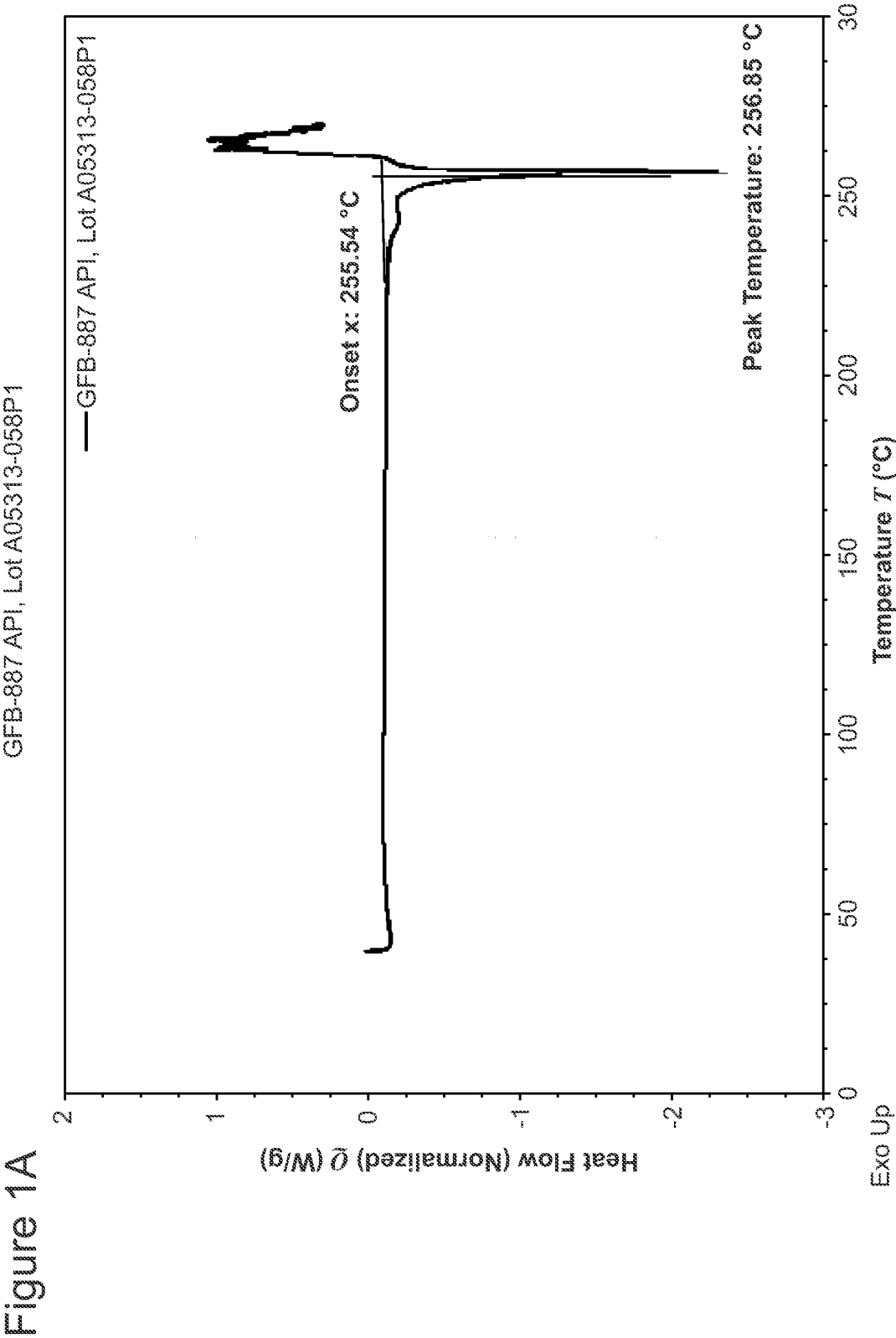
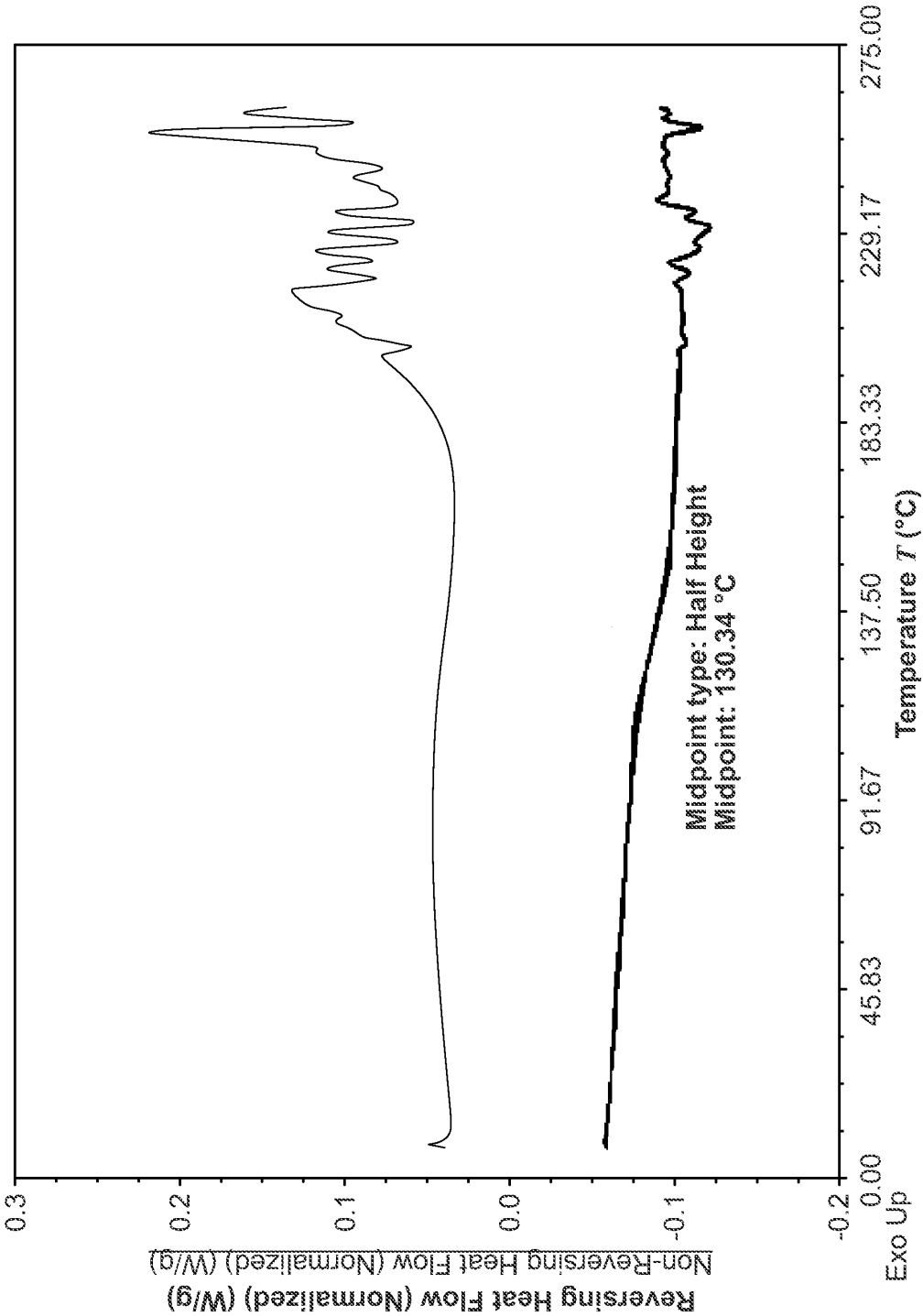




GFB-887

Figure 1B



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Figure 2

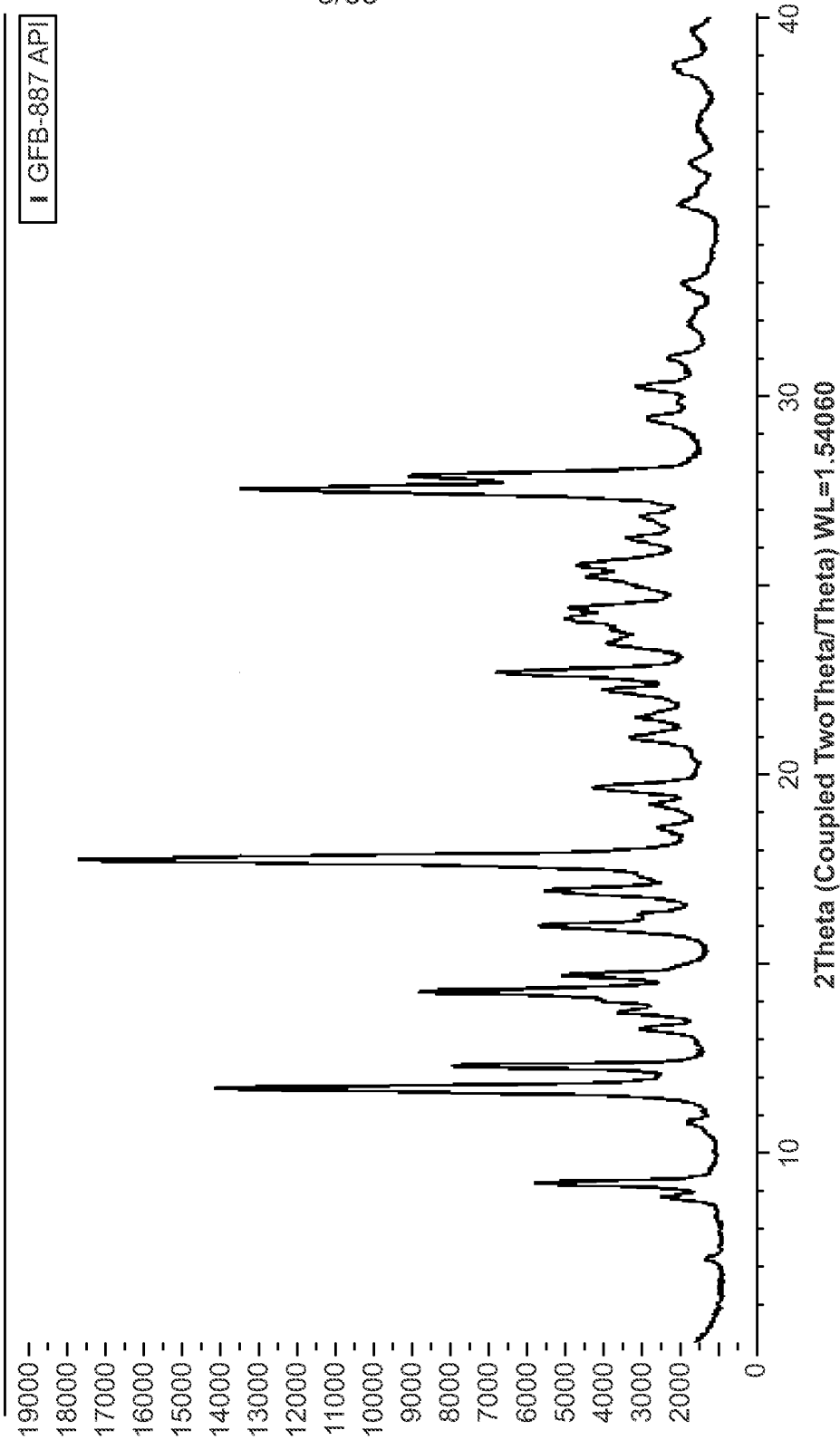
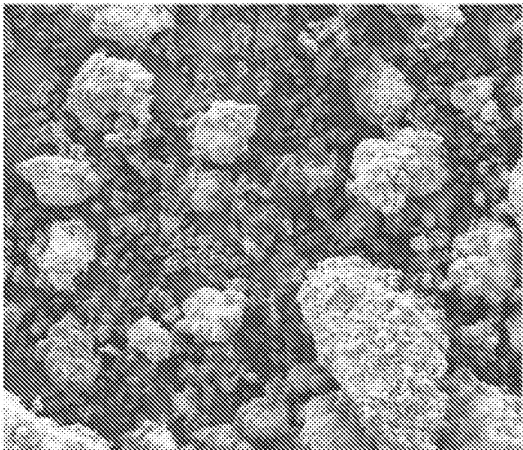


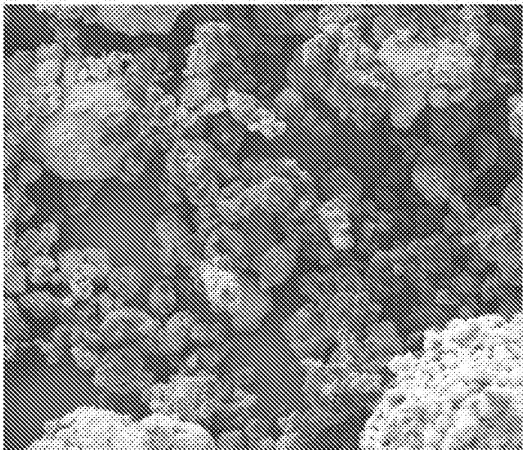
Figure 3

500X



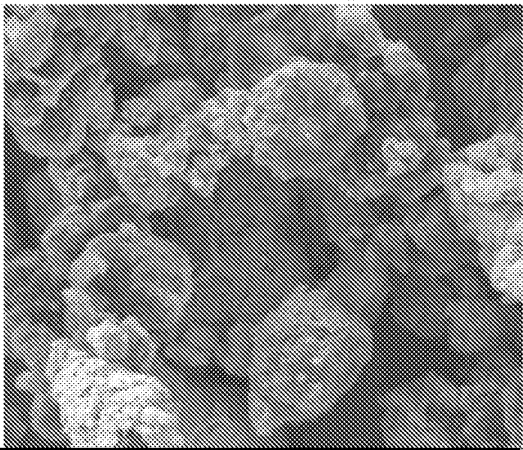
Mag 500x	Spot 3.0	HV 10.0kV	Det ETD	WD 10.0mm	10/15/2018 9:05:11AM	200.0μm GFB-887, Lot# A05313-058P1
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1,500X



