

Sequence and Chromatogram Overview



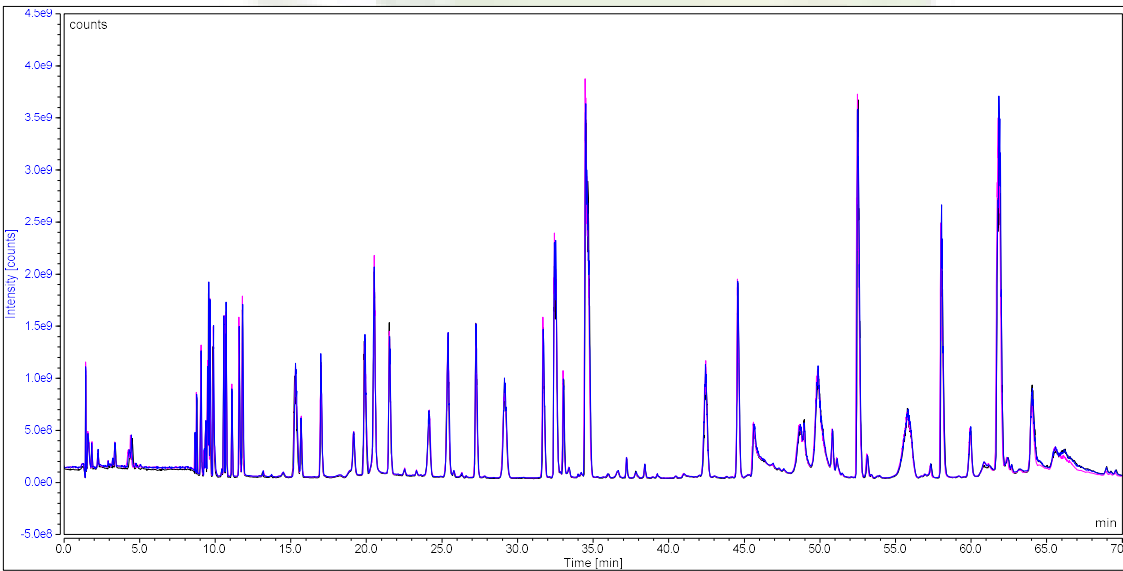
Sequence Details

Name:	3.InfliximAb Biosimilars	Created On:	15/Nov/2022 12:37
Instrument:	EMS1_001 n.a.	Updated On:	28/Nov/22 13:32:30
Imported Data:	True		
First Injection:	NIST_02		
Processing Method:	NIST_Reference_Peptides_InterLab		
MS Acquisition Time [min]	70.00		
Method Length [min]:	115.00		
Total Time [hrs]	27.50		
Data Vault:	ChromeleonLocal	Created By:	Silvia
No. of Injections:	15	Updated By:	Silvia

Injection Details

Injection Name	Position	Type	Volume μ L	Instrument Method	Processing Method	Status	Inject Time
NIST_02		Unknown	1.00		NIST_Reference	Finished	14/Nov/22 17:18:47
NIST_12		Unknown	1.00		NIST_Reference	Finished	15/Nov/22 12:37:53
NIST_22		Unknown	1.00		NIST_Reference	Finished	16/Nov/22 07:58:01

Chromatogram



Sequence and Chromatogram Overview



Sequence Details

Name:	3.InfliximAb Biosimilars	Criteria		Created On:	15/Nov/2022 12:37
Instrument:	EMS1_001 n.a.	RT %CV	2%	Updated On:	28/Nov/22 13:32:30
Imported Data:	True	Peak Area %CV	12%		
First Injection:	NIST_02	Peak Height Range	1.00E+07 7.00E+09		
Processing Method:	NIST_Reference_Peptides_InterLab	Peak Height %CV	10%		
MS Acquisition Time [min]:	70.00	Max Peak Width 10% Height	25		
Method Length [min]:	115.00	Peak Width 10% Height %CV	10%		
Total Time [hrs]	27.50	Mass Accuracy range	-5 5		
Data Vault:	ChromeleonLocal			Created By:	Silvia
No. of Injections:	15			Updated By:	Silvia

Injection Details

Injection Name	Area counts*min	Type	Volume µL	InstrumentMethod	Processing Method	Status	Inject Time
NIST_02	1.35e+08	Unknown	1.00		NIST_Reference_Peptic	Finished	14/Nov/22 17:18:47
NIST_12	1.38e+08	Unknown	1.00		NIST_Reference_Peptic	Finished	15/Nov/22 12:37:53
NIST_22	1.38e+08	Unknown	1.00		NIST_Reference_Peptic	Finished	16/Nov/22 07:58:01

Does this Sequence Pass System Suitability?

