Drug Discovery and Development



Enabling Single-Software Multiple Attribute Methodology (MAM) for Assessment of Biopharmaceutical Product Quality Attributes

Application of BioPharmaView™ 3.0 Software for a Streamlined MAM Workflow

Zoe Zhang², Fan Zhang², Sean McCarthy¹ ¹SCIEX Framingham, MA (USA), ²SCIEX Redwood City, CA (USA)

Introduction

Development and production of biopharmaceuticals is complex. Even minor impurities, or changes in attributes such as glycosylation or charge heterogeneity, can have a profound impact on the safety and efficacy of the final product. Traditionally, multiple analytical techniques have been required to assess the full range of biopharmaceutical product attributes. But the inevitable consequence of multiple analytical techniques is greater expenditures of time and resources.

The Multiple Attribute Methodology (MAM), an orthogonal approach based on peptide map separation coupled with highresolution mass spectrometry, is rapidly emerging as a powerful tool for characterization and monitoring of biopharmaceutical attributes. The range of attributes that can be monitored using this approach is extensive. MAM can be used to assess, track, and provide detailed data on multiple, specific biologic product quality attributes at the peptide level (Figure 1). In addition to tracking the therapeutic molecule itself, MAM can be used to detect known impurities related to production of the biotherapeutic, as well as unknown impurities (new peaks) present in samples but not in corresponding standards.

Essential to successful implementation of an MAM workflow is software that can manage all aspects of the workflow, including: product quality attribute (PQA) definition, tracking, and quantification; detection of known and unknown impurities; and reporting. This technical note describes the use of SCIEX BioPharmaViewTM 3.0 Software for MAM workflow management. BioPharmaView software can manage all aspects of an MAM workflow from a single project. It eliminates the unnecessary complexity that comes with using multiple software packages.

Key Features

 BioPharmaView software provides a single-software solution for MAM workflows, in addition to traditional core characterization workflows, such as intact mass analysis, subunit analysis, and peptide mapping

Biologic PQA Assessments	LC-MS MAM Workflow	SEC	CEX	CE- SDS	HILIC	ELISA
Deamidation						
Glycation						
High Mannose						
Methionine Oxidation					,	
Signal Peptide						
Glycosylation						
CDR Tryptophan Degradation						
C-terminal Lysine						
Misincorporations						
C-terminal amidation						
Fucosylation						
Residual Protein A						
Host Cell Protein						
Aggregate						
Cysteine Adduct Assessment						

Figure 1. Comparison of traditional assays to and accurate mass LC-MS MAM assay for a selected set of biotherapeutic attributes

- Simple method creation on a single platform
- Powerful product characterization, attribute definition and tracking, and quantitation
- Flexible custom calculations for attribute-level assessment based on specific user needs
- Reliable detection and monitoring of both specified and unspecified impurities
- Concise review and reporting of targeted attributes



Method Creation

Creation of a multiple attribute assay in BioPharmaView software is simple and streamlined. The assay starts with the definition of the target protein sequence. If multiple chains are required, each is defined separately as shown in Figure 2. Known disulfide linkages and any modifications that may be present are applied, entered, and positioned to specific amino acids within the sequence. Desired modifications not built into BioPharmaView software can easily be added. These custom modifications are then available for use across all BioPharmaView projects.

In addition to the target biotherapeutic, any known impurity sequences are entered separately as a targeted peptide or protein sequence. Impurity sequences are treated identically to the target molecule during in-silico digestion, using the parameters defined for the biotherapeutic. Impurity sequences are searched and presented separately throughout the workflow for easy distinction from the biotherapeutic.

