

Pen peptide certificate of analysis (CoA)

Product:	Mots-C		
Source:	Hybrid synthesis (recombinant using peptide secretion system and chemical synthesis)		
Intended use:	For stability, viability and activity testing only.		
Order number:		Lot:	25AUG18MOT
Production:	08/2025	Expiry:	08/2027
Formulation:	0.2 µm-filtered solution in 20mM glycine, 200mM Mannitol, 20mM NaH ₂ PO ₄ , pH 5.4; m-cresol 1 mg/ml, glycerol 2 mg/ml (when liquid)		
Protein/peptide concentration per 3 ml cartridge:	15 mg		

<u>Release Testing:</u>	<u>Specification</u>	<u>Lot Result</u>
Purity:	≥ 97%	> 98%
Identity:	Complies	Complies
Sterility:	Sterile	Complies
Endotoxin level:	< 10 EU/mg	< 0.20 EU/mg
Host-cell DNA	≤ 200 ng/mg	Complies (1.1 ng/mg)

Activity was determined using a Nb2-11 cell proliferation assay.
 Purity was determined by SDS PAGE and coomassie stain (under reducing and non-reducing conditions).
 Identity was confirmed by *end-of-production* DNA sequencing and N-terminal protein sequencing.
 Sterility test of vial product was performed according to Eur.Pharm. (Inoculation method).
 Endotoxin was determined using the gel clot assay according to Eur.Pharm.
 Host-cell DNA was determined using fluorimetric assay.

Handling Instructions:

General usage:	Open cap, clean the rubber stopper with disinfectant napkin or other cleaning disinfection method / material. Puncture rubber stopper with sterile needle by screwing needle on. Remove the plastic protective cover. Set the index to physician prescribed position, remove the pink plastic cover and let out the air from the cartridge by several button presses into the air. Put on the plastic protective cover back.
Using liquid product:	Liquid products are ready to use according to physician recommendations.
Storage and stability:	Store material at +2 - +8°C. Do not freeze!

Quality Statement:

This product is manufactured, tested and realized in compliance with the relevant GMP-guidelines. No animal- or human-derived materials were used during manufacturing. USP chapter <1043> “ancillary materials for cell, gene, and tissue-engineered product” has been considered in the design of this product.

Stability report

Mots-C

Data Provided:

- Initial concentration of Mots-C: **95,58%**.
- Concentration after 7 days at:
 - **+4°C: 95,37%**.
 - **+42°C: 93,2%**.

Analysis Plan:

