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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	FMPV2020L SAMPLE #B1 SAMPLE #B2 SAMPLE #B3 SAMPLE #B4 SAMPLE #B5
Purchase Order:	NGPO_O182020
Study number:	1274106-S01
Study received date:	05 March 2020
Testing facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A
Test procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performer to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of Staphylococcus aureus was earosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 – 3.0 x 10(3) colony forming units (CFU) with a mean particle size (MPS of 3.0 +0.3um. The earosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performer to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performer in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test side:	Sponsor labeled side
BFE Test area:	-40cm 2
BFE Flow rate:	28,3 liters per minute (L/min)
Delta P flow rate:	8 liters per minute (L/min)
Conditioning parameters:	85+5% relative humidity (RH) and 21+5C for a minimum of 4 hours
Positive control average:	1,8 x 10(3) CFU
Negative monitor count:	< 1 CFU
MPS:	3.0um

Study Director James W. Luskin

Study Completion Date 21 Mar 2020

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Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.9
3	99.9
4	99.9
5	>99.9

Test Article	Delta P (mm H2O/cm2)	Delta P (Pa/cm2)
1	4,9	48,2
2	4,9	48,3
3	6,0	58,6
4	5,0	48,6
5	5,6	55,2

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Viral Filtration Efficiency (VFE) Final Report

Test Article:	FMPV2020L SAMPLE NO:V1 SAMPLE NO:V2 SAMPLE NO:V3 SAMPLE NO:V4 SAMPLE NO:V5
Purchase Order:	NGPO_O182020
Study number:	1274106-S01
Study received date:	05 March 2020
Testing facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A
Test procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The VFE test is performer to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of bacteriophage OX174 was earosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 – 3.3 x 10(3) colony forming units (CFU) with a mean particle size (MPS) of 3.0 +0.3um. The earosols were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performer in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test side:	Sponsor labeled side
Test area:	-40cm 2
VFE Flow rate:	28,3 liters per minute (L/min)
Conditioning parameters:	85+5% relative humidity (RH) and 21+5C for a minimum of 4 hours
Positive control average:	1,9 x 10(3) PFU
Negative monitor count:	< 1 PFU
MPS:	3.2 um

Study Director — James W. Luskin — Study Completion Date: 23 MAR 2020

Results:

Test Article Number	Percent BFE (%)
V1	99.8
V2	>99.9*
V3	99.9
V4	99.7
V5	99.8

*****There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C}\,x\,100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Učinkovitost filtriranja bakterija (BFE) i diferencijalni tlak (Delta P)
Konačno izvješće

Ispitivani artikl:	FMPV2020L UZORAK #B1 UZORAK #B2 UZORAK #B3 UZORAK #B4 UZORAK #B5
Narudžba:	NGPO_O182020
Broj studije:	1274106-S01
Datum zaprimanja studije:	5. ožujka 2020.
Postrojenje za ispitivanje:	NelsonLaboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 SAD
Postupak (postupci) ispitivanja:	Broj standardnog protokola ispitivanja (STP): STP0004 Rev 18
Odstupanje(a):	Nikakva

Sažetak: BFE test koristi se za određivanje učinkovitosti filtracije ispitivanih predmeta usporedbom kontrolnog broja bakterija ispred ispitivanog predmeta s brojem bakterija iza njega. Suspenzija bakterija Staphylococcus aureus pretvorena je u aerosol pomoću nebulizatora i dovedena do ispitivanog predmeta pri konstantnoj brzini protoka i fiksnom tlaku zraka. Isporuka izazivanja je održavana na razini 1,7 - 3,0 x 10(3) jedinica koje tvore kolonije (CFU) sa srednjom veličinom čestica (MPS) od 3,0 +0,3 um. Aerosoli su provučeni kroz šesterostupanjski Andersenov uzorkivač živih čestica u svrhu prikupljanja.
Ova metoda ispitivanja u skladu je s normama ASTM F2101-19 i EN 14683:2019, Dodatak B.

Delta P test provodi se radi određivanja prozračnosti ispitivanih predmeta mjerenjem razlike u tlaku zraka s obje strane ispitivanog predmeta pomoću manometra pri konstantnom protoku zraka. Ispitivanje Delta P u skladu je s normama EN 14683:2019, Dodatak C i ASTM F2100-19.