	n bev	guence														
otein T	me	Antibody	*	Add Ch	uin Ur	modified Pro	ten MW	14								
					8.6	onoiootopic	2609.15	12 Averag	e: 72734.32							
hain 1	HC	1														
	A	A Indexes														Delote Ch
1-1 14-2 27-3 40-4	13 9 26 1 39 3 50 8	IVTLRES TVTVEG ITVTVEG ITVTVEG ITVTVEG ITVTVEG	GPALVKS ASTROPS ADELLOS REPOVIS	TQTLTL VFPLAP PSVPLP LPPSRE	ACTINGIA RESILETEGO REPRESENTA REPRESENTANO	LSTAGMSV FTAALGCLV MISRTPEV SLTCLVKSF	GWINQE KDYFRE FCVVVI YPSD17	PGRALEWI PVTVDMNS VSHEDDEV VENESNGC	ADIWWEDKKHYN GALTOGVHTPPA YEFNWYVDGVEVR DENNYKTTPPVL	PSLKDRLTISKI VLQSSGLYSLSS NAFTKPREEQYI DSDGSFFLYSKI	775F.N IVVIV ISTYR 777DR	QVVL PODO VVSV SRWQ	KVTNHI LGTQ71 LTVLH QGNVF3	DPADTAI VICNVNI DDWINGP SCSVMHE	TYYCARDM IRPUNTEV GEYKCEVS SALENHYT	IFNFTFDVW DRRVEPKSC NFALDADIE GKSLSLSPG
hain 2	LCI															
	A	A Indexes														Dekte Ch
Chai	n N	ame	Seque	nce											Digest	Acd., Dr Notes
chai	n N	lame Littet	Seque	nce Doninate Mikanito	anotooorio STROLINSS	ogiebiousen rackomstole	GROVINI MIRONO	I ALDATI VO III B VOAFOF	TRUCKE OF PACWOR	ICONGASYOD II D GOTIOPOVOKATYI	LAMN SKISE	191010	ooloew	чрузон	Digest	Acd., Dr Notes
chai 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	n N ation	isport lame doi:1 10 e Modifica	Seque Contro Arrivo tions Can I	nce Denover Micanes Replace D	isulide Doni	oqiso curv ici somo i b	usion vi il Vilestro	Eveloriti ve In RiveArge	4 PTELASSNALLING TDENGEN; PAGWER	econicasyobilico cicrispowiesacivi dd. Delete.	Disul Impo	recco fide B	ociarsi orids - Esport	N PLASON	Digest	Add. De
chai 1 a bdific 0 0	n N ation steine	ame Cost 10 11 12 13 13 14 Modifica Type	Seque Scale ACCOR Lions Can I Name	nce Mitable Teplace D	isulfide Doni	do na kontra ta do Mode per Chain	Modi	Applies To	- THUSS ALLING THUS ALLING THUS ALLING THUS ALLING Workflow Usage	ACONTRACIONALI D CONTRACTOR Adha Deleta Mass Shift	Disul	ficle B ficle B from Chain	orids Crost To Chain	From Cysteine 254	Digest	Add. De
chai chai odific Cy chai	n N ation steine ains	iame Cort 10 12 Modifica Type Internal	Seque tions Can I Name Otidation	nce Replace D	Isulfide Doni	ds Maximum Mode per Chain	Modi Al	Applies To	4 Workflow Usage Ecth	st. Deleta. Mass Shift 13.9949	Disul Disul	ficle B rt I= From Chain 1	onds - Coord Te Chan 1	From Cystaine 254	Digest	Add. De
chai chai chai chai chai chai chai chai	ation ation alms	izportu iame con to to to to to to to to to to to to to	Seque Sons Lons Can I Name Oridition Deamidat	nce Doctore Replace D	Southide Dona	ds Maximum Mods per Chain * 10	Modi AA n/a	Applies To NQ	Workflow Urage Both Reprice Mapping	dt. Deleta. Mass Shift 13.9949 0.9940	Disul Disul 1 2 3	Fiche B Fiches Ficom Chain 1 1 1	Toologies	From Cysteline 254 370 147	Digest Digest To Cysteline 324 428 203	Add. Del
chai chai chai chai chai chai chai chai	n N ation steine ains 1-2 1 1-2 1	inne ion o r Modifica Type internal internal	Seque Joint tions Can I Name Oridation Deamidat	nce Domination Replace D ed	isulfide Doni	ds Maximum Morks per Chain * 10 * 10	Modi. AA n/a n/a	Applies To M	TRUCES A FLOOD TRUCK A PARAMET (A Workflow Usage Both Peptide Mapping Both	ACOMICANOSI C CONTRACTOR AL. Belete. Marc Shift 13.9949 0.9940 -17.055	Disul Disul 1 2 3 4	Ficker B From Chain S 3 3 3	Toolds Toolds Toold Too Chain 1 1 1 1	7 From Cysteine 264 370 147 22	Digest PCCI CONSER To Cysteine 324 428 203 87	Add. De
chai 1 1 1 1 1 1 2 1 2 1 4	ation ation	inne lon b r Modifica Type internal internal internal	Seque Jointo Can I Name Oridation Deamidat Contexts	nce coord with replace D legisce D eGu	auf de Doni Isulf de Doni Podtion	ds Maximum Mods per 10 10 10 10 10	Modi AA n/a n/a Q N	Applies To M NQ N	Workflow Usage Both Repride Mapping Both Peptide Mapping	dd. Delete. Maris Shift 13.9949 -17.0455 1095.3966	Disul Disul 1 2 3 4 5	ficle B ficle B from Chain 3 3 3 1 3	Conds Export Te Chain 1 1 1 1 2	77 From Cystaine 264 370 147 22 223	Digest 1001 V 100 Cystelise 324 428 203 97 215	Add. De
tootific chai 1 2 3 4 3	alins 1-2 1-2 1 1 1	inportu iarne coci coci e Modifica Type internal internal internal internal	Seque SCAL ACCOR Econs Can I Name Ottoblion Deamicat Chorpon C0-Hona ManS	nce voor diven Mit KAOP Replace D Noor Noor Noor Noor Noor Noor Noor Noo	Fodtion	do concerno a concerno	Modi AA n/a n/a N N	Applies To M NO N N	Monthland Control of C	dd. Deleta. Marc Shift 13.9949 0.9840 -17.055 1055.2065 1215.4229	Disul Disul 1 2 3 4 5 6	From Chain 1 1 1 1 2	Teoret Chain 1 1 1 1 2 2	From Cystelle 254 370 147 22 223 23	Digest 1001 V 100 Cysteine 324 428 203 97 213 87	Add_ De