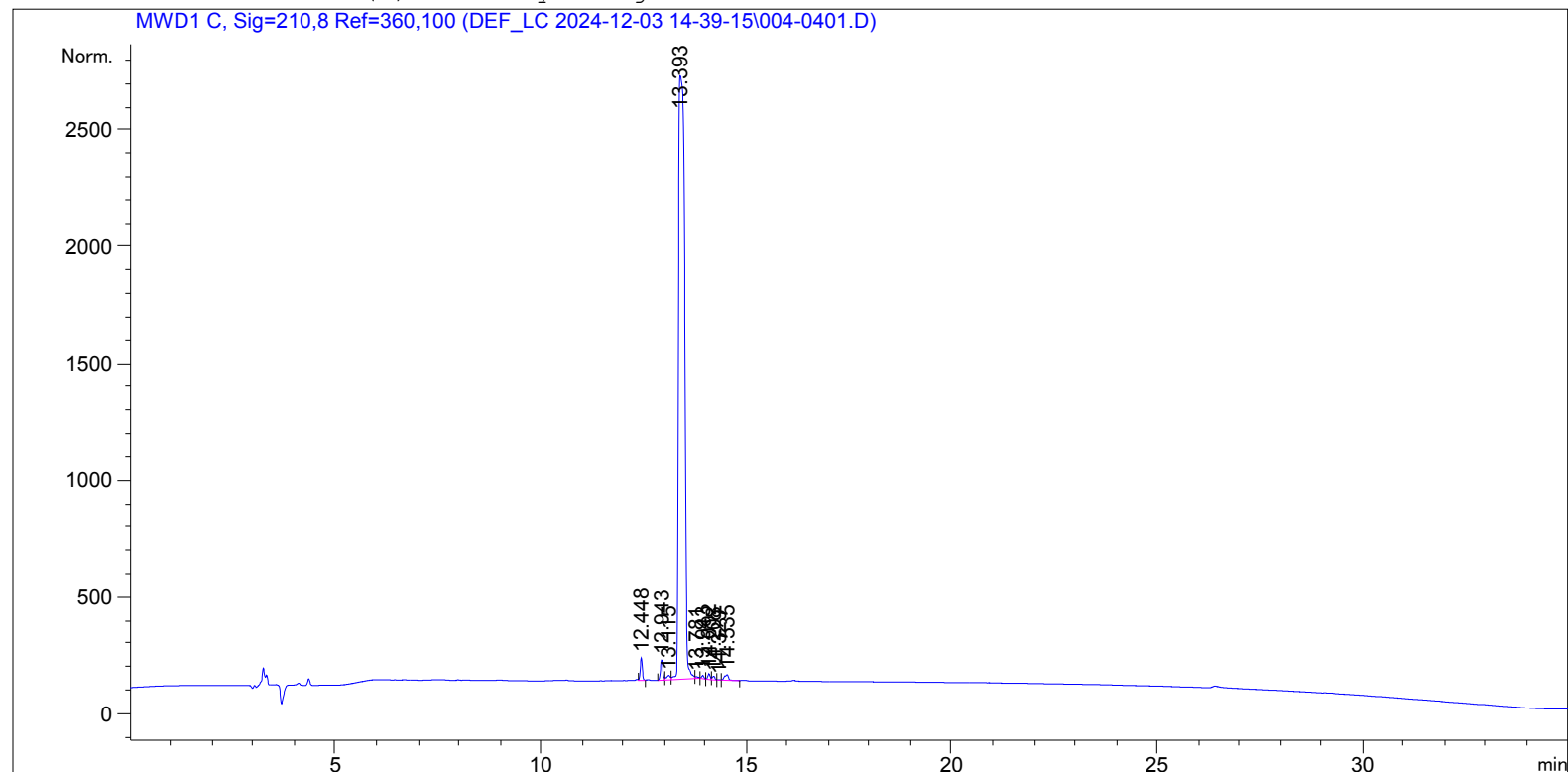
- Use the Arrhenius equation to calculate the degradation rate constants.
- Determine the activation energy (Ea) based on the temperature and degradation rates.
- Predict time to 90% stability at **+4°C**.

Summary of Results:

- **Activation Energy (Ea): 50 kJ/mol.**
- **Time to 90% Stability at +4°C: 228 days.**

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Acq. Operator	:		Seq. Line	:	4
Acq. Instrument	:	Instrument 1	Location	:	Vial 4
Injection Date	:	12/3/2024 4:45:38 PM	Inj	:	1
			Inj Volume	:	10.0 µl
Different Inj Volume from Sequence !			Actual Inj Volume	:	5.0 µl
Acq. Method	:	C:\CHEM32\1\DATA\DEF_LC 2024-12-03 14-39-15\C18 RP-HPLC ACN 5-95 30 MIN.M			
Last changed	:	7/31/2024 10:51:05 AM			
Analysis Method	:	C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M			
Last changed	:	12/19/2024 1:44:58 PM			
		(modified after loading)			
Additional Info : Peak(s) manually integrated					



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Area Percent Report

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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	12.448	VV	0.0550	338.63840	96.38873	1.2225
2	12.943	BV	0.0601	341.15732	86.40877	1.2316
3	13.115	VV	0.0853	120.64160	19.74680	0.4355
4	13.393	VV	0.1435	2.64758e4	2584.21509	95.5810
5	13.781	VB	0.0698	39.06900	7.61643	0.1410
6	13.943	BB	0.0587	52.68184	14.40280	0.1902
7	14.092	BV	0.0626	96.56801	24.15544	0.3486
8	14.208	VB	0.0646	65.03172	15.61985	0.2348