RETENTION TIME

Peak Name	Pass or Fail?	Ret.Time min	NIST_02 MS Quantitation	NIST_12 MS Quantitation	NIST_22 MS Quantitation	%RSD counts*min
First Injection	First Injection					First Injection
MS Quantitation						MS Quantitation Peak
EEQYN[A2G1F]STYR	Pass	9.34	9.36	9.35		0.09%
EEQYN[A2G0F]STYR	Pass	9.37	9.40	9.38		0.11%
HYNPSLK	Pass	9.63	9.66	9.65		0.16%
ALPAPIEK	Pass	15.32	15.36	15.32		0.14%
LLIYDTSK	Pass	21.51	21.53	21.52		0.03%
NQVSLTC[Carboxymethylation]LVK	Pass	31.70	31.70	31.67		0.05%
TTPPVLSDSGSFFLYSK	Pass	44.58	44.57	44.54		0.04%
VVSVLTVLHQDWLNGK	Pass	52.53	52.51	52.47		0.05%
ALEWLADIWDDKK	Pass	58.03	58.03	58.01		0.02%

PEAK AREA

Peak Name	Pass or Fail?	Area counts*min	NIST_02 MS Quantitation	NIST_12 MS Quantitation	NIST_22 MS Quantitation	%RSD counts*min
First Injection	First Injection					First Injection
MS Quantitation						MS Quantitation Peak
EEQYN[A2G1F]STYR	Pass	8.41e+06	9.32e+06	9.51e+06		6.46%
EEQYN[A2G0F]STYR	Pass	8.29e+06	9.32e+06	9.46e+06		7.07%
HYNPSLK	Pass	7.04e+07	7.55e+07	7.68e+07		4.59%
ALPAPIEK	Pass	1.35e+08	1.38e+08	1.38e+08		1.41%
LLIYDTSK	Pass	1.64e+08	1.66e+08	1.68e+08		1.21%
NQVSLTC[Carboxymethylation]LVK	Pass	1.74e+08	1.78e+08	1.82e+08		2.17%
TTPPVLSDSGSFFLYSK	Pass	2.25e+08	2.31e+08	2.30e+08		1.36%
VVSVLTVLHQDWLNGK	Pass	5.40e+08	5.57e+08	5.47e+08		1.54%
ALEWLADIWDDKK	Pass	3.38e+08	3.39e+08	3.28e+08		1.84%

PEAK HEIGHT

Peak Name	Pass or Fail?	Height counts	NIST_02 MS Quantitation	NIST_12 MS Quantitation	NIST_22 MS Quantitation	Min Peak Height counts	Max Peak Height counts
First Injection	First Injection					First Injection	First Injection
MS Quantitation						MS Quantitation Peak	MS Quantitation Peak
EEQYN[A2G1F]STYR	Pass	1.69e+08	1.74e+08	1.82e+08		1.69e+08	1.82e+08
EEQYN[A2G0F]STYR	Pass	1.92e+08	2.13e+08	2.11e+08		1.92e+08	2.13e+08
HYNPSLK	Pass	1.21e+09	1.27e+09	1.26e+09		1.21e+09	1.27e+09
ALPAPIEK	Pass	6.62e+08	7.26e+08	6.83e+08		6.62e+08	7.26e+08
LLIYDTSK	Pass	1.30e+09	1.19e+09	1.21e+09		1.19e+09	1.30e+09
NQVSLTC[Carboxymethylation]LVK	Pass	1.28e+09	1.25e+09	1.35e+09		1.25e+09	1.35e+09
TTPPVLSDSGSFFLYSK	Pass	1.48e+09	1.50e+09	1.49e+09		1.48e+09	1.50e+09
VVSVLTVLHQDWLNGK	Pass	3.13e+09	3.07e+09	3.15e+09		3.07e+09	3.15e+09
ALEWLADIWDDKK	Pass	1.97e+09	2.04e+09	1.95e+09		1.95e+09	2.04e+09