Figure 2. Definition of protein sequence, disulfide bonds, and modifications within BioPharmaView software

The assay information is completed by definition of digestion parameters using a range of built-in cysteine alkylation reagents and digestion enzymes. The maximum number of modifications and missed cleavages to search within the data is also defined, as shown in Figure 3.



Figure 3. Definition of search parameters and definition of New Peak Detection criteria for batch analysis.

Characterization

Using the defined assay information, acquired data is submitted for processing. Characterization of samples is accomplished automatically by the BioPharmaView software. Peptide assignments are based on defined search parameters by correlation of MS- and MS/MS-level data. After processing, peptide results are easily reviewed using a single interface. To expedite review, results are easily sorted using a wide range of available filters.

Peptide modifications defined in the assay are automatically annotated in the peptide results and are easily filtered to expedite review. In cases where modifications are not automatically positioned, assignment of the position is guided using prepopulated scoring results from processed data. When a modification has been positioned, the position information is used in ongoing studies. After characterization is complete, the assay information is updated for use in batch analyses.

Attribute Definition

Targeted attributes are easily defined within BioPharmaView software as shown in Figure 4. Applying the same filter criteria used in characterization, targeted attributes can be compiled in peptide sets. Each attribute is captured within its own peptide set, which contains all of the data that matched the defined filter criteria. The attribute peptide sets are named and can be shared within and between projects. Sharing peptide sets reduces the overall time required to define assays and may reduce variability in set definition.