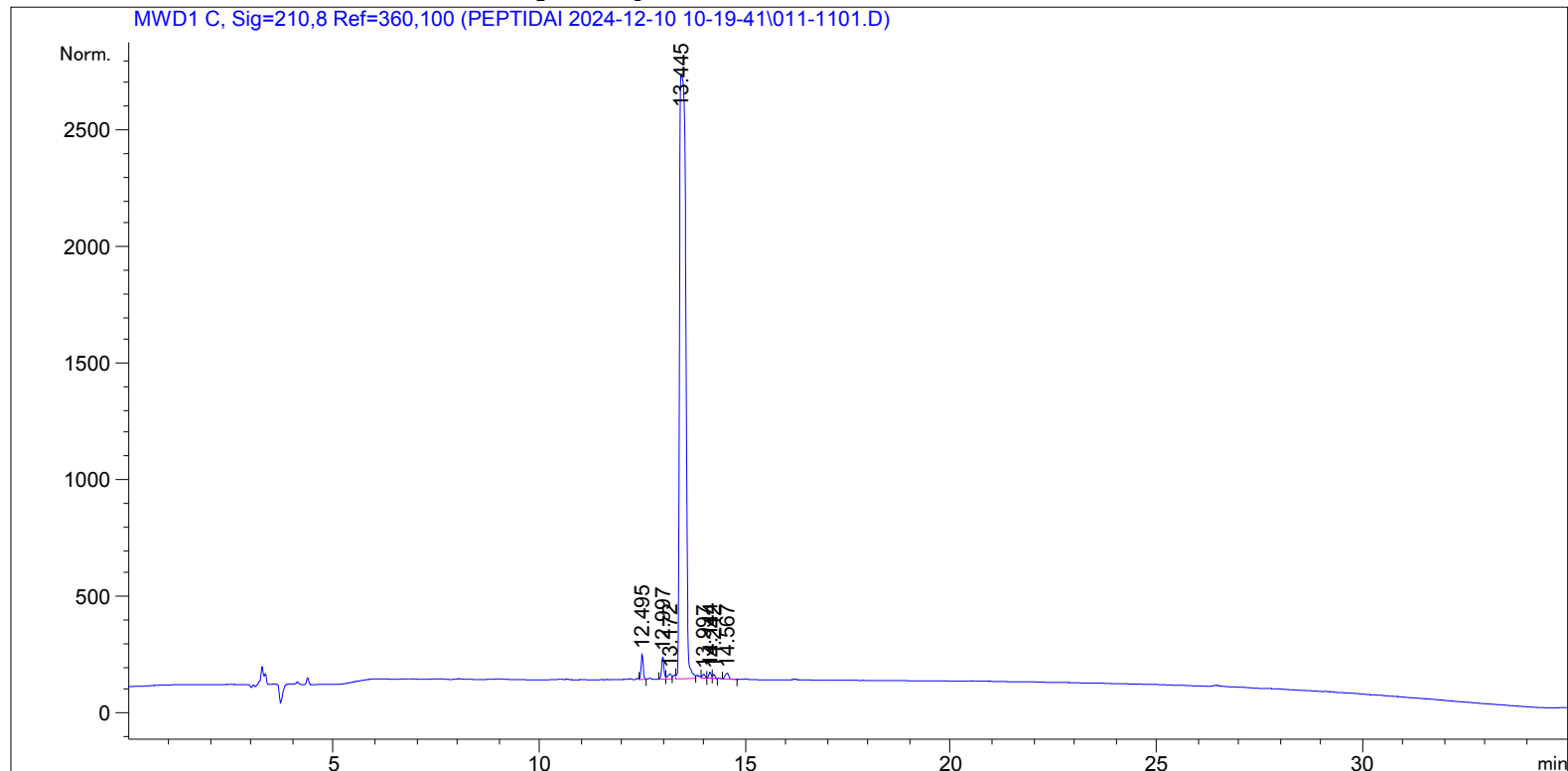
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
9	14.329	BV	0.0580	6.53004	1.73127	0.0236
10	14.535	VV	0.0915	163.74097	24.66253	0.5911