PEAK WIDTH AT 10% HEIGHT

Peak Name	Pass or Fail?	Peak Width (10%) sec	NIST_02 MS Quantitation	NIST_12 MS Quantitation	NIST_22 MS Quantitation	Max Peak Height sec	Peak Width (10%) %CV
First Injection	First Injection					First Injection	First Injection
MS Quantitation						MS Quantitation Peak	MS Quantitation Peak
EEQYN[A2G1F]STYR	Pass	5.09	5.32	5.32		5.32	2.54%
EEQYN[A2G0F]STYR	Pass	4.51	4.54	4.60		4.60	1.01%
HYNPSLK	Pass	6.09	6.19	6.23		6.23	1.21%
ALPAPIEK	Pass	20.76	20.08	20.85		20.85	2.05%
LLIYDTSK	Pass	13.84	14.54	14.44		14.54	2.69%
NQVSLTC[Carboxymethylation]LVK	Pass	14.24	14.65	14.36		14.65	1.47%
TTPPVLSDSGSFFLYSK	Pass	16.11	16.14	16.38		16.38	0.92%
VVSVLTVLHQDWLNGK	Pass	18.06	18.23	18.20		18.23	0.47%
ALEWLADIWDDKK	Pass	18.01	17.47	17.38		18.01	1.93%

COMPOSITE SCORING AND MASS ACCURACY

Peak Name	Pass or Fail	Composite Score			Mass Accuracy			Min MA Conf1 ppm
		First Injection	MS Quantitation	MS Quantitation	MS Quantitation	ppm	NIST_02	
(+2) EEQYN[A2G1F]STYR	Pass	Confirmed	Confirmed	Confirmed	-1.70	-1.09	0.83	-1.88
(+3) EEQYN[A2G1F]STYR	Pass	Confirmed	Confirmed	Confirmed	-1.78	-1.06	0.84	-1.88
(+2) EEQYN[A2G0F]STYR	Pass	Confirmed	Confirmed	Confirmed	-1.76	-1.11	0.74	-1.88
(+3) EEQYN[A2G0F]STYR	Pass	Confirmed	Confirmed	Confirmed	-2.19	-1.42	0.24	-2.19
(+1) HYNPSLK	Pass	Confirmed	Confirmed	Confirmed	-1.77	-1.13	0.79	-1.88
(+2) HYNPSLK	Pass	Confirmed	Confirmed	Confirmed	-1.35	-0.57	1.13	-1.88
(+2) ALPAPIEK	Pass	Confirmed	Confirmed	Confirmed	-2.25	-0.95	0.44	-2.25
(+1) ALPAPIEK	Pass	Confirmed	Confirmed	Confirmed	-1.95	-0.78	0.09	-1.95
(+1) LLIYDTSK	Pass	Confirmed	Confirmed	Confirmed	-0.64	0.07	1.73	-1.88
(+2) LLIYDTSK	Pass	Confirmed	Confirmed	Confirmed	-0.60	0.10	1.83	-1.88
(+2) NQVSLTC[Carboxymethylation]LVK	Pass	Confirmed	Confirmed	Confirmed	-2.12	-0.55	0.81	-2.12
(+1) NQVSLTC[Carboxymethylation]LVK	Pass	Confirmed	Confirmed	Confirmed	-2.06	-0.48	0.57	-2.06
(+2) TTPPVLSDGSFFLYSK	Pass	Confirmed	Confirmed	Confirmed	-2.02	-1.50	0.19	-2.02
(+3) TTPPVLSDGSFFLYSK	Pass	Confirmed	Confirmed	Confirmed	-2.17	-1.69	0.07	-2.17
(+2) VVSVLTVLHQDWLNGK	Pass	Confirmed	Confirmed	Confirmed	-1.35	-0.27	0.41	-1.88
(+3) VVSVLTVLHQDWLNGK	Pass	Confirmed	Confirmed	Confirmed	-1.23	0.09	0.59	-1.88
(+2) ALEWLADIWDDKK	Pass	Confirmed	Confirmed	Confirmed	-1.41	-0.66	0.77	-1.88
(+3) ALEWLADIWDDKK	Pass	Confirmed	Confirmed	Confirmed	-1.26	-0.54	0.89	-1.70



