

Validation Services

Service Level Description

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 Essential, Classic or Advanced Package

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

	Essential	Classic	Advanced
Satisfies Applicable Global Regulatory Expectations	✓	✓	✓
Regulatory Query/Inquiry Assistance	✓	✓	✓
Online Support	✓	✓	✓
Call-in Support from Project Management Team	✓	✓	✓
Test Customization ¹	Not applicable	Not applicable	✓
Bacterial Retention and Compatibility Study Conditions	Process duration 24hrs max Room temp range ²	Process duration 48hrs 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 24hrs	Model solvent(s) selected based on risk level Extraction temp 40 °C & duration 24hrs, 7d or 21d	Customizable
Integrity Testing	1 product lot 1 filter	1 product lot 3 filters	Up to 3 product lots
Documentation	Generic No hard copy	Templated Hard copy included	Customizable Hard copy included
Documentation Revision	Not applicable	1 on specific sections ³	Up to 3 on full document

¹ Essential, and Classic testing covers predetermined range of process conditions with defined study parameters

² Advanced testing provides higher level of customization, including process conditions, additional test equipment/resources, and more complex study requirements as per Pharmacopoeias

³ Drug product and process information sections

Bacterial Retention Test Parameters – For filters with sterilizing grade claim

	Essential	Classic	Advanced
Viability study	1 product/1 control + 1 modified solution max Up to 3 time points	1 product/1 control + 2 modified solutions max Up to 5 time points + 1 additional/day	1 product/1 control + 4 modified solutions max Up to 6 time points + 2 additional/day
Recovery study	1 recovery study included 1 solution/1 control 0.45 µm Mixed cellulose esters recovery filter	1 recovery study included 1 solution/1 control 0.45 µm Mixed cellulose esters recovery filter	Up to 2 recovery studies included 1 solution/1 control Customizable flush scheme On demand recovery filter
Low Bubble Point (BP) membrane	3 test filters & 1 control Inc. at least one low BP	3 test filters & 1 control Inc. at least one low BP	3 test filters & 1 control Inc. at least one low BP
Test parameters			
Duration	≤24 hrs	≤48 hrs	
Temperature	within RT range ⁴	within RT range ⁴	
Bacteria	<i>Brevundimonas diminuta</i>	<i>Brevundimonas diminuta</i>	
#batch	1	1	
#solution	1 fluid filtered	1 fluid filtered	Customizable
Sterilization	Predefined by Validation Services	Predefined by Validation Services	
Filtration Intermittency	Predefined by Validation Services	Predefined by Validation Services	
#PUPSIT ⁵	None	≤ 2	

⁴ Room Temperature range as per Pharmacopoeias

⁵ Pre-use post sterilization integrity test

Extractables Test Parameters

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

⁶ as per USP <665>

⁷ LC-MS negative mode and LC-UV are supplementary and only analyzed if unique compounds are identified as defined by Validation Services

Leachables Test Parameters

	Essential	Classic	Advanced
Feasibility	Product Up to 1 modified solution	Product Up to 1 or 2 modified solutions	Neat product Includes 2 modified solutions
Process parameters (temperature, duration)	Room temperature 24 hrs	-20 °C, 2 - 8 °C, room temp, 40 °C Maximum duration 21 days	Process conditions & customizable
Pretreatment	Available	Available	Available
Soaking study (orbital shaking/static soak)	2 lots	2 lots	3 lots
Flush study design (point of use filtration)	2 lots + up to 8 sampling points	2 lots + up to 8 sampling points	2 lots + >8 sampling points
Test Analytics	LC-QToF ⁸ & GC-MS	LC-UV, MS pos/neg mode & GC-MS	Same as Classic

⁸ LC-MS negative mode and LC-UV are supplementary and only analyzed if unique compounds are identified as defined by Validation Services

Chemical Compatibility Test Parameters - Filters

	Essential	Classic	Advanced
Test filter	1 filter device	3 membranes discs from 1 lot + 1 filter device	3 membranes discs from 1 lot + 1 filter device
# filter lot	Single lot	Single lot	Up to 3 lots
Evaluation parameters	Macroscopic examination, bubble point test ⁸	Flow rate, mass variation, macroscopic examination, bubble point test ⁸	Flow rate, mass variation, macroscopic examination, bubble point test ⁸
Temperature	Within RT range	Within RT range	Maximum process temperature
Process sterilization simulation	-	-	Available
Contact time	Up to 24 hrs process	Up to 48 hrs process	Maximum process

⁸ as per the Certificate of Quality

Integrity Test Parameters – Bubble Point, Diffusion, Enhanced Bubble Point

	Essential	Classic	Advanced
Filter	1 filter	3 filters from 1 lot	3 to 9 filters from 1 to 3 lots
Product	1 lot	1 lot	1-3 lots
Temperature	Within RT range	Within RT range	Maximum process temperature

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