Totals : 2.76998e4 2874.94771

*** End of Report ***

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Acq. Operator	:		Seq. Line	:	11
Acq. Instrument	:	Instrument 1	Location	:	Vial 11
Injection Date	:	12/10/2024 5:15:36 PM	Inj	:	1
			Inj Volume	:	10.0 µl
Different Inj Volume from Sequence !			Actual Inj Volume	:	5.0 µl
Acq. Method	:	C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\C18 RP-HPLC ACN 5-95 30 MIN.M			
Last changed	:	7/31/2024 10:51:05 AM			
Analysis Method	:	C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M			
Last changed	:	12/19/2024 3:04:50 PM			
		(modified after loading)			
Additional Info : Peak(s) manually integrated					



Area Percent Report

Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

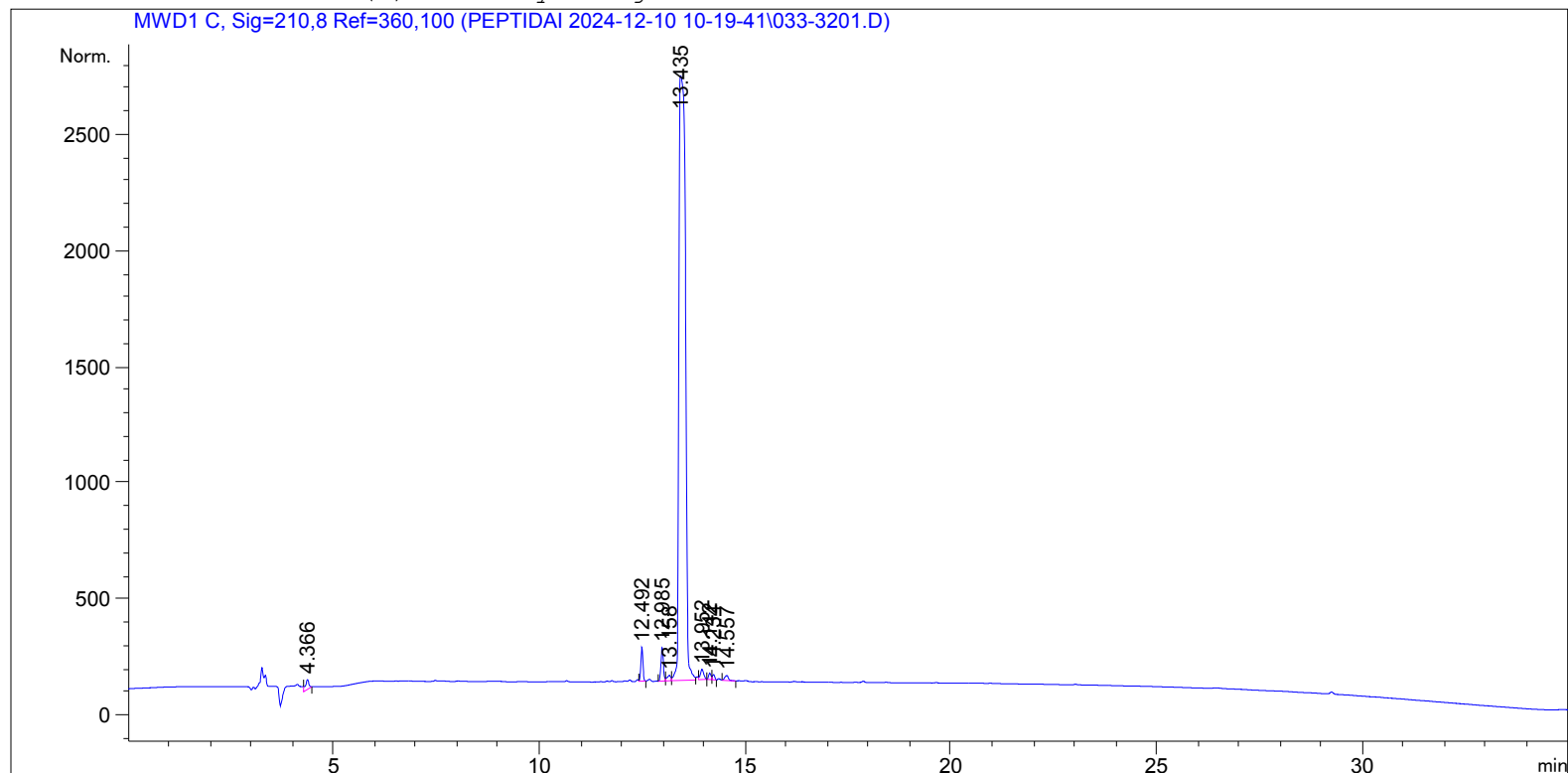
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	12.495	VV	0.0553	379.44492	107.19172	1.3512
2	12.997	BV	0.0635	384.39917	94.44322	1.3689
3	13.172	VV	0.0892	134.56662	21.44510	0.4792
4	13.445	VV	0.1705	2.67824e4	2593.91040	95.3740
5	13.997	VB	0.0677	76.25173	17.20708	0.2715
6	14.144	BV	0.0619	102.64217	26.10171	0.3655
7	14.242	VB	0.0627	67.75105	16.91708	0.2413
8	14.567	VB	0.1027	153.98509	24.69469	0.5484