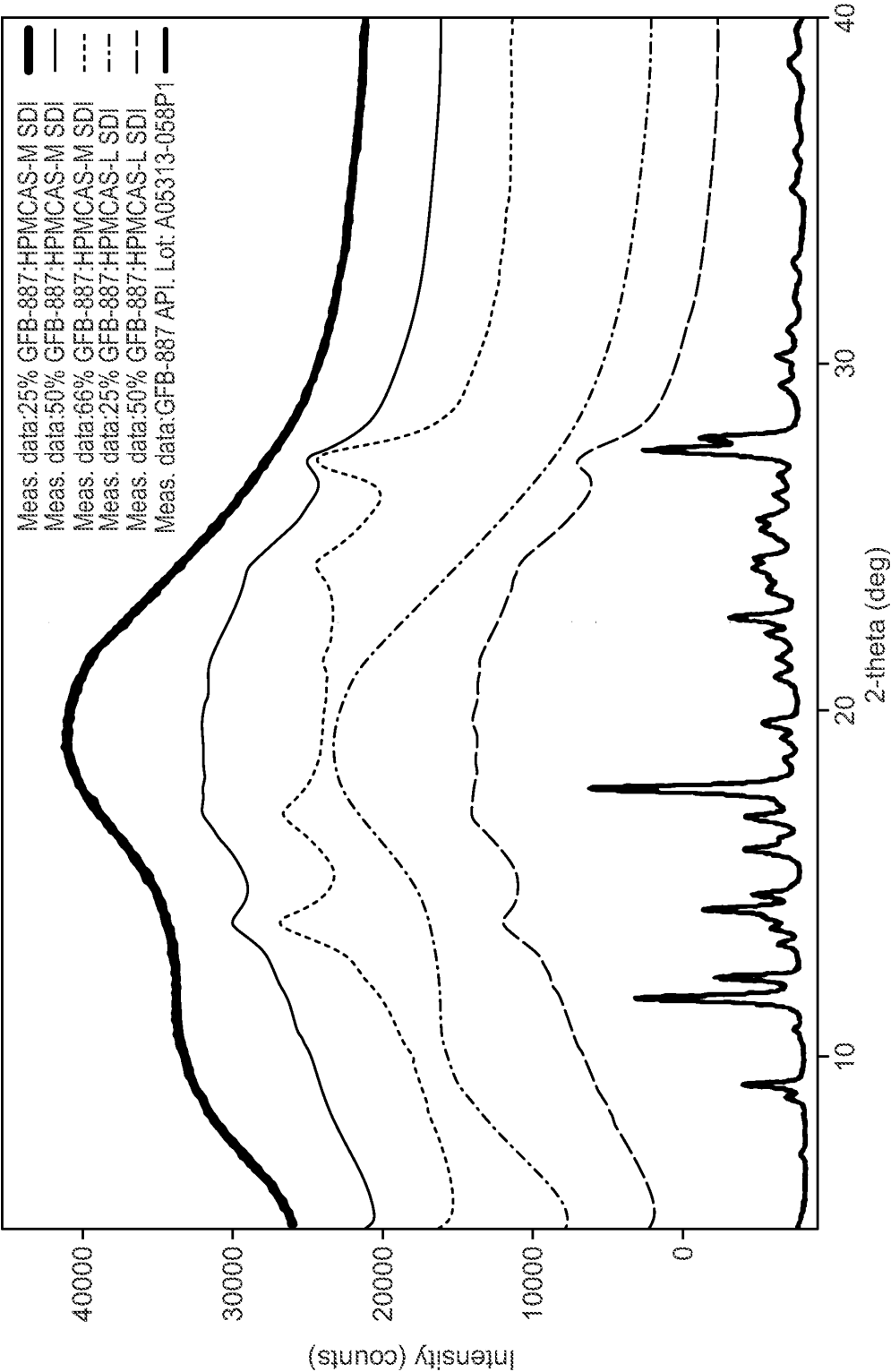
Mag 1500x	Spot 3.0	HV 10.0kV	Det ETD	WD 10.0mm	10/15/2018 9:01:37 AM	50.0μm GFB-887, Lot# A05313-058P1
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5,000X

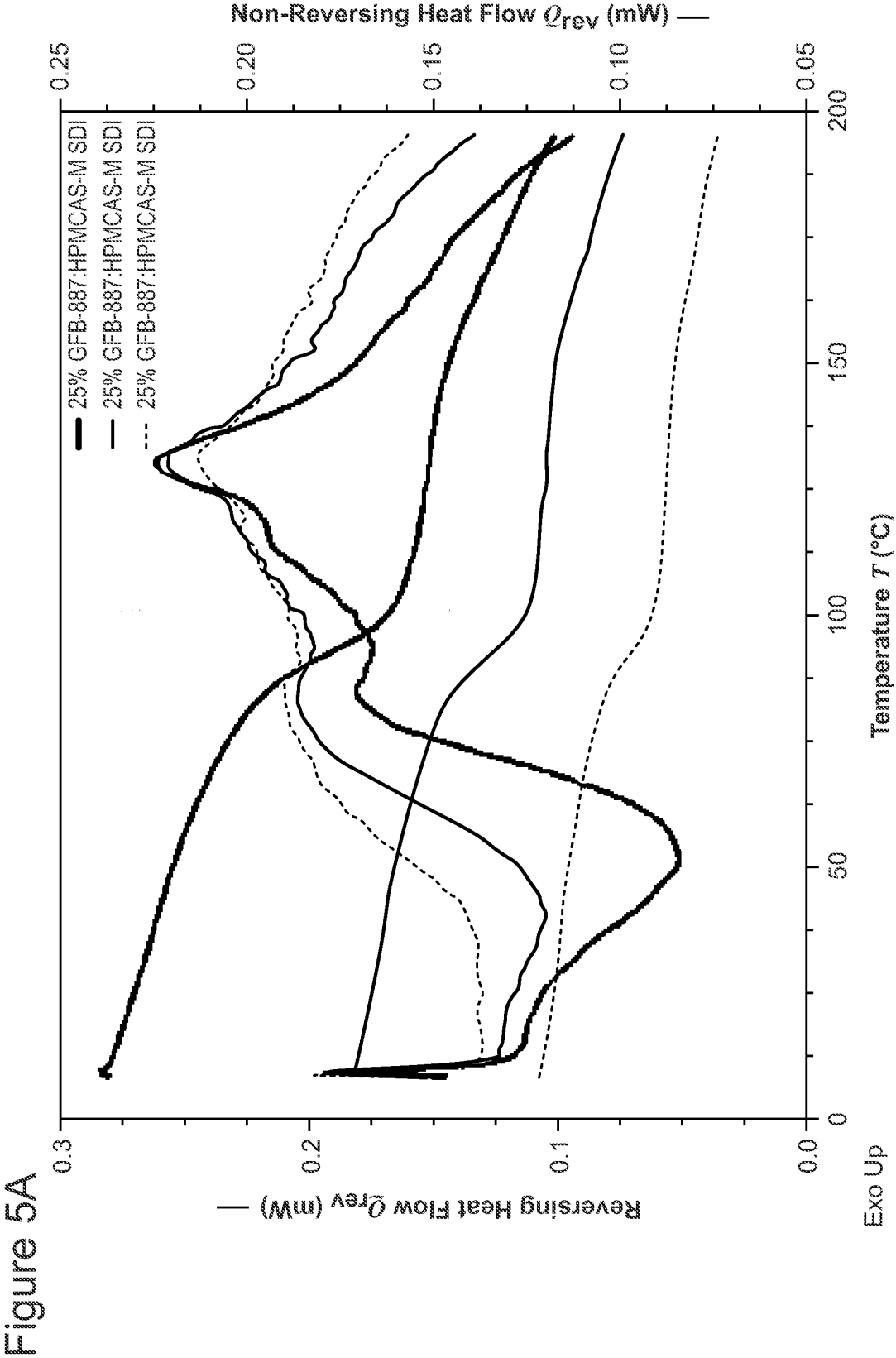


Mag 5000x	Spot 3.0	HV 10.0kV	Det ETD	WD 10.0mm	10/15/2018 8:58:01 AM	20.0μm GFB-887, Lot# A05313-058P1
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Figure 4



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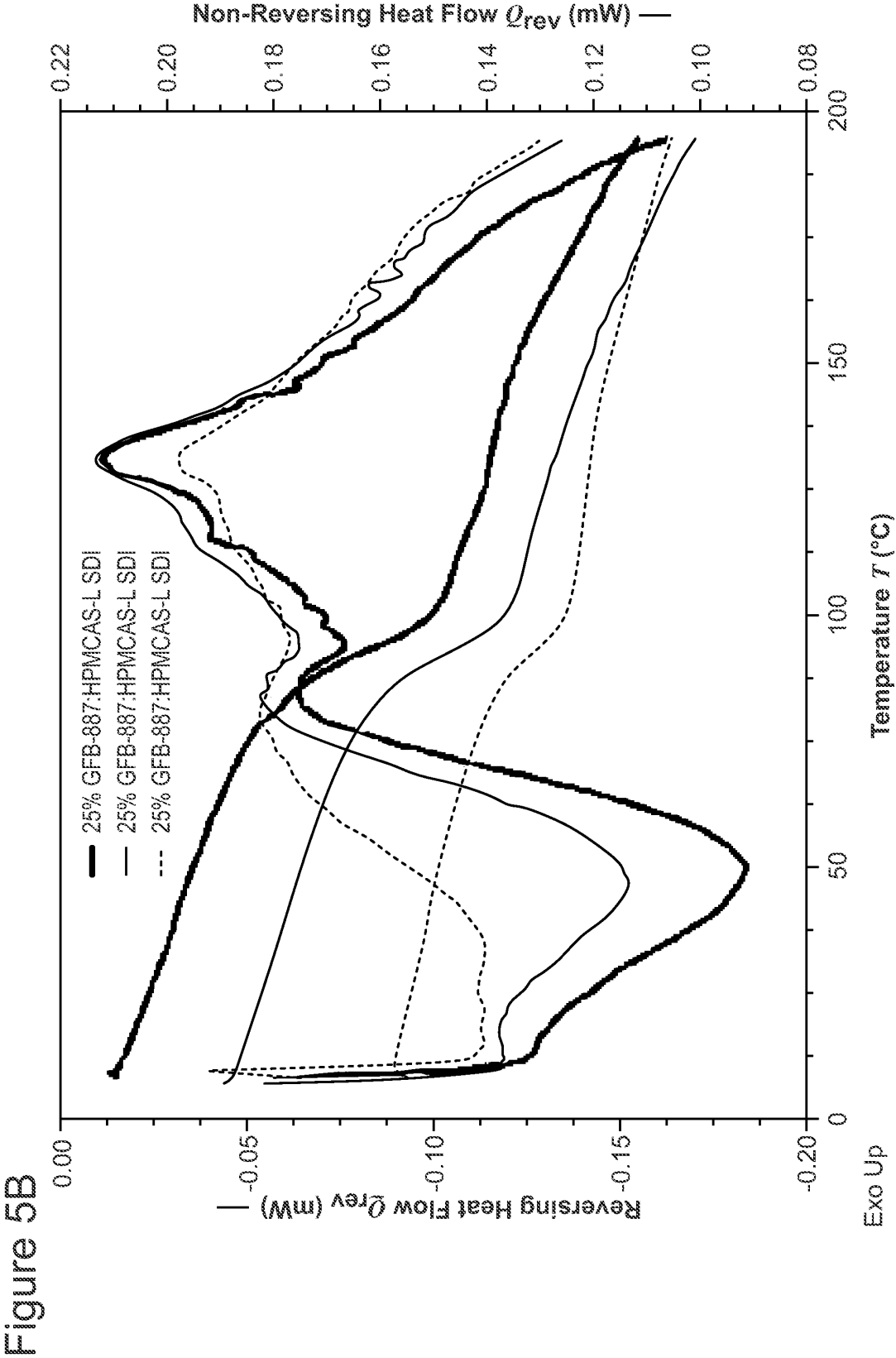