Using the defined peptide sets, attribute levels are calculated using a highly flexible custom calculation engine. Use of custom calculations enables users to define how each attribute level will be determined, as shown in Figure 4. As each attribute is defined, the calculated values are added to the assay displayed within a table. There is no practical limit to the number of attributes that



can be defined or monitored as part of an assay, providing the flexibility to monitor a large number of attributes simultaneously.

accessed in the Matched tab. Investigation can be completed on each sample individually or by comparison between two or more samples.

Add ₁₀	Delete-	Import	· Oport.	Name	027			Celculated Val	Le: 6.00%	V V 3	renda	· Inset Fur	witer -	anier1-5
	Attribute	Name	Value	a marine							1.1.1			
1 00			40.09%	SUN	A(G2F)/SU	M Total G	lycoper	tide						
2 61	£		45.66 %											
1				la construction de la construcción de la construcci								-	_	_
4 No	n-glycosylat	ed	0.79%									Edit-	A56	Defete-
5.A1	50		0.16%		(3) ×	e Still Obe 🛛 🗙								
6 A2	ig100F		0.12%		as ~ L	** ***Coyee								
7 M3	6 . ·		0.61%	640	on Usage Chains	Feotoe AA	inder 54	esnece .		Modificions		Deute	e Ronda	
8 A1	501		1.53%	1.1	Ortera 1	775	204.304	whittys		0.10.00.000				
9. A1	51F		1,65 %											+
10 AT	G1M4F		0.69%	Deside	6.00								8.64	Caleta.
11 A1	G1M5F		0.00%	Pepco	e set Query									
12 A3	G1F		0.20%	Us	e Column	Val	Ur							
11 A2	Salo14		1.13%	1	Sequence	-10	OWNSTAR"							
14 A3	52F		0.24%	2	Modificati	ions 'G2	F@5(300)*							
IS AL	5g101F		6.00%	3	Use for Qu	uant "Up	e" Unknown							
10 A2	Gal25		0.51%	4	Retention	Time 6.03	Constantine and							1
17 Ma	nó		0.00 %	5	Charge	2 0								
-	A.,										Terror I	and the second		
reptic	les										(Solor)		er iserig	14946
	atch Usage	chairs	Peptide	AA index	Sequence	Modifications		Use for Quark	Use for ID	Mono. Mass	Matched	Mono. m/z	charge	XUC ANE
4	Optional	3	/721-23	190-198	SKEWFSKOK			Unknown	Unknown	1143.5924	~	572.8035	2	1.0
5	Optional	2	T17-19	188-210	HKYNACEYTH_	Carboxymethy106	(193)	Unknown	Unknown	2545.3020	~	1323.6583	2	1.1
6	Optional	2	T17-18	188-204	HKYNACEVTH	Carboxymethy106	(192)	Unknown	Unknown	2141.0575	1	429.2188	5	2.1
7	Optional	2	117-18	188-206	HKYSACEVIH.	Carbox/methy106	(19)5	Use	Use	2141.0575	~	536.2717	4	5.7
8	Optional	2	T17-18	103-206	HKYSACEVTH_	Carboxymethyl@6	(193).	Use	Use	2141.0575	~	714.6931	3	5.3
0	Optional	2	T16-18	183-206	ADVERSHOUNDC.	Carboxymathy101	1(193), Deamid	z Unknown	Unknown	2748.3065	~	550.6685	5	43
10	Optional	2	T10-18	103-206	ADYDOHOVIAC_	Cerboximeth/101	1(193)	Unknown	Unknown	2747.1225	~	550.4718	5	6.5
- State 1														

Figure 4. Definition of quality attributes and custom calculations within BioPharmaView software

For each attribute defined in an assay, acceptance criteria are also defined. The range of values that are acceptable for each calculated attribute response is defined independently. Ranges may be set based on a percentage deviation from a defined value or as needed to be greater/less than a specific value. The defined ranges are used to determine overall pass/fail status of their corresponding attributes.