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
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Totals :				2.80815e4	2901.91100	

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*** End of Report ***

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Acq. Operator	:		Seq. Line	:	32
Acq. Instrument	:	Instrument 1	Location	:	Vial 33
Injection Date	:	12/11/2024 7:48:11 AM	Inj	:	1
			Inj Volume	:	10.0 µl
Different Inj Volume from Sequence !			Actual Inj Volume	:	5.0 µl
Acq. Method	:	C:\CHEM32\1\DATA\PEPTIDAI 2024-12-10 10-19-41\C18 RP-HPLC ACN 5-95 30 MIN.M			
Last changed	:	7/31/2024 10:51:05 AM			
Analysis Method	:	C:\CHEM32\1\METHODS\C414\C4 GLP1 30-70 ACN.M			
Last changed	:	12/19/2024 3:15:57 PM			
		(modified after loading)			
Additional Info : Peak(s) manually integrated					



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Area Percent Report
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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: MWD1 C, Sig=210,8 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	4.366	VB	0.0829	241.35577	42.07383	0.7844
2	12.492	VB	0.0545	507.84985	146.39426	1.6506
3	12.985	BV	0.0634	586.23096	144.26767	1.9053
4	13.158	VV	0.0902	149.65152	23.54208	0.4864
5	13.435	VV	0.1826	2.86770e4	2602.29004	93.2036
6	13.952	VB	0.0828	259.83942	45.39191	0.8445
7	14.142	BV	0.0619	115.61417	29.40185	0.3758
8	14.234	VB	0.0625	94.06371	23.62398	0.3057

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
9	14.557	VB	0.1047	136.52803	21.31784	0.4437