Figure 6

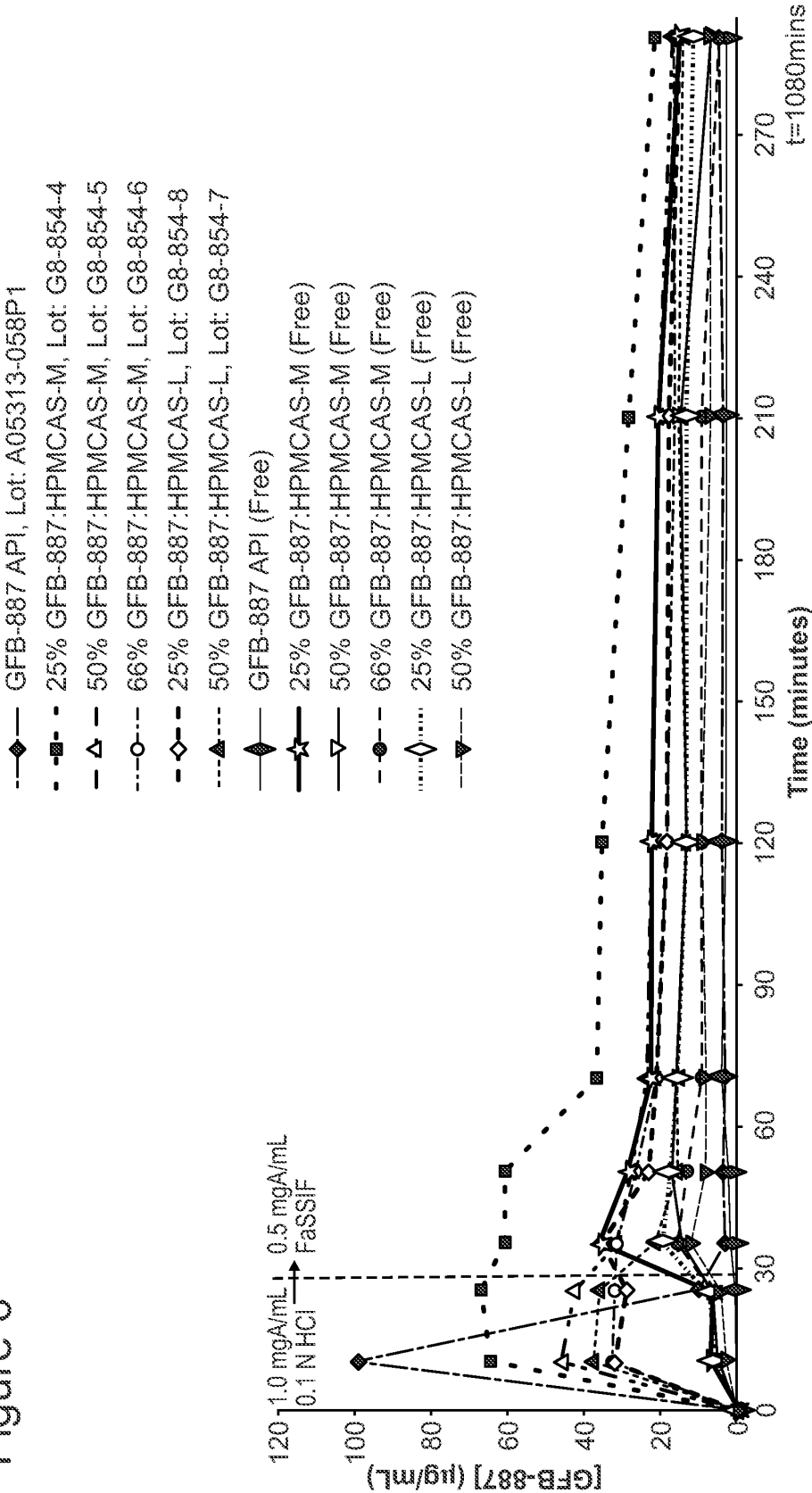


Figure 7

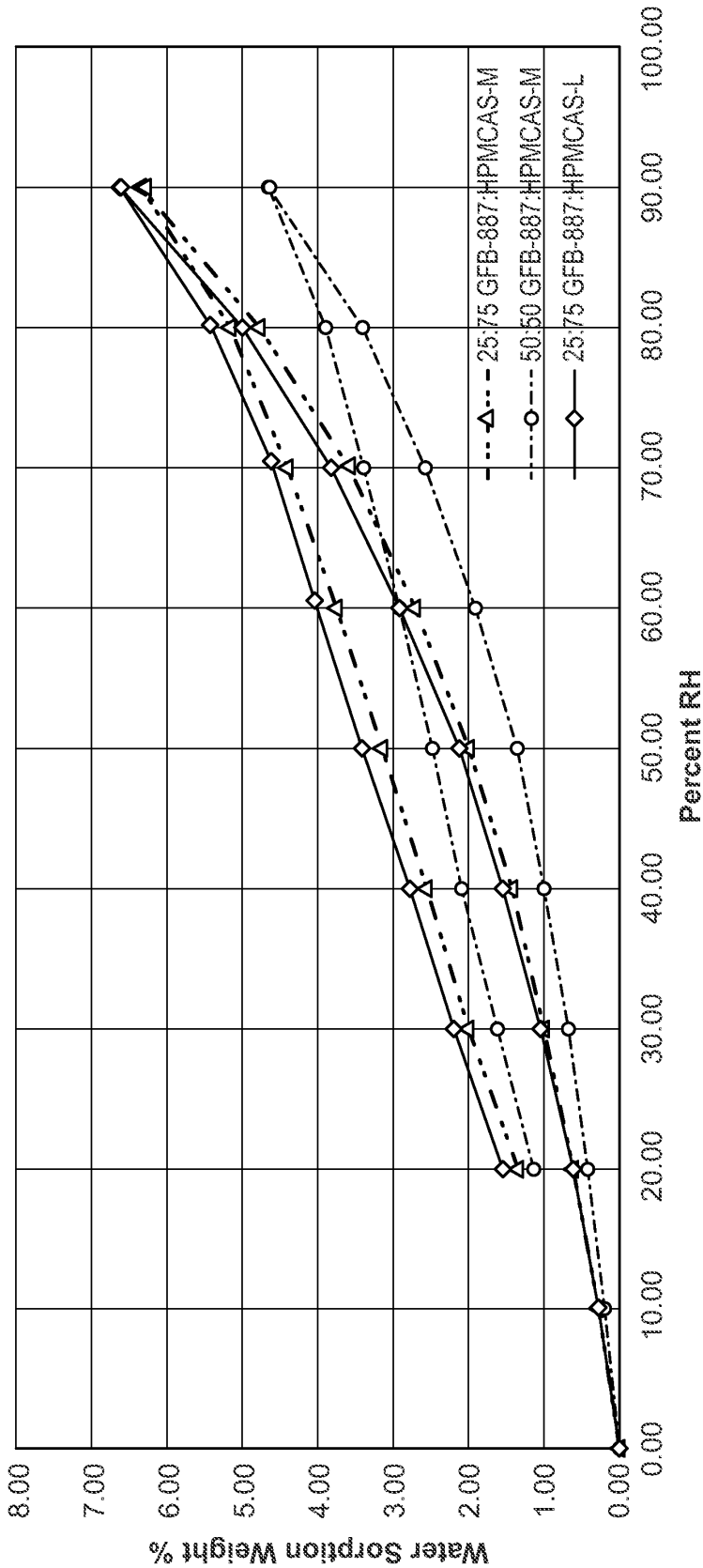


Figure 8

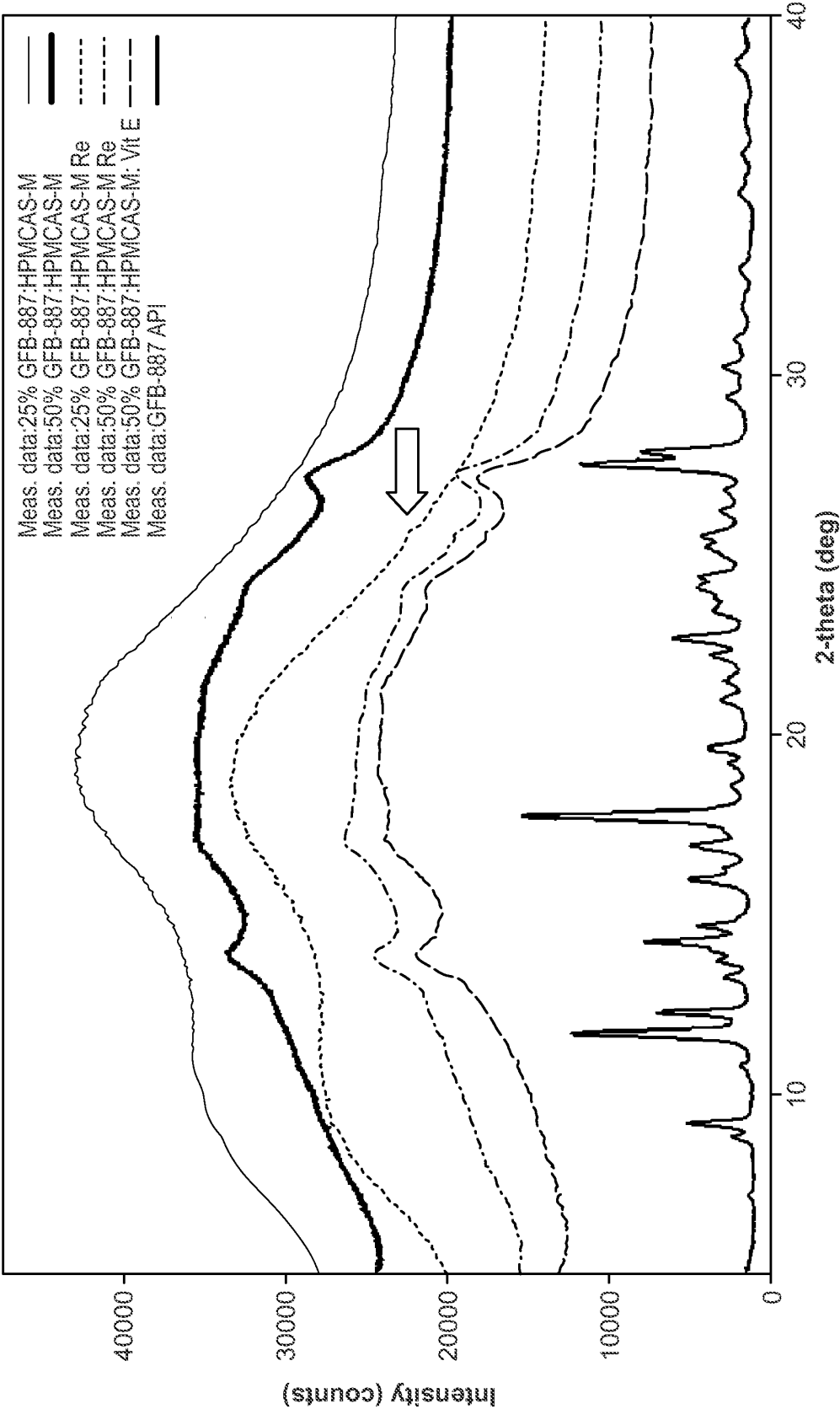


Figure 9

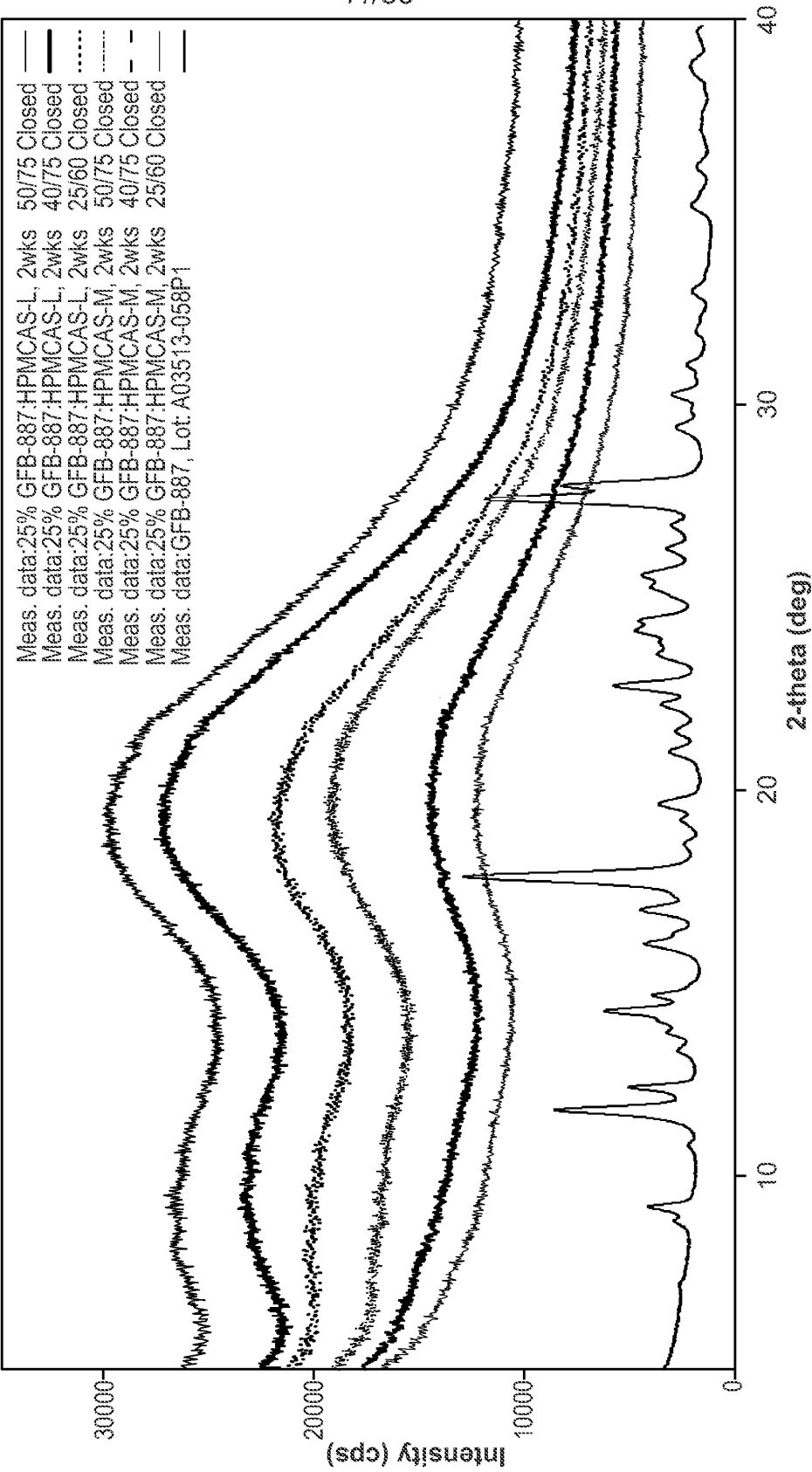


Figure 10

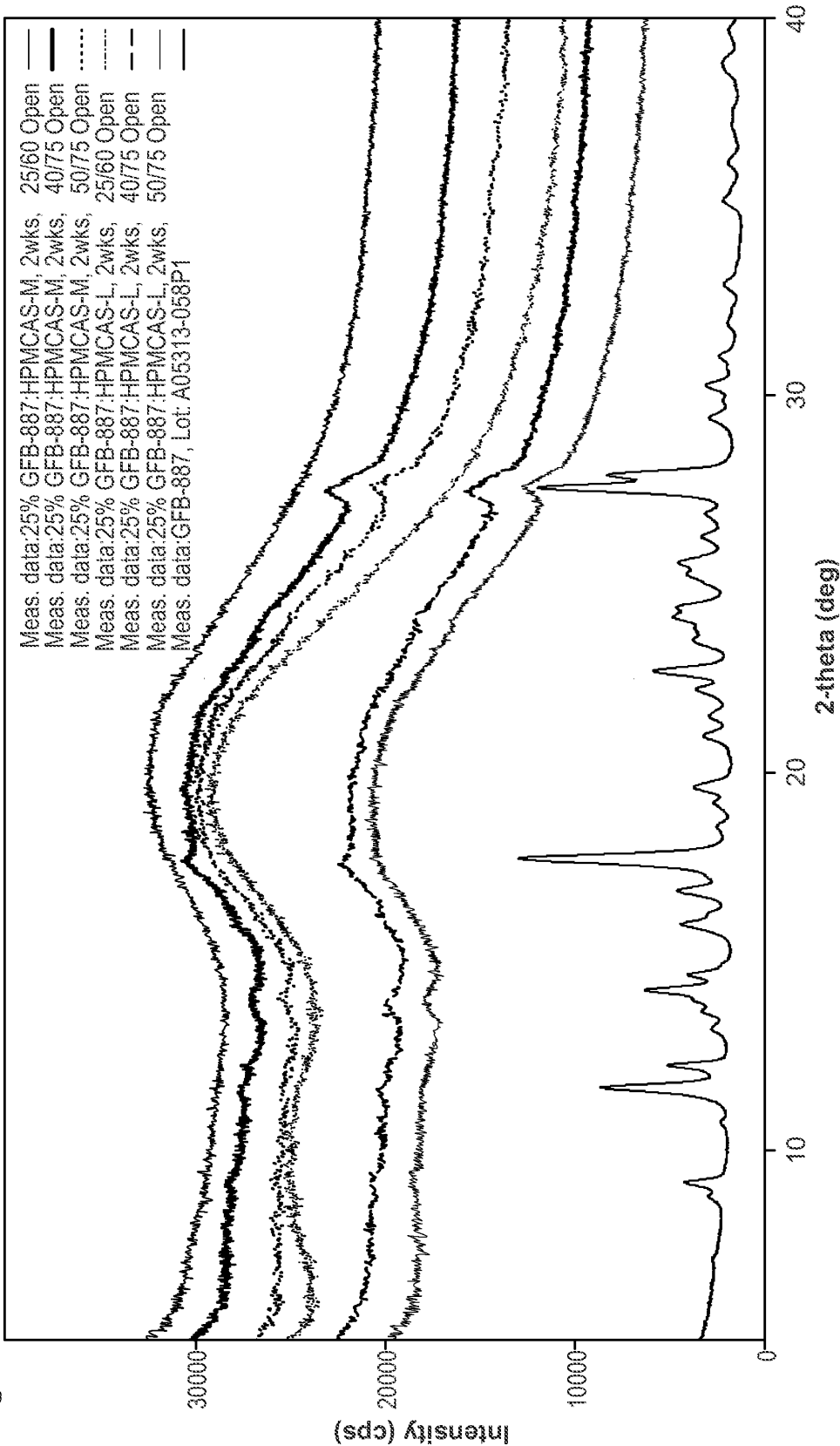


Figure 11

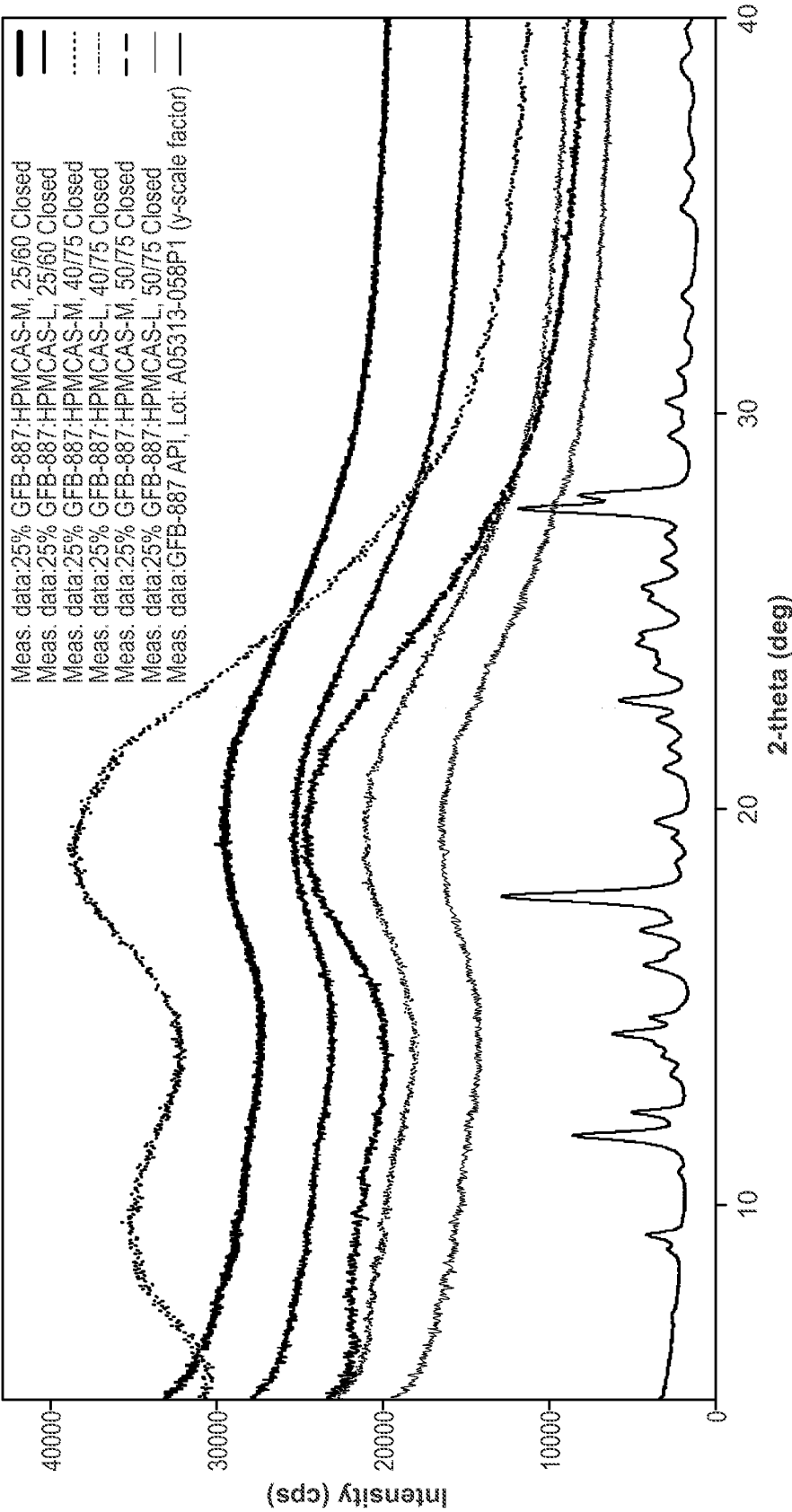


Figure 12

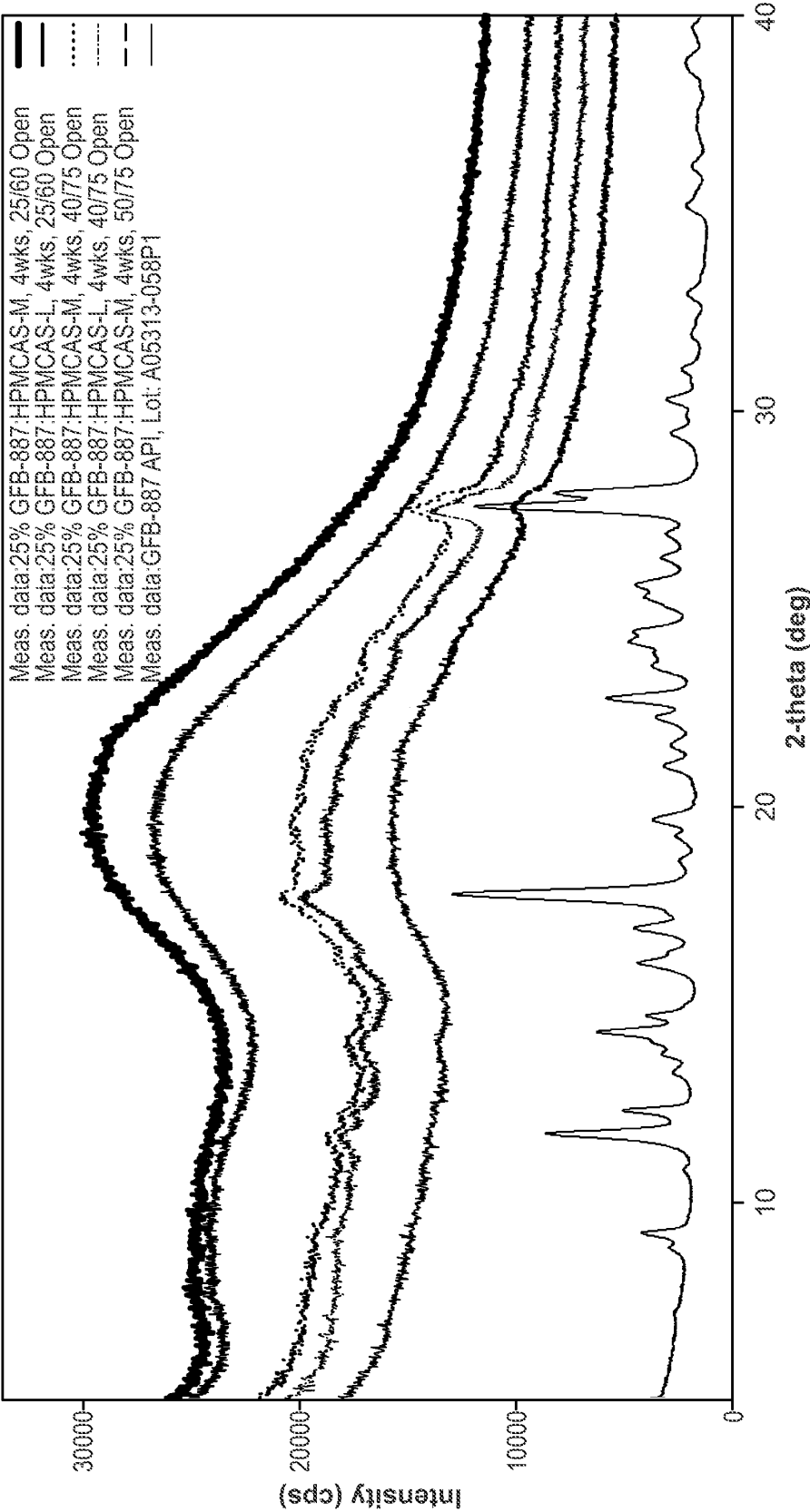


Figure 13

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
 Patheon Lot #: D-18-078
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: room Temperature
 Certificate Rev #: 1
 Page: 1 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Reporting Requirements	Result	
Appearance	AM-0002/ G8-852-40	Report Results	Off-white, tannish powder	
Identification (HPLC, Retention Time Comparison)	DM-0240 (Draft)/ G8-852-13	%Agreement Compared to Reference Standard	100%	
Assay (HPLC)	DM-0240 (Draft)/ G8-852-13	Report Results (wt%)	24.5%	
Individual Impurities and Related Substances (HPLC)	DM-0240 (Draft)/ G8-852-13	Report Results (% peak area)	RRT	%Peak Area
			0.34	0.20
			0.36	0.09
			0.37	<0.05
			0.38	<0.05
			0.56	<0.05
			0.65	<0.05
			0.68	<0.05
			0.72	0.09
			0.80	0.05
			0.85	0.39
			0.91	<0.05
			1.02	0.08
			1.05	0.05
			1.10	<0.05
			1.13	<0.05
			1.44	<0.05
			1.47	0.06
			1.50	<0.05
			1.58	<0.05