Ispunjeni su svi kriteriji prihvatljivosti ispitne metode. Ispitivanje je provedeno u skladu s propisima dobre proizvođačke prakse (GMP) američke Agencije za hranu i lijekove (FDA) 21 CFR dijelovi 210, 211 i 820.

Ispitana strana: strana označena od strane sponzora

Ispitno područje BFE:	-40cm 2
Brzina protoka BFE:	28,3 litara u minuti (L/min)
Protok Delta P:	8 litara za minuti (L/min)
Parametri kondicioniranja:	85+5% relativna vlažnost (RH) i 21+5^{o}C tijekom najmanje 4 sata
Pozitivni kontrolni prosjek:	1,8 x 10(3) CFU
Negativan zbroj na monitoru:	< 1 CFU
MPS:	3,0um

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Study Director James W. Luskin — 21 Mar 2020 Study Completion Date

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Rezultati:

Broj ispitivanog artikla	Postotak BFE (%)
1	99.8
2	99.9
3	99.9
4	99.9
5	>99.9

Ispitivani artikl	Delta P (mm H2O/cm2)	Delta P (Pa/cm2)
1	4,9	48,2
2	4,9	48,3
3	6,0	58,6
4	5,0	48,6
5	5,6	55,2

Postotak učinkovitosti filtracije izračunat je prema sljedećoj jednadžbi:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = pozitivni kontrolni prosjek
T = ukupan broj ploča dobivenih iza ispitivanog artikla
Napomena: Ukupan broj ploča dostupan je na zahtjev.

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Konačno izvješće o učinkovitosti filtriranja virusa (VFE)

Ispitivani artikl:	FMPV2020L UZORAK BR.:V1 UZORAK BR.:V2 UZORAK BR.:V3 UZORAK BR.:V4 UZORAK BR.:V5
Narudžba:	NGPO_O182020
Broj studije:	1274106-S01
Datum zaprimanja studije:	05 March 2020
Postrojenje za ispitivanje:	NelsonLaboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 SAD
Postupak (postupci) ispitivanja:	Broj standardnog protokola ispitivanja (STP): STP0004 Rev 18
Odstupanje(a):	Nikakva

Sažetak: VFE test koristi se za određivanje učinkovitosti filtracije ispitivanih predmeta usporedbom kontrolnog broja virusa ispred ispitivanog predmeta s brojem virusa iza njega. Suspenzija bakteriofaga OX174 pretvorena je u aerosol pomoću nebulizatora i dovedena do ispitivanog predmeta pri konstantnoj brzini protoka i fiksnom tlaku zraka. Isporuka izazova održavana je na razini 1,1 - 3,3 x 10(3) jedinica koje tvore kolonije (CFU) sa srednjom veličinom čestica (MPS) od 3,0 +0,3 um. Aerosoli su prikupljeni pomoću šesterostupanjskog Andersenovog uzorkivača živih čestica u svrhu prikupljanja. Postupak ispitivanja VFE prilagođen je iz ASTM F2101.

Ispunjeni su svi kriteriji prihvatljivosti ispitne metode. Ispitivanje je provedeno u skladu s propisima dobre proizvođačke prakse (GMP) američke Agencije za hranu i lijekove (FDA) 21 CFR dijelovi 210, 211 i 820.

Ispitana strana: strana označena od strane sponzora

Ispitna površina:	-40cm 2
Protok VFE:	28.3 litara u minuti (L/min)
Parametri kondicioniranja:	85+5% relativna vlažnost (RH) i 21+5^{o}C tijekom najmanje 4 sata
Pozitivni kontrolni prosjek:	1.9 x 10(3) PFU
Negativan zbroj na monitoru:	< 1 PFU
MPS:	3,2 um

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Study Director — James W. Luskin

23 Mar 2020
Study Completion Date

Rezultati:

Broj ispitivanog artikla	Postotak BFE (%)
V1	99.8
V2	>99.9*
V3	99.9
V4	99.7
V5	99.8

*Ni na jednoj ploči Andersenovog uzorkivača za ovaj ispitivani proizvod nisu otkrivene

nikakve naslage. Postotak učinkovitosti filtriranja izračunat je prema sljedećoj jednadžbi:

$$\%\,VFE = \frac{C - T}{C}\,x\,100$$

C = pozitivni kontrolni prosjek
T = ukupan broj ploča dobivenih iza ispitivanog artikla
Napomena: Ukupan broj ploča dostupan je na zahtjev.