Totals : 3.07681e4 3078.30346

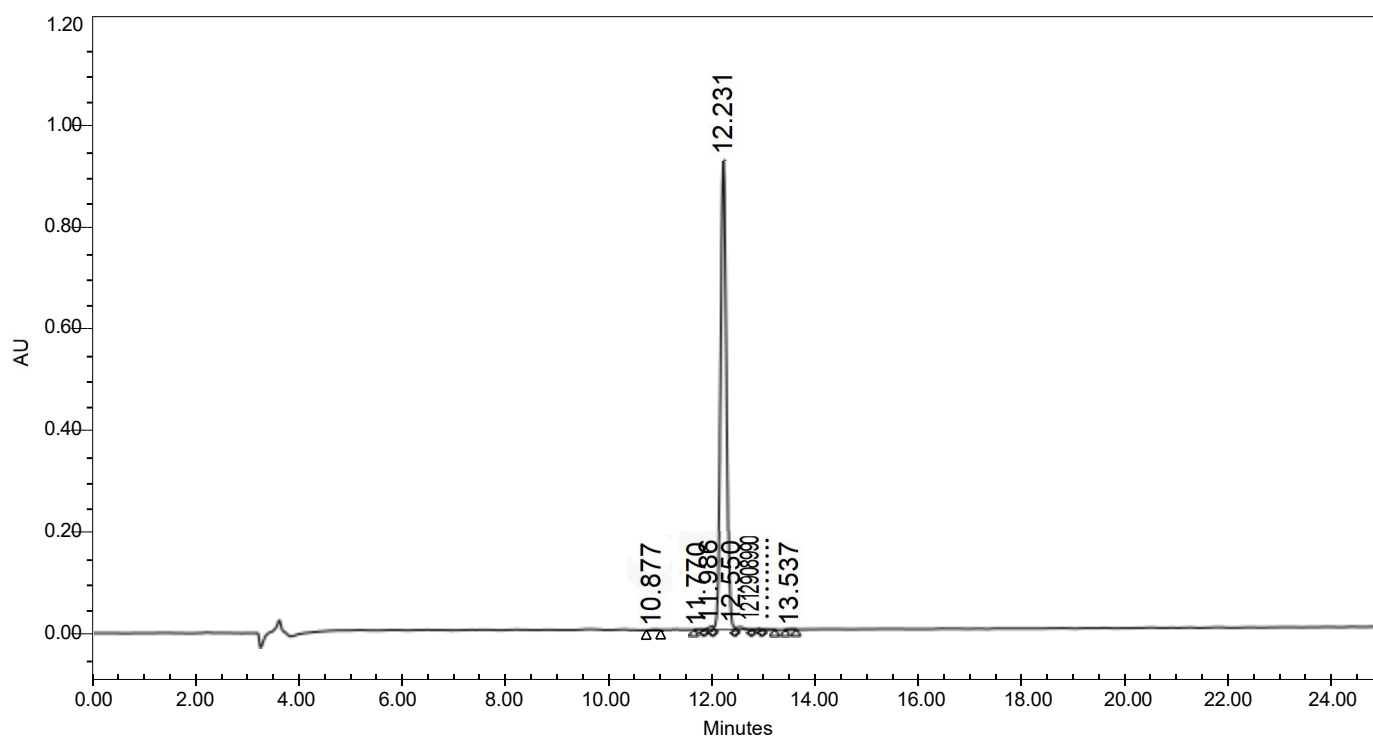
*** End of Report ***

SAMPLE INFORMATION

Sample Name: Mots-C Acquired By: System
Sample Type: PU2n4k w11n-A030-1.0480MG/ML-C24S3 Sample Set Name: 202508
Vial: 3 Acq. Method Set: TFA
Injection #: 1 Processing Method: 7
Injection Volume: 5.00 ul Channel Name: W2489 ChA
Run Time: 45.0 Minutes Proc. Chnl. Descr.: W2489 ChA 220nm

Date Acquired: 8/18/2024 11:31:12 PM CST

Date Processed: 8/18/2024 7:45:39 AM CST



	RT	Area	% Area	Height
1	10.877	7813	0.11	941
2	11.770	5689	0.08	765
3	11.986	38076	0.51	5811
4	12.231	7274099	98.37	928579
5	12.550	48749	0.66	4966
6	12.908	10591	0.14	1209
7	12.990	6223	0.08	792
8	13.537	3141	0.04	498

P240611-A030 9 (0.153) Cm (6:11)

Scan ES+

1.48e7

A: 2174.94±0.29