Figure 13 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
 Patheon Lot #: D-18-078
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: Room Temperature
 Certificate Rev #: 1
 Page: 2 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Reporting Requirements	Result
Total impurities (HPLC)	DM-0240 (Draft)/ G8-852-13	Report Results, $\geq 0.05\%$ (%area)	1.01%
Water Content (KF)	AM-0233 (Draft) USP<921>/ G8-852-42	Report Result (wt%)	0.20%
Residual Solvent (GC) a. Dichloromethane b. Methanol	AM-0021/ G8-852-49	a. NMT 660 PPM b. NMT 3000 PPM	a. Not Detected b. Not Detected
Thermal analysis (MDSC)	DM-0046 USP<891>/ G8-852-39	Report Results	$T_g = 93^\circ\text{C} \pm 2^\circ\text{C}$ (See Figure 1)
Crystallinity (XRPD)	DM-0044 USP<941>/ G8-852-38	Report Results	Small diffraction peak observed at $26^\circ 2\theta$ (See Figure 2)
Particle size Distribution by Laser Light Diffraction	DM-0166 USP<429> (n=4)/ G8-852-50	Report the average results for Dv10, Dv50, Dv90 in μm	d10- 6.3 μm d50- 23.9 μm d90- 69.5 μm
Particle Morphology (SEM)	USP<1181>/ G8-852-48	Report Results	See Figure 3

Figure 13 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
Patheon Lot #: D-18-078
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: Room Temperature
Certificate Rev #: 1
Page: 3 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

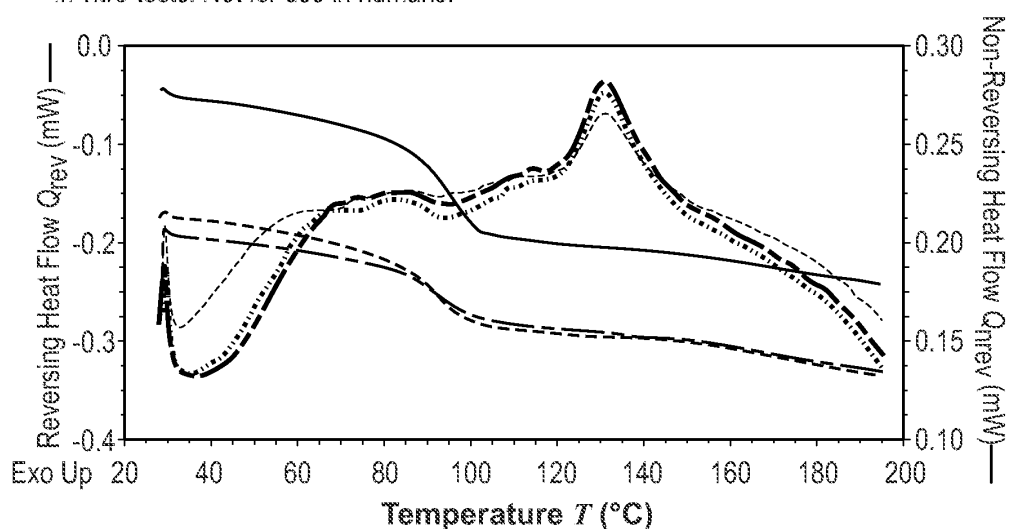


Figure 1. MDSC of 25:75 GFB-887:HPMCAS-M SDI (Lot: D-18-078)

Figure 13 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
Patheon Lot #: D-18-078
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: room Temperature
Certificate Rev #: 1
Page: 4 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

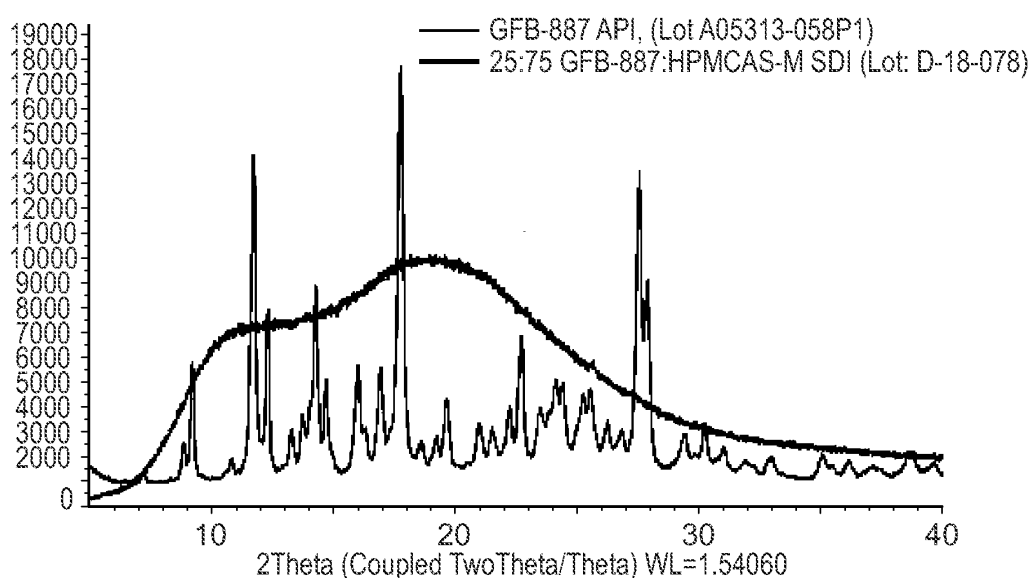


Figure 2. XRPD of 25:75 GFB-887:HPMCAS-M SDI (Lot: D-18-078)

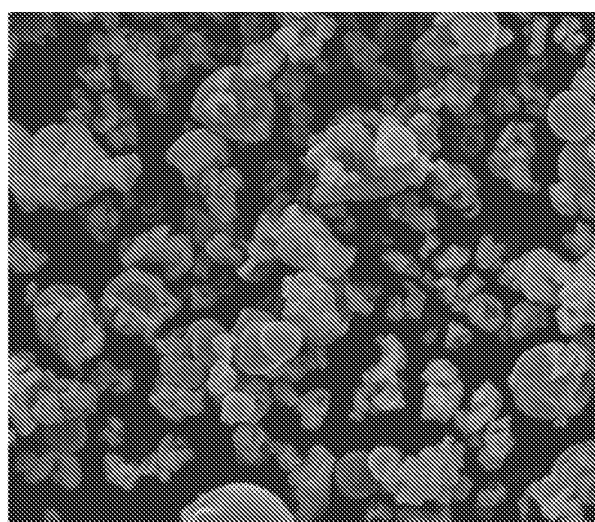
Figure 13 (cont.)

ThermoFisher
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CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
Patheon Lot #: D-18-078
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: room Temperature
Certificate Rev #: 1
Page: 5 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for in vitro tests. Not for use in humans.



Mag	Spot	HV	Det	WD	12/27/2018	50.0µm	
1500x	3.0	30.0kV	ETD	10.8mm	4:53:23PM	25:75 GFR*887:HPMCAS-M SDI	1

Figure 3. SEM of 25:75 GFB-887: HPMCAS-M SDI (Lot: D-18-078)

Figure 13 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: 25:75 GFB-887:HPMCAS-M SDI
Patheon Lot #: D-18-078
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: Room Temperature
Certificate Rev #: 1
Page: 6 of 6

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Revision History:

Revision #	Change	Date
00	New document	10Jan2019
01	Update SEM Figure Title	09May2019

Prepared By/Date:



Ashley Moon
I am the author of this
document
2019.05.09 13:31:24-07'00'

Reviewed By/Date:



James, Jamie L.
I am approving this
document
2019.05.09 14:53:50-07'00'

SUBSTITUTE SHEET (RULE 26)

Figure 14A

Sample Description GFB-887 API (Lot: TJ-GDF-9815-0-A-1)	Timepoint t=0	SSID 5593	RRT	0.35	0.37	0.38	0.39	0.56	0.65	0.68	0.80	0.85	0.91	1.00
				0.19	0.06	0.03	0.02	0.04	0.02	0.05	0.07	0.42	0.04	98.83
				0.19	0.06	<0.05	<0.05	<0.05	<0.05	0.05	0.07	0.42	<0.05	N/A

Sample Description GFB-887 API (Lot: TJ-GDF-9815-0-A-1)	Timepoint t=0	SSID 5593	RRT	1.02	1.06	1.10	1.42	1.46	Total Impurities	
				0.05	0.03	0.4	0.02	0.07		
				0.05	<0.05	<0.05	<0.05	0.07	0.91%	

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Figure 14B

Sample Description	Timepoint	SSID	RRT	0.35	0.37	0.38	0.40	0.56	0.65	0.68	0.80	0.85	0.91	1.00
7wt% Solids 25:75 Compound 1 HPMCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10	t=1day @40°C	5593	%Peak Area	0.18	0.06	0.03	0.02	0.02	0.03	0.03	0.08	0.43	0.05	98.85
			Report % Peak Area	0.18	0.06	<0.05	<0.05	<0.05	<0.05	<0.05	0.08	0.43	0.05	N/A
			Absolute Change in Impurity (%)	0.01	0.00	0.00	0.00	0.01	0.02	0.02	0.01	0.02	0.02	N/A
			% Peak Area	0.17	0.06	0.02	0.02	0.03	0.04	0.03	0.08	0.40	0.06	98.87
			Reported % Peak Area	0.17	0.06	<0.05	<0.05	<0.05	<0.05	<0.05	0.08	0.43	0.05	N/A
			Absolute Change in Impurity (%)	0.02	0.00	0.01	0.00	0.01	0.02	0.02	0.01	0.02	0.2	N/A

Sample Description	Timepoint	SSID	RRT	1.02	1.06	1.10	1.42	1.46	Total Impurities
7wt% Solids 25:75 Compound 1 HPMCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10	t=1day @40°C	5593	%Peak Area	0.05	0.02	0.05	0.02	0.0	
			Report % Peak Area	0.05	<0.05	0.05	<0.05	0.07	
			Absolute Change in Impurity (%)	0.00	0.01	0.01	0.00	0.00	0.97%
			% Peak Area	0.05	0.02	0.05	0.02	0.07	
			Reported % Peak Area	0.05	<0.05	0.05	<0.05	0.07	
			Absolute Change in Impurity (%)	0.00	0.01	0.01	0.00	0.00	0.94%

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Figure 14C

Sample Description 7wt% Solids 25:75 Compound 1 HPCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10	Timepoint t=3day @40°C	SSID 6599	RRT	0.35	0.37	0.38	0.40	0.56	0.65	0.68	0.80	0.85	0.91	0.96		
			%Peak Area	0.16	0.07	0.02	0.03	0.03	0.03	0.03	0.03	0.07	0.41	0.07		
			Report % Peak Area	0.16	0.07	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.07	0.41	0.07	<0.05
			Absolute Change in Impurity (%)	0.03	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.00	0.01	0.03	0.00
			% Peak Area	0.17	0.07	0.02	0.04	0.03	0.03	0.03	0.03	0.03	0.07	0.42	0.07	0.02
			Reported % Peak Area	0.17	0.07	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.07	0.42	0.07	<0.05
			Absolute Change in Impurity (%)	0.02	0.01	0.01	0.02	0.01	0.01	0.02	0.00	0.00	0.03	0.02		
Sample Description 7wt% Solids 25:75 Compound 1 HPCAS- M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10	Timepoint t=3day @40°C	SSID 6599	RRT	1.00	1.02	1.06	1.10	1.42	1.46	1.48	Total Impurities					
			%Peak Area	98.84	0.04	0.03	0.05	0.02	0.07	0.03						
			Report % Peak Area	N/A	<0.05	<0.05	0.05	<0.05	0.07	<0.05						
			Absolute Change in Impurity (%)	N/A	0.01	0.00	0.01	0.00	0.00	0.03	0.90%					
			% Peak Area	98.87	0.04	0.02	0.02	0.02	0.08							
			Reported % Peak Area	N/A	<0.05	<0.05	<0.05	<0.05	0.08							
			Absolute Change in Impurity (%)	N/A	0.01	0.01	0.02	0.00	0.01	0.01	0.88%					

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Figure 14D

Sample Description	Timepoint t=6day @40°C	SSID 7188	RRT	0.35	0.37	0.38	0.40	0.56	0.65	0.68	0.80	0.85	0.89	0.92
7wt% Solids 25:75 Compound 1 HPMCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10			Peak Area	0.17	0.06	0.02	0.02	0.03	0.02	0.02	0.04	0.38	0.03	0.14
			Report Peak Area	0.17	0.06	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.38	<0.05	0.14
			Absolute Change in Impurity (%)	0.02	0.00	0.01	0.00	0.01	0.00	0.03	0.03	0.04	0.03	0.10
			Peak Area	0.17	0.06	0.03	0.02	0.03	0.03	0.03	0.05	0.38	0.02	0.15
			Reported Peak Area	0.17	0.06	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	0.38	<0.05	0.15
			Absolute Change in Impurity (%)	0.02	0.00	0.00	0.00	0.00	0.01	0.00	0.02	0.04	0.02	0.11
Sample Description	Timepoint t=6day @40°C	SSID 7188	RRT	0.96	1.0	1.02	1.05	1.10	1.43	1.46	1.48	1.49	1.51	1.56
7wt% Solids 25:75 Compound 1 HPMCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10			%Peak Area	0.05	98. 61	0.04	0.03	0.05	0.02	0.06	0.03	0.03	0.05	0.03
			Report % Peak Area	0.05	N/A	<0.05	<0.05	0.05	<0.05	0.06	<0.05	<0.05 5	0.05	<0.05
			Absolute Change in Impurity (%)	0.05	N/A	0.01	0.00	0.01	0.00	0.01	0.03	0.03	0.05	0.03
			% Peak Area	0.05	98. 62	0.04		0.05	0.02	0.07			0.05	0.04
			Reported % Peak Area	0.05	N/A	<0.05	<0.05	0.05	<0.05	0.07			0.05	<0.05 5
			Absolute Change in Impurity (%)	0.05	N/A	0.01	0.03	0.01	0.00	0.00			0.05	0.04

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Figure 14D (cont.)