Attribute Quantification

Sample batches are submitted for processing in BioPharmaView software, which tracks defined attributes across submitted sample sets. Batch analysis can be performed on TOF-MS data or SWATH[®] acquisition data. SWATH acquisition provides greater detail by generating MS <u>and</u> MS/MS data for all detectable components in each sample. The additional fragment data provided by SWATH acquisition enables identification of detected new components without the need for reanalysis.

Processing a batch of two or more data files enables the comparison of samples processed in the batch. For each selected attribute in the assay, a concise summary is presented within the Attribute tab. This tab provides an overview of the calculated attribute levels for each sample, a pass/fail indication, and the range over which the attribute will pass (Figure 5).

Each attribute can be selected independently to view the underlying data used for each calculation. Selection of dentified species within the peptide results provides a view of the MS and, if acquired, MS/MS data for the selected component. Data for matched peptides not included in the attribute method are



Figure 5. Review of batch analysis results in BioPharmaView software. Results for defined attributes are presented for review with pass fail indication and acceptance ranges. Supporting data is easily accessed in the same window.

Monitoring of Known Impurities

When defined in the assay, known impurity results are presented in the Impurities tab of the peptide results (Figure 6), separate from the defined therapeutic. Each impurity is clearly indicated with distinct nomenclature and indication of which peptides were identified.

eptic	de M	appi	ng Batch Re	sults Sampl	ies Q	uality	Attri	butes Pro	cessing Param	eters				
Oper	n Batc	h Resi	New	Peak Detection										
vi	iew		Туре	Filename	1	Sa	E #	# Unique Peptides	# Impurities	# Newly Detected	% Sequen Coverage	e Par	ss/Marginal/Fail	
1		1	Control	20180213_N	vist_tr 1		1	151	1		- 9	7.6		Pass
2	. /		Sample	20180213 8	dict to 1	1		151		1 1		7.0		Fail
-			adition	ev tobe ta_t										
eptic	de Re	esults	Matched	linestchad	imour	rition	0	ality Attribus				ilter	View Sequence	0
eptic	de Re	sults	Matched	Unmatched	Impur	rities	Qu	ality Attribu	tes			ilter	View Sequence	•
eptic	de Re lenam	esults	Matched	Unmatched	impur	rities Batc Usag	Qu	ality Attribu Auto- Validatee	tes Review d Required	Chains I	eptide .	ilter Sequei	View Sequence	•
eptic Fil 1 20	de Re lenam	esults	Matched	Unmatched	Impur #	ities Batc Usag Opti	Qu th ge onal	ality Attribu Auto- Validatee	tes Review d Required	Chains I 3 f	Peptide 14-6	itter Sequei	View Sequence nce YRGKYVVFFFYPLD	¢

Figure 6. Detection of defined impurities. Impurity information is provided in a separate tab and clearly indicated as impurities.

New Peak Detection

BioPharmaView software supports new peak (unknown impurity) detection during batch analysis if selected within the assay. The detection of new peaks is performed by comparing each sample with a control. It is important that both the control and sample are prepared and analyzed as part of the same study to account for



variability in sample preparation. To execute new peak detection, the threshold for detection is defined, guided by ongoing characterization work. It is possible to define the threshold based on absolute or relative signal intensity (Figure 3). Samples may be automatically failed if new peaks are detected, even if all other attribute parameters pass.

When executing new peak detection in batch analysis, one of the data files must be defined as the control. The control sample serves as the benchmark against which the other samples that are compared. Often, the control sample is one that has been previously characterized and is well understood.

New peak detection results are presented in a concise summary within the batch results. As shown in Figure 7, the overall number of peptides for each sample is listed, as well as the impurities detected. The number of new peaks detected is also provided in the results.