Sequence and Chromatogram Overview



Sequence Details

Name:	3.InfliximAb Biosimilars	Criteria		Created On:	15/Nov/2022 12:37
Instrument:	EMS1_001 n.a.	% Oxidation < or =	3	Updated On:	28/Nov/22 13:32:30
Imported Data:	True	% Oxidation %CV < or =	10		
First Injection:	NIST_02	% C-term Lys Clip range % < or =	13		
Processing Method:	NIST_Reference_Peptides_InterLab	% C-term Lys %CV < or =	10		
MS Acquisition Time [min]	70.00	% EEQYN[A2G0F]STYR range	35	18	
Method Length [min]:	115.00	% EEQYN[A2G1F]STYR range	35	45	
Total Time [hrs]	27.50	% EEQYN[A2G0F]STYR %CV < or =	10		
Data Vault:	ChromeleonLocal	% EEQYN[A2G1F]STYR %CV < or =	10	Created By:	Silvia
No. of Injections:	15			Updated By:	Silvia

Injection Details

Injection Name	Position	Type	Volume µL	InstrumentMethod	Processing Method	Status	Inject Time
NIST_02		Unknown	1.00		NIST_Reference_P	Finished	14/Nov/22 17:18:47
NIST_12		Unknown	1.00		NIST_Reference_P	Finished	15/Nov/22 12:37:53
NIST_22		Unknown	1.00		NIST_Reference_P	Finished	16/Nov/22 07:58:01

Oxidation

Peak Name	Pass or Fail	% Oxidation %CV	Max % Oxidation	Rel.Area (REF)	Ret.Time min	Peak Area counts*min
First Injection	First Injection	First Injection	First Injection	NIST_02	NIST_02	NIST_02
MS Quantitation Peak	MS Quantitation Peak	MS Quantitation Peak	MS Quantitation Peak	NIST_12	NIST_12	NIST_12
				NIST_22	NIST_22	NIST_22
DTLM[Oxidation]SR	Pass	6.42	1.23	1.08	13.704	1.10e+06
DTLMISR				1.14	13.719	1.21e+06
				1.23	13.73	1.27e+06
				100.00	16.988	1.02e+08
				100.00	16.993	1.06e+08
				100.00	16.98	1.04e+08

C-term Lys

Peak Name	Pass or Fail	% C-term Lys %CV	Max % C-term Lys	Rel.Area (REF)	Ret.Time min	Peak Area counts*min
First Injection	First Injection	First Injection	First Injection	NIST_02	NIST_02	NIST_02
MS Quantitation Peak	MS Quantitation Peak	MS Quantitation Peak	MS Quantitation Peak	NIST_12	NIST_12	NIST_12
				NIST_22	NIST_22	NIST_22
SLSLSPG[Lys]	Pass	0.28	15.40	15.40	14.503	6.38e+06
SLSLSPG				15.32	14.503	6.73e+06
				15.32	14.49	6.71e+06
				100.00	19.154	4.15e+07
				100.00	19.162	4.39e+07
				100.00	19.15	4.38e+07

