



Validation Services

Test Parameters by Service Level

You rely on our expertise and consultative support to meet your global regulatory requirements. But choosing the right validation package can be a challenge.

Choose the Classic or Advanced Package

We've simplified our service offerings so you can easily find what you need. Both Classic and Advanced services rely on our experienced technical team, and differ only in the extent of support offered. The table below provides the framework of the 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 48hr max Cold and room temperature	Maximum process duration Maximum process temperature
Extractables Study Conditions	Standard model streams in accordance with industry guidance	Custom
Integrity Testing	1 product lot	3 product lots
Templated Documentation	•	-
Customized Documentation	-	•
Documentation Revision	1 on specific fields ²	Up to 3 on full document
Validation Summary Report ³	-	•

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 Drug product & process information fields

³ Validation summary report is integrated when two or more services are ordered.

Bacterial Retention Test Parameters - For filters with sterilizing grade claim

	Classic	Advanced
Viability study	1 product/1 control + 2 modified solutions max Time points: up to 5 time points + 1/add. day	1 product/1 control + 4 modified solutions max <24h: ≤6 time points ≥24h: 6+ 2 additional/day
Recovery study	1 recovery study included 1 solution/1 control Single Flush scheme Ester of cellulose 0.45µm	Up to 2 recovery studies included 1 solution/ 1 control Customization flush On demand recovery filter
Low Bubble Point (BP) membrane	3 test filters Inc. at least one low BP/ 1 control	3 test filters Inc. at least one low BP/ 1 control
Process parameters (temperature, flow rate/pressure, processing/contact time, scale down volume)	Process conditions range: Cold or Room temperature Up to 48hrs process	Process conditions
Filtration cycles	Predefined	Customization of filtration cycles
Process sterilization simulation	-	Available
Filter re-use, Sequential filtration, Other strain than <i>Brevundimonas diminuta</i>	-	Available

Extractables Test Parameters

	Classic	Advanced
Sterilization (autoclave, Sterilization in Place (SIP))	Autoclave & SIP: device validation parameters	Autoclave & SIP: outside of device validation parameters
# lot	2 lots	3 lots
Streams	Standard model streams in accordance with industry guidance	Customization
Process parameters (temperature, duration) aligned with USP <665> recommendations	Preset temperature: 40°C Duration: 24h, 7d (or 21d for bags)	Temperature: On-demand Duration: custom
Pretreatment	-	Available
Calculation for Analytical Evaluation Threshold (AET) based on customer information	-	Available
Gamma irradiation	≥40kGy	Customizable (e.g. >45kGy)
Mass Spec Analytics	GCMS and/or LCMS	GCMS and/or LCMS

Extractables documentation report will be provided whenever existing data sets are available, using worst case approach, to cover a customer's product and process. Extraction conditions and model streams that are provided may be outside of BioPhorum or USP <665> standard conditions

Leachables Test Parameters

	Classic	Advanced
Feasibility study	Neat product Incl. 1 modified solution	Neat product Incl. 2 modified solutions
Process parameters (temperature, duration)	-20°C, 2-8°C, CRT, 40°C Max duration 21 days	Process conditions
Mass Spec Analytics	GCMS and/or LCMS	GCMS and/or LCMS
Pretreatment	Available	Available
Calculation for Analytical Evaluation Threshold (AET) based on customer information	-	Available
Long term study (orbital shaking/static soak)	3 lots	3 lots + analysis of pre-use flush sample included upon request
Flush study design (point of use filtration)	2 lots + up to 8 sampling points + 1 point threshold standard	2 lots + >8 process interruptions sampling points + 1 point threshold standard

Chemical Compatibility Test Parameters – Filters

	Classic	Advanced
Test filter	3 membranes discs+ 1 filter device	3 membranes discs+ 1 filter device
# filter lot	Single lot	Single to 3 lots
Evaluation parameters	Flow rate, mass variation, macroscopic examination, bubble point test ⁴	Flow rate, mass variation, macroscopic examination, bubble point test ⁴
Temperature	Cold or Room Temperature	Process temperature
Process sterilization simulation	-	Available
Contact time	Up to 48hrs process	Maximum process

⁴ As per the Certificate of Quality

Chemical Compatibility Test Parameters – Bags

Mobius® System / NovaSeptum® System

	Classic	Advanced
Test bag	(3x 1L bag + 1 control) + (3x 50 ml bag + 1 control)	(3x 1L bag + 1 control) + (3x 50 ml bag + 1 control)
# bag lot	Single lot	Single to multiple lots ⁵
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	Cold or Room Temperature	Process / storage temperature (incl. freeze/thaw)
Sterilization	Gamma irradiation (25-40 kGy)	Customization of sterilization conditions
Contact time	Up to 48hrs process	Maximum process

⁵ 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 ⁶
Evaluation parameters	Macroscopic examination, Leak test, Handling/actuation test	Macroscopic examination, Leak test, Handling/actuation test
Temperature	Cold or Room Temperature	Process temperature
Sterilization	Gamma irradiation (25-40 kGy)	Customization of sterilization conditions
Contact time	Up to 48hrs process	Maximum process

⁶ Upon availability

Integrity Test Parameters

Bubble Point, Diffusion, Enhanced Bubble Point

	Classic	Advanced
Filter	3 filters from 1 lot	3 to 9 filters from 1 to 3 lots
Product	1 lot	1-3 lots
Temperature	Cold or Room temperature	Process temperature

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