If further interrogation of new peaks is required, peptide results are easily filtered to display only those components which are flagged as newly detected. For detailed information on new peaks, each can be selected and the corresponding MS and MS/MS spectra viewed. If a new peak has been seen previously in characterization efforts, or is not a specific concern, its designation is easily changed. Changing the status of a new peak requires a justification for the change to be provided. This justification is captured as part of the assay. Detection of a new peak can also cause the sample to automatically fail, as evidenced by the red dot for the sample shown in Figure 7.

Open Batch Results New Per	ak Detection								
View Type	Filename	Sa #	E #	Unique eptides # In	mpurities	# Newly Detected	% Sequence Coverage	Pass/Marginal/	Fail
1 1 Control	20180213_Nist_t	1	1	151	1		97.6		Pass
2 🗸 2 Sample	20180213_Nist_1	1	1	151	1	12	97.0		Fail
eptide Results Matched U	Unmatched Imp	urities	Quality	/ Attributes			Filter	View Seque	nce 🔹
eptide Results Matched U	Jnmatched Imp	urities	Quality	Attributes Observed			Filter	View Seque	nce 🌣
eptide Results Matched U Filename	Jnmatched Imp	urities #	Quality Charge	/ Attributes Observed Mono m/2	RT		Filter XIC Area	View Seque	Details
Filename 1 20180213_Nist_tryp_2ug_SWAT	Inmatched Imp I TH02.wiff2	urities 2	Quality Charge 2	Attributes Observed Mono m/2 475.171	RT 8	15.00	Filter XIC Area 4.50e4	View Seque Newly Detected Yes	Details
Filename 1 20180213_Nist_tryp_2ug_SWAT 2 20180213_Nist_tryp_2ug_SWAT	Inmatched Imp ITH02.wiff2 TH02.wiff2	urities 2 2	Quality Charge 2 2	Attributes Observed Mono m/2 475.171 645.345	RT 8 0	15.00 15.21	Filter XIC Area 4.50e4 4.20e4	View Seque Newly Detected Yes Yes	Details
Epide Results Matched U Filename 1 20180213_Nist_tryp_2ug_SWA1 2 2 20180213_Nist_tryp_2ug_SWA1 3 20180213_Nist_tryp_2ug_SWA1	Inmatched Imp TH02.wiff2 TH02.wiff2 TH02.wiff2	2 2 2 2	Quality Charge 2 2 1	Attributes Observed Mono m/z 475.171 645.345 711.306	RT 8 0 9	15.00 15.21 24.86	Filter XIC Area 4.50e4 4.20e4 5.66e4	View Seque Newly Detected Yes Yes Yes	Details
Ender Results Matched U Filename 1 20180213_Nist_tryp_2ug_SWA1 2 2 20180213_Nist_tryp_2ug_SWA1 3 20180213_Nist_tryp_2ug_SWA1 4 20180213_Nist_tryp_2ug_SWA1 5 3	TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2	2 2 2 2 2 2	Quality Charge 2 2 1 6	Attributes Observed Mono m/2 475.171 645.345 711.306 1123.229	RT 8 0 9 6	15.00 15.21 24.86 48.33	Filter XIC Area 4.50e4 4.20e4 5.66e4 6.60e4	View Seque Newly Detected Yes Yes Yes Yes	Details
Epitide Results Matched L Filename 1 20180213_Nist_tryp_2ug_SWAI 2 2 20180213_Nist_tryp_2ug_SWAI 3 20180213_Nist_tryp_2ug_SWAI 4 20180213_Nist_tryp_2ug_SWAI 5 20180213_Nist_tryp_2ug_SWAI	TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2	2 2 2 2 2 2 2 2	Quality Charge 2 2 1 6 1	Attributes Observed Mono m/2 475.171 645.345 711.306 1123.229 1241.950	RT 8 0 9 6 9	15.00 15.21 24.86 48.33 46.76	Filter XIC Area 4.50e4 4.20e4 5.66e4 6.60e4 4.29e4	View Seque Newly Detected Yes Yes Yes Yes Yes	Details
Ended Results Matched U Filename 1 20180213_Nist_tryp_2ug_SWA1 2 2 20180213_Nist_tryp_2ug_SWA1 3 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 0180213_Nist_tryp_2ug_SWA1 5 20180213_Nist_tryp_2ug_SWA1 5 20180213_Nist_tryp_2ug_SWA1 5 20180213_Nist_tryp_2ug_SWA1	Inmatched Imp TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2 TH02.wiff2	2 2 2 2 2 2 2 2 2 2 2	Quality Charge 2 2 1 6 1 2	Attributes Observed Mono m/2 475.171 645.345 711.306 1123.229 1241.950 1272.819	RT 8 0 9 6 9 5	15.00 15.21 24.86 48.33 46.76 30.03	Filter XIC Area 4.50e4 4.20e4 5.66e4 6.60e4 4.29e4 1.26e5	View Seque Newly Ves Ves Ves Ves Ves Ves Ves Ves	Details
Ende Matched L Filename 1 20180213_Nist_tryp_2ug_SWA1 2 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1	Jnmatched Imp TH02.wiff2 TH02.wiff2 TH02.wif	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Quality Charge 2 2 1 6 1 2 5	Attributes Observed Mono m/2 475.171 645.345 711.306 1123.229 1241.950 1272.819 1347.673	RT RT 88 0 9 9 5 7	15.00 15.21 24.86 48.33 46.76 30.03 48.32	Filter XIC Area 450e4 420e4 5.66e4 6.60e4 429e4 1.26e5 4.93e4	View Seque Newly Ves Yes Yes Yes Yes Yes Yes Yes	Details
Efferame 1 1 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1 3 20180213_Nist_tryp_2ug_SWA1 2 20180213_Nist_tryp_2ug_SWA1	Jnmatched Imp TH02.wiff2 TH02.wiff2 TH02.wif	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Quality Charge 2 2 1 6 1 2 5 5 5	Attributes Observed Mono m/2 475.171 645.345 711.306 1123.229 1241.950 1272.819 1347.673 1401.418	RT RT 0 0 0 0 0 0 0 0 0 0 0 0 0	15.00 15.21 24.86 48.33 46.76 30.03 48.32 47.19	Filter, XIC Area 4.50e4 5.66e4 6.60e4 4.29e4 1.26e5 4.93e4 6.60e4	View Seque Newly Ves Yes Yes Yes Yes Yes Yes Yes Yes	Details