Glycosylation

Injection Name	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min	Area counts*min
	EEQYN[A2G0F]STYR	EEQYN[A2G1F]STYR	EEQYN[A2G2F]STYR	EEQYN[A1G0F]STYR	EEQYN[A1G1F]STYR	EEQYN[A2Ga1G1F]STYR	EEQYN[A1G1M4F]STYR	EEQYN[A1G1M5]STYR	EEQYN[A2Ga2F]STYR	EEQYN[M5]STYR	EEQYN[A3G1F]STYR	EEQYN[A3G2F]STYR
NIST_02	8.29e+06	8.41e+06	1.99e+06	5.49e+05	5.37e+05	3.37e+05	2.40e+05	3.70e+04	1.75e+05	1.79e+05	1.18e+05	9.59e+04
NIST_12	9.32e+06	9.32e+06	2.20e+06	6.18e+05	6.04e+05	3.70e+05	2.58e+05	4.22e+04	1.92e+05	1.86e+05	1.36e+05	1.02e+05
NIST_22	9.46e+06	9.51e+06	2.25e+06	6.34e+05	6.23e+05	3.83e+05	2.77e+05	4.28e+04	1.93e+05	1.88e+05	1.41e+05	1.03e+05
Average Area	9.02E+06	9.08E+06	2.15E+06	6.00E+05	5.88E+05	3.63E+05	2.58E+05	4.06E+04	1.87E+05	1.84E+05	1.32E+05	1.00E+05
%CV (RT)	7.07%	6.46%	6.62%	7.57%	7.74%	6.58%	7.06%	7.74%	5.44%	2.73%	9.20%	3.89%

% Glycosylation

Pass

Injection Name	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation	% Glycosylation
	EEQYN[A2G0F]STYR	EEQYN[A2G1F]STYR	EEQYN[A2G2F]STYR	EEQYN[A1G0F]STYR	EEQYN[A1G1F]STYR	EEQYN[A2Ga1G1F]STYR	EEQYN[A1G1M4F]STYR	EEQYN[A1G1M5]STYR	EEQYN[A2Ga2F]STYR	EEQYN[M5]STYR	EEQYN[A3G1F]STYR	EEQYN[A3G2F]STYR
NIST_02	38.74	39.30	9.27	2.56	2.51	1.57	1.12	0.17	0.82	0.83	0.55	0.45
NIST_12	39.11	39.11	9.23	2.59	2.53	1.55	1.08	0.18	0.81	0.78	0.57	0.43
NIST_22	38.92	39.13	9.27	2.61	2.56	1.58	1.14	0.18	0.79	0.77	0.58	0.42
Average % Modification	38.92	39.18	9.26	2.59	2.54	1.57	1.11	0.18	0.81	0.80	0.57	0.43
%CV (Mod.)	0.48	0.27	0.24	0.90	1.13	0.74	2.59	1.17	1.45	4.14	2.58	2.94

Criteria for Special Check



Sequence Details

Name:	3.InfliximAb Biosimilars	Criteria		Created On:	15/Nov/2022 12:37	
Instrument:	EMS1_001	PR Element	=	0	Updated On:	28/Nov/22 13:32:30
Imported Data:	True	PR Size	>	1		
Injection:	NIST_12	Charge State	> or =	1		
Processing Method:	NIST_Reference_Peptides_InterLab	Ratio	<	6		
MS Acquisition Time [min]:	70.00		is not between	0.1	10	
Method Length [min]:	115.00					
Total Time [hrs]:	27.5					
Data Vault:	ChromeleonLocal					Created By: Silvia
No. of Injections:	15					Updated By: Silvia

DOES NEW PEAK DETECTION PASS **Pass**

Frame ID	Component ID	Mass m/z	RT min	Ratio	Base Component	PR Element	PR Root	PR Size	Charge	Molecular Weight m/z
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All frames are filtered

Property	Value
Global Settings:	
Description	
Max Threads	8
Reference Injection Mode	Fixed
Reference Injection	NIST_22
Alignment Parameters:	
Alignment Bypass	False
Alignment Min Intensity	1000
Correlation Bin Width	1
Max RT Shift	1
RT Limits For Alignment	True
Tile Size	300
Frame Parameters:	
Maximum Number of Frames	15000
m/z Min	200
m/z Max	1800
m/z Width [ppm]	5
Retention Time Start [min]	5
Retention Time Stop [min]	70.01
Frame Time Width [min]	1
Peak Intensity Threshold	5396219
Scan Filter	FTMS + p ESI Full ms [200.0000-2000.0000]
Additional Parameters:	
Injection	LC
KM Clusters	0
PCA Process	BYPASS_MORE_THAN_8K