Sample Description 7wt% Solids 25.75 Compound 1 HPMCAS-M in 6:4 DCM:MeOH Spray sol Lot: G8-936-10	Timepoint t=6day @40°C	SSID 7188	RRT	1.78	Total Impurities
			%Peak Area	0.05	
			Report % Peak Area	0.05	
			Absolute Change in Impurity (%)	0.05	1.01%
			% Peak Area	0.09	
			Reported % Peak Area	0.09	
			Absolute Change in Impurity (%)	0.09	1.12%

Figure 14E

Sample Description	Timepoint t=7day @40°C	SSID 8039	RRT	0.35	0.37	0.39	0.56	0.65	0.68	0.80	0.85	0.89	0.92
7wt% Solids 25:75 Compound 1			%Peak Area	0.17	0.06	0.03	0.06	0.02	0.04	0.07	0.38	0.05	0.17
HPMCAS-M in 6:4 DCM:MeOH			Report % Peak Area	0.17	0.06	ND	0.06	<0.05	<0.05	0.07	0.38	0.05	0.17
Spray sol			Absolute Change in Impurity (%)	0.02	0.00	0.03	0.02	0.00	0.01	0.00	0.04	0.05	0.13
Lot: G8-936-10			% Peak Area	0.17	0.06	0.02	0.03	0.04	0.02	0.05	0.39	0.03	0.17
			Reported % Peak Area	0.17	0.06	ND	<0.05	<0.05	<0.05	0.05	0.39	<0.05	0.17
			Absolute Change in Impurity (%)	0.02	0.00	0.03	0.01	0.02	0.01	0.02	0.03	0.03	0.13

Sample Description	Timepoint t=7day @40°C	SSID 8039	RRT	0.96	1.00	1.02	1.05	1.10	1.43	1.46	1.51	1.57	Total Impurities
7wt% Solids			%Peak Area	0.06	98.56	0.04	0.02	0.05	0.04	0.08	0.07	0.04	
25:75 Compound 1			Report % Peak Area	0.06	N/A	<0.05	<0.05	0.05	<0.05	0.08	0.07	<0.05	
HPMCAS-M in 6:4 DCM:MeOH			Absolute Change in Impurity (%)	0.06	N/A	0.01	0.01	0.01	0.02	0.01	0.07	0.04	1.22%
Spray sol			% Peak Area	0.06	98.55	0.04	0.02	0.06	0.04	0.08	0.08	0.08	
Lot: G8-936-10			Reported % Peak Area	0.06	N/A	<0.05	<0.05	0.06	<0.05	0.08	0.08	0.08	
			Absolute Change in Impurity (%)	0.06	N/A	0.01	0.01	0.02	0.02	0.01	0.08	0.08	1.20%

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Figure 14F

Sample Description	Timepoint t=9day @40°C	SSID 8972	RRT	0.35	0.37		0.39	0.45	0.56	0.66	0.68	0.80	0.85	0.89
7wt% Solids 25:75 Compound 1			%Peak Area	0.17	0.06		0.05	0.03	0.03	0.03	0.02	0.06	0.41	0.02
HPMCAS-M in 6:4 DCM:MeOH Spray sol			Report % Peak Area	0.17	0.06	ND	0.05	<0.05	<0.05	<0.05	<0.05	0.06	0.41	<0.05
Lot: G8-936-10			Absolute Change in Impurity (%)	0.02	0.00	0.03	0.03	0.03	0.01	0.01	0.03	0.01	0.01	0.02
			% Peak Area	0.17	0.06		0.02		0.03	0.02	0.03	0.05	0.41	0.02
			Reported % Peak Area	0.17	0.06	ND	<0.05		<0.05	0.05	<0.05	0.05	0.41	<0.05
			Absolute Change in Impurity (%)	0.02	0.00	0.03	0.00		0.01	0.00	0.02	0.02	0.01	0.02

Sample Description	Timepoint t=9day @40°C	SSID 8972	RRT	0.92	0.96	1.00	1.02	1.05	1.10	1.43	1.46	1.48	1.51	1.57	Total Impurities
7wt% Solids 25:75			%Peak Area	0.12	0.06	98.63	0.04	0.02	0.05	0.03	0.07	0.02	0.03	0.05	
Compound 1			Report % Peak Area	0.12	0.06	N/A	<0.05	<0.05	0.05	<0.05	0.07	<0.05	<0.05	0.05	
HPMCAS-M in 6:4			Absolute Change in Impurity (%)	0.08	0.06	N/A	0.01	0.01	0.01	0.01	0.00	0.02	0.03	0.05	1.10%
DCM:MeOH			% Peak Area	0.11	0.06	98.66	0.04	0.02	0.04	0.04	0.06	0.02	0.05	0.09	
Spray sol			Reported % Peak Area	0.11	0.06	N/A	<0.05	<0.05	<0.05	<0.05	0.06	<0.05	0.05	0.09	
Lot: G8-936-10			Absolute Change in Impurity (%)	0.07	0.06	N/A	0.01	0.01	0.00	0.02	0.01	0.02	0.05	0.09	1.06%

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Figure 14G

Sample Description	Timepoint t=13day @40°C	SSID 10085	RRT	0.34	0.36	0.37	0.38	0.56	0.66	0.68	0.78	0.80	0.85	0.86
7wt Solids			Peak Area	0.22	0.11	0.04	0.07	0.06	0.02		0.03	0.04	0.33	0.06
25.75			Report Peak Area	0.22	0.11	<0.05	0.07	0.06	<0.05		<0.05	<0.05	0.33	0.06
Compound 1			Absolute Change in Impurity (%)	0.03	0.05	0.01	0.05	0.02	0		0.02	0.03	0.09	0.06
HPMCAS-M			Peak Area	0.23	0.12	0.04	0.06	0.06	0.02	0.02	0.02	0.05	0.33	0.06
In			Report Peak Area	0.23	0.12	<0.05	0.06	0.06	<0.05	<0.05	<0.05	0.05	0.33	0.06
6.4			Absolute Change in Impurity (%)	0.04	0.06	0.01	0.04	0.02	0	0.02	0.03	0.02	0.09	0.06
DCM:MeOH														
Spray sol														
Lot: G8-936-10														

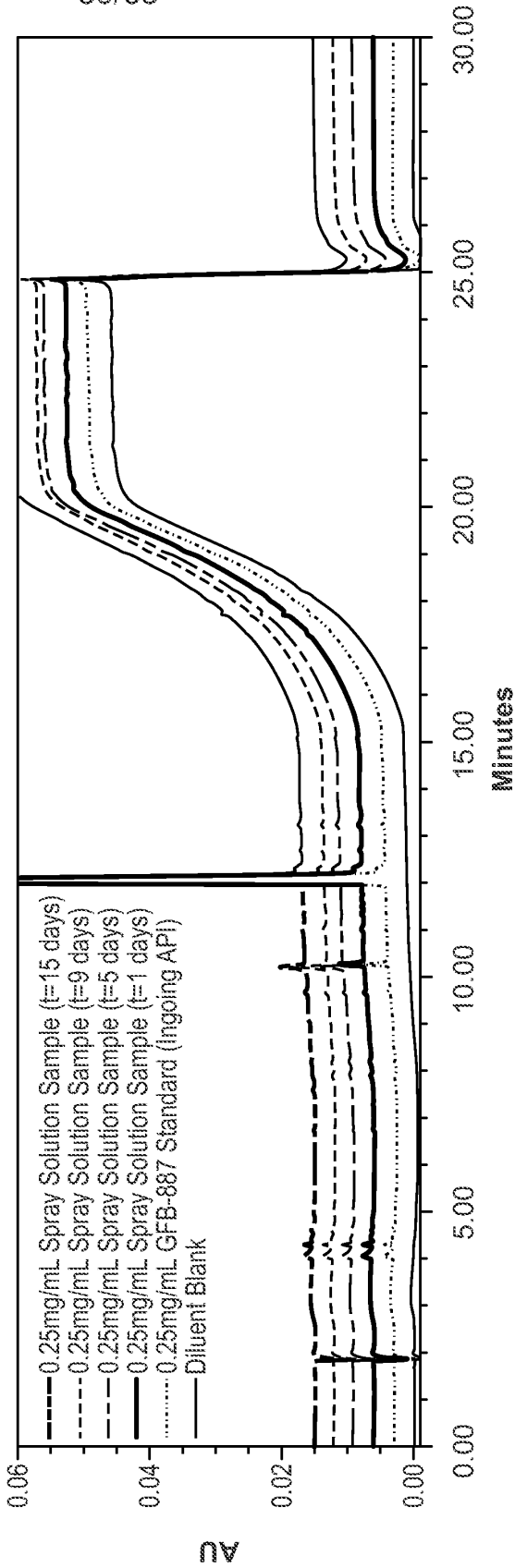
Sample Description	Timepoint t=13day @40°C	SSID 10085	RRT	0.88	0.92	0.94	0.96	1.00	1.02	1.10	1.43	1.47	1.52	1.56	1.58	Total Impurities
7wt Solids			Peak Area	0.03	1.09	0.10	0.10	96.48	0.06	0.04	0.03	0.38	0.57	0.10	0.04	
25.75			Report Peak Area	<0.05	1.09	0.10	0.10	N/A	0.06	<0.05	<0.05	0.38	0.57	0.10	<0.05	
Compound 1			Absolute Change in Impurity (%)	0.03	1.05	0.1	0.1	N/A	0.01	0	0.01	0.31	0.57	0.09	0.04	3.25%
HPMCAS-M			Peak Area	0.03	1.08	0.1	0.1	96.44	0.06	0.05	0.03	0.39	0.57	0.09	0.04	
In			Report Peak Area	<0.05	1.08	0.1	0.1	N/A	0.06	0.05	<0.05	0.39	0.57	0.09	<0.05	
6.4			Absolute Change in Impurity (%)	0.03	1.04	0.1	0.1	N/A	0.01	0.01	0.01	0.32	0.57	0.09	0.04	3.35%
DCM:MeOH																
Spray sol																
Lot: G8-936-10																

Figure 15A

Sample Description GFB-887 API (Lot: TJ-GDF-9815-0-A-I)	Timepoint t=0	RRT	0.85	0.91	1.00	1.02	1.05	1.10	1.44	1.47	1.58	Total Impurities 0.97%
		% Peak Area	0.40%	0.04%	98.74%	0.08%	0.02%	0.04%	0.02%	0.07%	0.03%	
		Reported % Peak Area	0.40%	<0.05%	N/A	0.08%	<0.05%	<0.05%	ND	0.07%	<0.05%	
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=1day	RRT	0.85	0.91	1.00	1.02	1.05	1.10	1.43	1.47	1.58	Total Impurities
		% Peak Area	0.40%	0.03%	98.78%	0.07%	0.02%	0.05%	0.03%	0.07%	0.04%	
		Reported % Peak Area	0.40%	<0.05%	N/A	0.07%	<0.05%	0.05%	ND	0.07%	<0.05%	0.93%
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=5day	Absolute Change in Impurity	0.00%	0.01%	N/A	0.01%	0.00%	0.01%	0.00%	0.00%	0.01%	Total Impurities
		RRT	0.85	0.91	1.00	1.02	1.05	1.10	1.13	1.44	1.47	1.58
		% Peak Area	0.39%	0.03%	98.72%	0.08%	0.02%	0.05%	0.06%	0.02%	0.07%	0.06%
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=9day	Reported % Peak Area	0.39%	<0.05%	N/A	0.08%	<0.05%	0.05%	<0.05%	0.07%	<0.05%	1.04%
		Absolute Change in Impurity	0.01%	0.01%	N/A	0.00%	0.00%	0.01%	0.06%	0.00%	0.03%	
		RRT	0.85	0.91	1.00	1.02	1.05	1.10	0.00%	0.00%	0.04%	0.03%
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=15day	RRT	0.85	0.91	1.00	1.02	1.05	1.10	1.43	1.47	1.58	Total Impurities
		% Peak Area	0.41%	0.04%	98.73%	0.08%	0.02%	0.05%		0.07%	0.03%	0.06%
		Reported % Peak Area	0.41%	<0.05%	N/A	0.08%	<0.05%	0.05%	ND	0.07%	<0.05%	0.06%
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=15day	Absolute Change in Impurity	0.01%	0.00%	N/A	0.00%	0.00%	0.01%	0.00%	0.00%	0.03%	1.02%
		RRT	0.85	0.91	1.00	1.02	1.05	1.10	1.43	1.47	1.49	1.58
		% Peak Area	0.42%	0.03%	98.77%	0.07%	0.03%	0.07%	0.02%	0.07%	0.04%	0.05%
Sample Description 25.75 GFB-887:HPMCAS- M Wet SDI Lot: D-18-078	Timepoint t=15day	Reported % Peak Area	0.42%	<0.05%	N/A	0.07%	<0.05%	0.07%	ND	0.07%	<0.05%	0.05%
		Absolute Change in Impurity	0.02%	0.01%	N/A	0.01%	0.01%	0.03%	0.00%	0.00%	0.04%	0.02%
		RRT	0.85	0.91	1.00	1.02	1.05	1.10	0.00%	0.00%	0.04%	0.02%