Figure 7. Results for new peak detection within BioPharmaView software. The number of new peaks, as well as the data supporting their detection, is easily displayed.

Reporting

Results from batch analyses are compiled in a concise report which includes assay information and processing parameters as well as a summary table of attributes defined in the assays. The report template is a standard template within the software. Within the report, each attribute is flagged as to whether it has passed or failed. The number of impurities and new peaks detected is also summarized. For every sample, an overall pass/fail indication is included to expedite review.

Conclusion

The BioPharmaView software provides a single software package for automating a complete MAM workflow, including: characterization, attribute definition, custom calculations, known impurity detection, unknown impurity (new peak) detection, and reporting. The ability to complete the entire workflow within a single software solution reduces the effort and eliminates potential transcription errors associated with the use of multiple software solutions. Taken together, BioPharmaView software provides a superior solution for the development and execution of MAM assays.

AB Sciex is doing business as SCIEX.

© 2017 AB Sciex. For Research Use Only. Not for use in diagnostic procedures. The trademarks mentioned herein are the property of AB Sciex Pte. Ltd. or their respective owners. AB SCIEXTM is being used under license.

Document number: RUO-MKT-02-7507-A



Headquarters 500 Old Connecticut Path | Framingham, MA 01701 USA Phone 508-383-7700 sciex.com International Sales For our office locations please call the division headquarters or refer to our website at sciex.com/offices