3 x 1 L and 50 mL bag	3 x 1 L and 50 mL bag
# bag lot	Single lot	Single to multiple lots[10]
Evaluation parameters	Macroscopic examination, mass variation, sealing resistance (pressurized immersion test & burst test), infrared surface analysis, tensile strength, thickness variation	Macroscopic examination, mass variation, sealing resistance (pressurized immersion test & burst test), infrared surface analysis, tensile strength, thickness variation
Temperature	within RT range[4]	Maximum process/storage temperature point (incl.freeze/thaw)
Sterilization	Gamma irradiation (25–40 kGy)	Customization of sterilization conditions
Contact time	Up to 48 hrs process	Maximum process

[10]Upon availability

Chemical Compatibility Test Parameters – Connectors

Mobius® System

	Classic	Advanced
Test connector	3 units	3 units
# connector lot	Single lot	Single to multiple lots[11]
Evaluation parameters	Macroscopic examination, Leak test, Handling/actuation test	Macroscopic examination, Leak test, Handling/actuation test
Temperature	within RT range[4]	Maximum process temperature
Sterilization	Gamma irradiation (25–40 kGy)	Customization of sterilization conditions
Contact time	Up to 48 hrs process	Maximum process

[11]Upon availability

Integrity Test Parameters

Bubble Point, Diffusion, Enhanced Bubble Point

	Classic	Advanced
Filter	3 filters from 3 lots	9 filters from 3 lots
Product	1 lot	1–3 lots
Temperature	within RT range[4]	Maximum process temperature

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