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Figure 15B



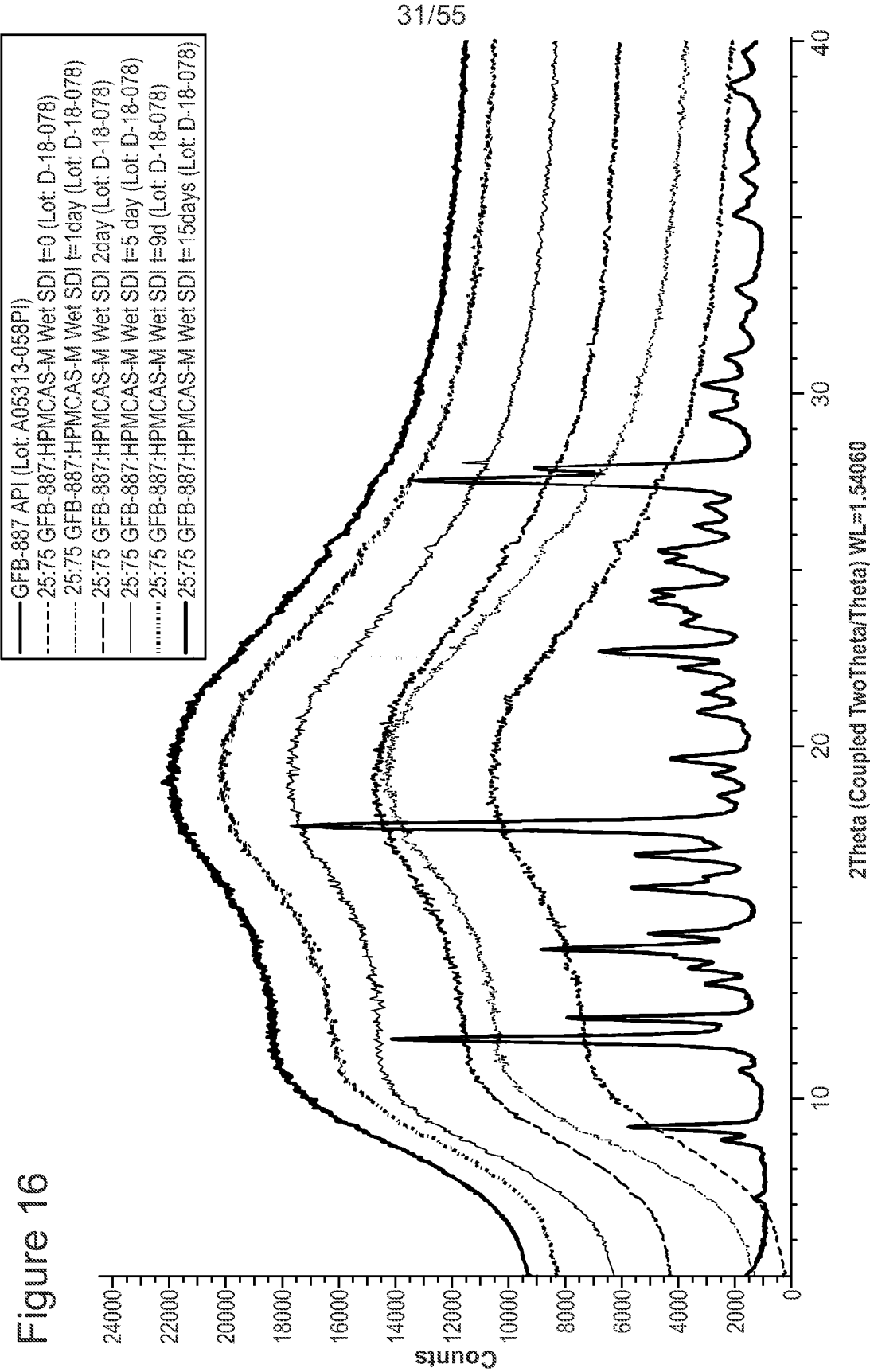


Figure 17

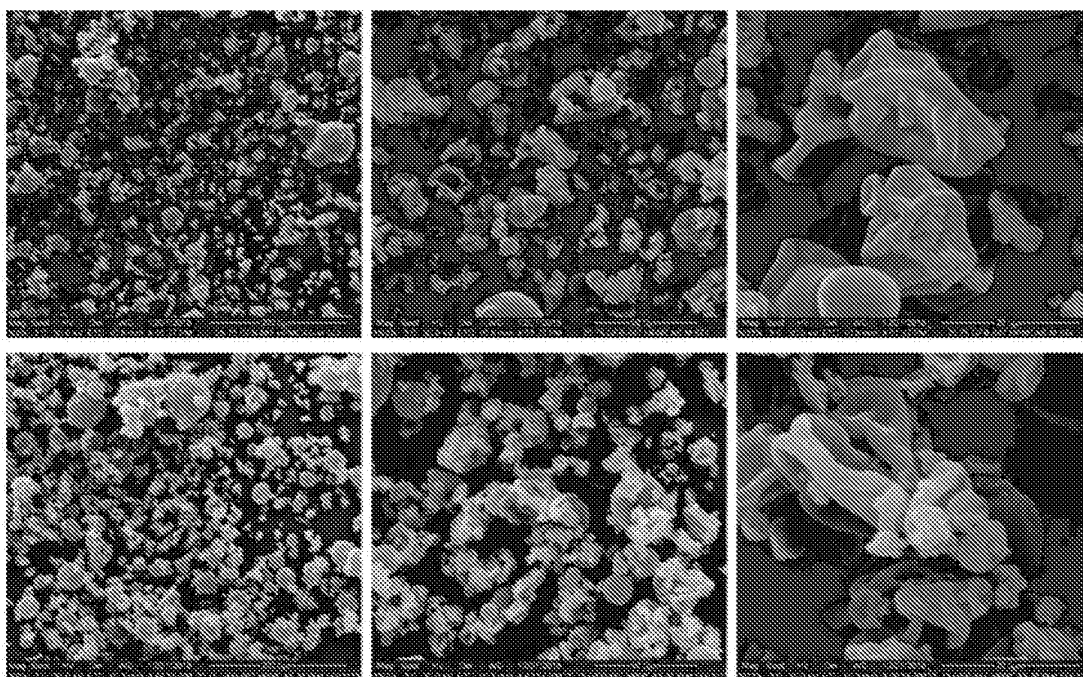
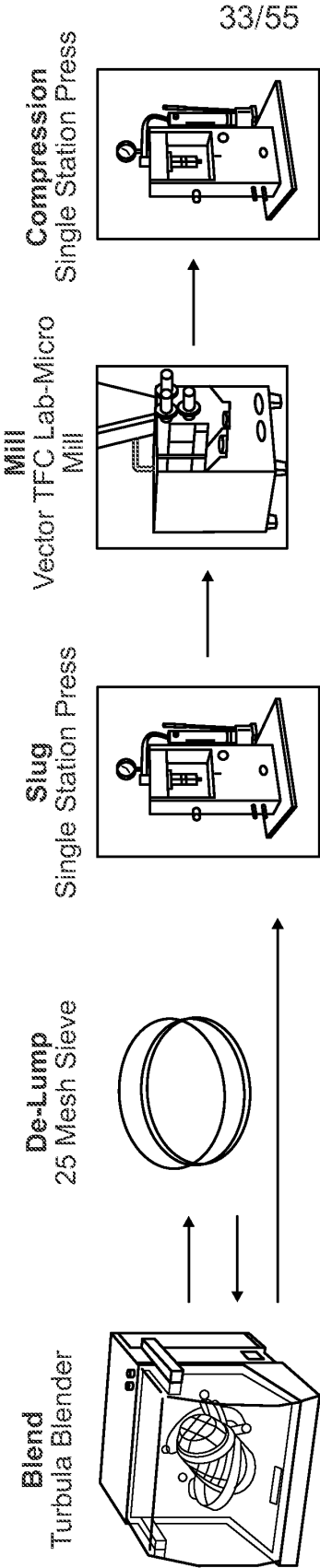
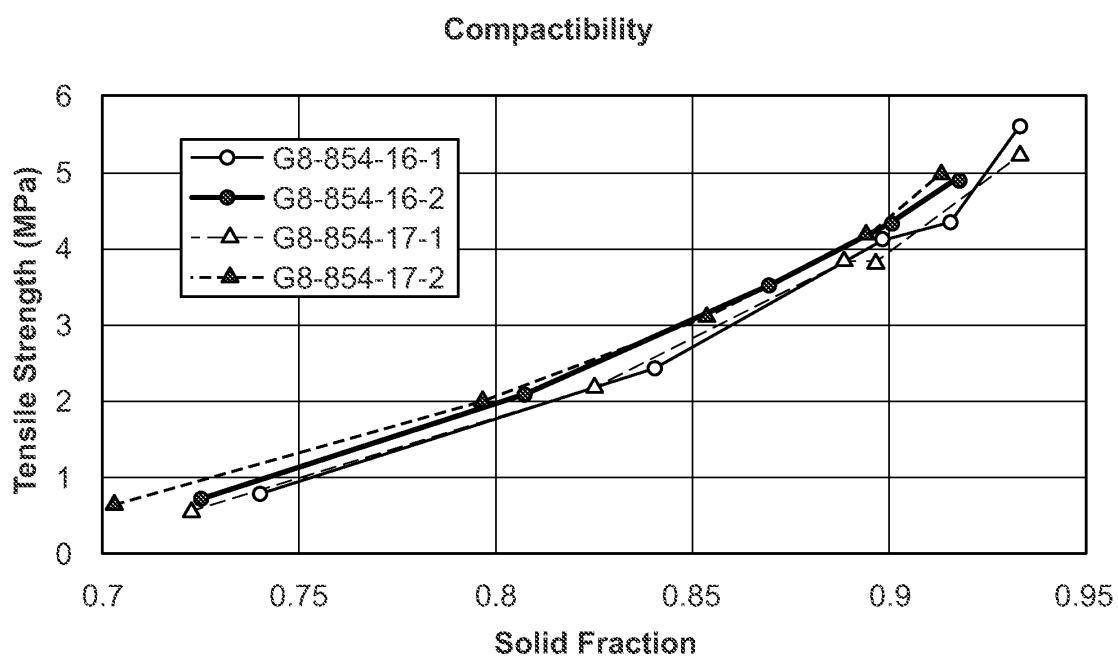
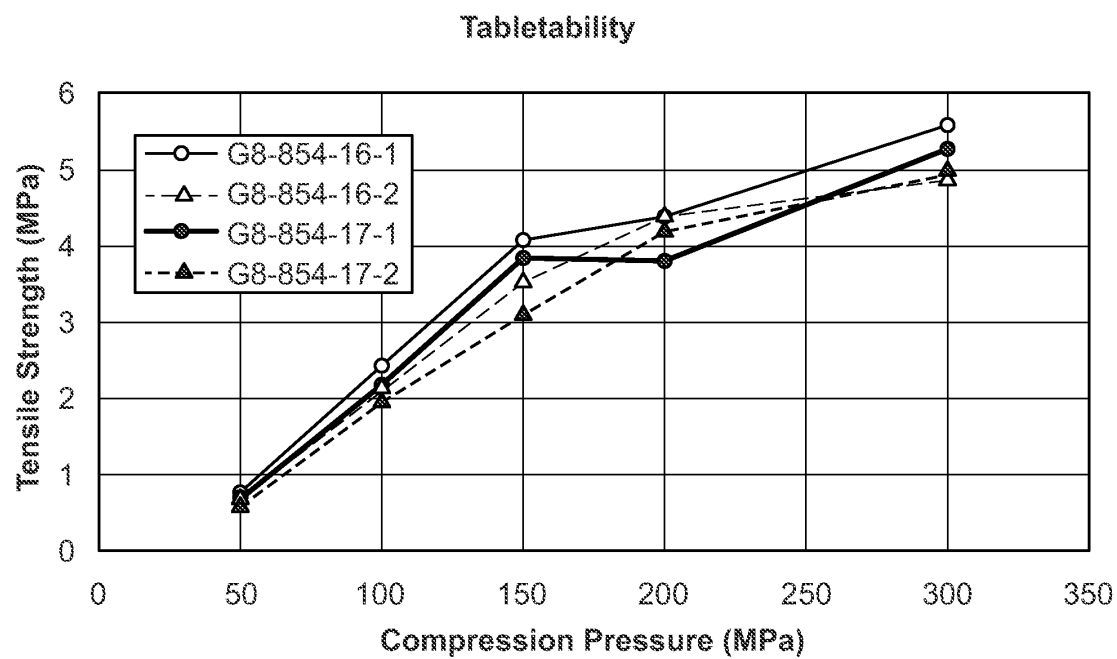


Figure 18



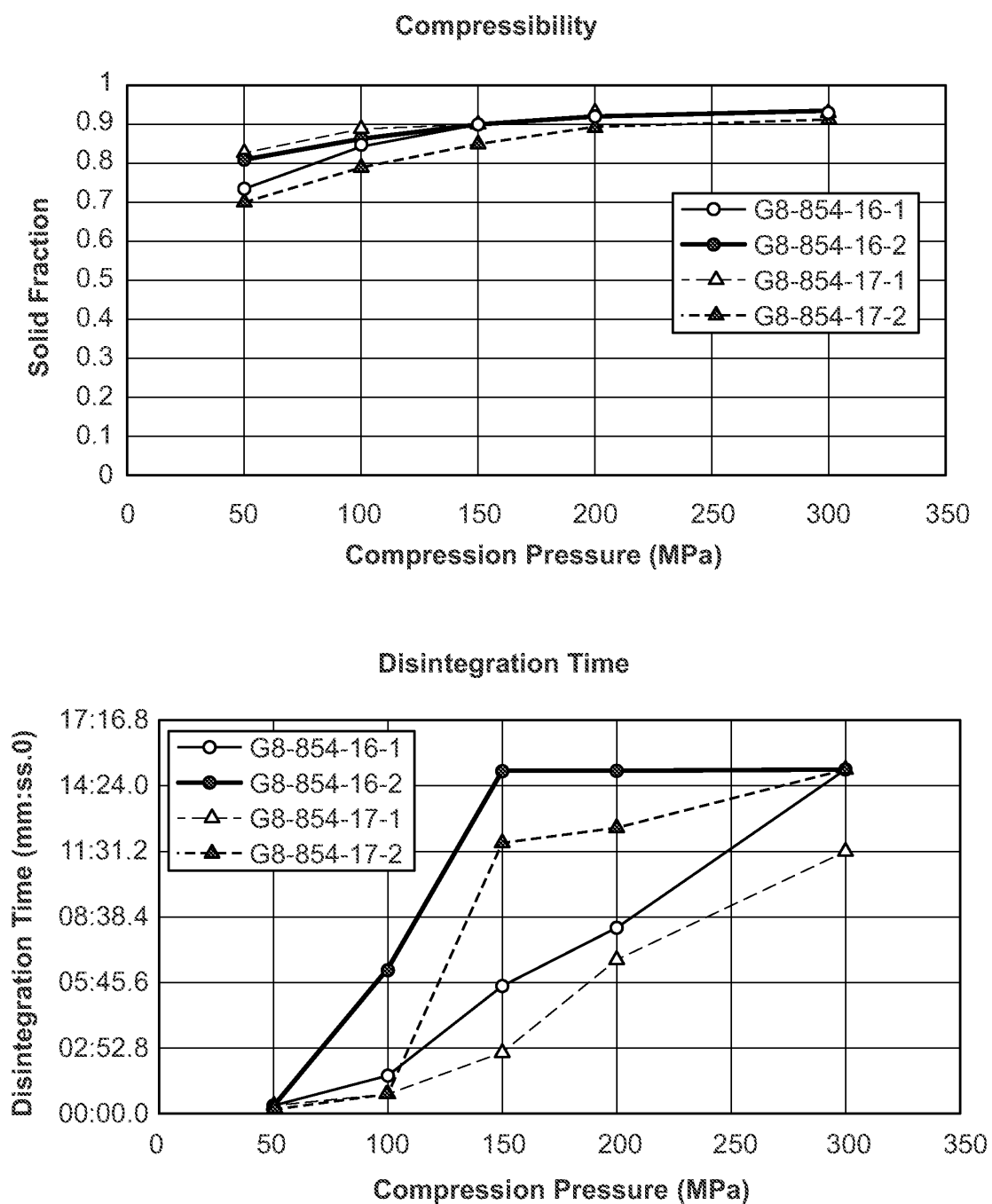
34/55

Figure 19



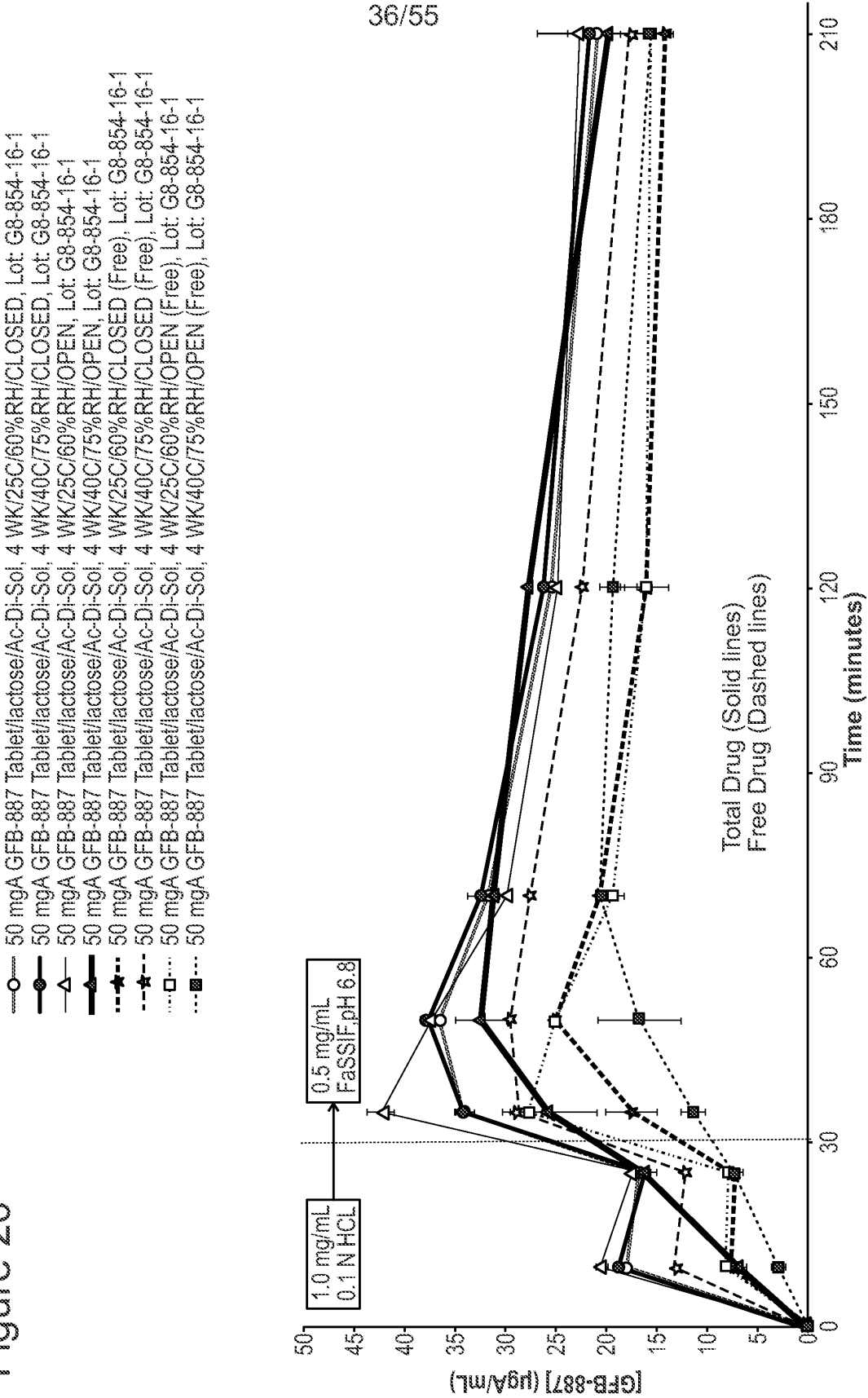
35/55

Figure 19 (cont.)



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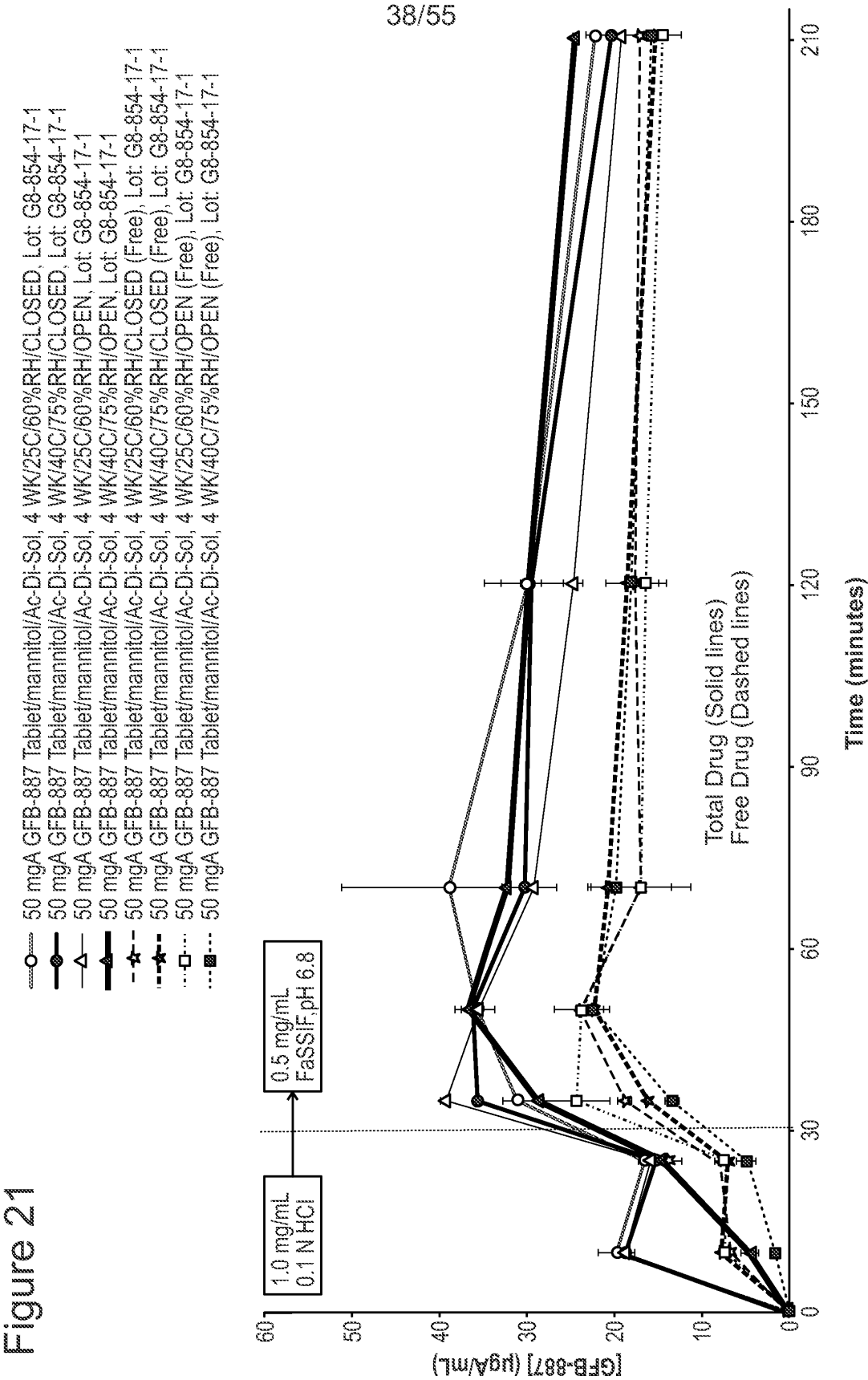
Figure 20



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Figure 20 (cont.)

Sample	Lot#	Drug C _{maxGR} (µgA/mL)	Drug C _{maxFAS} (µgA/mL)	Drug AUC _{0-24h FAS} (min*µgA/mL)	Drug C _{24h} (µgA/mL)
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/25C/60%RH/CLOSED	G8-854-16-1	18	36.7	4700	20.9
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/40C/75%RH/CLOSED	G8-854-16-1	19	37.7	4900	21.7
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/25C/60%RH/OPEN	G8-854-16-1	21	42.3	4800	22.7
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/40C/75%RH/OPEN	G8-854-16-1	16	32.4	4700	19.8
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/25C/60%RH/CLOSED (Free)	G8-854-16-1	8	25.0	3100	14.3
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/40C/75%RH/CLOSED (Free)	G8-854-16-1	13	29.6	4100	17.7
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/25C/60%RH/OPEN (Free)	G8-854-16-1	8	28.0	3200	15.6
50 mgA GFB-887 Tablet/lactose/Ac-Di-Sol, 4 WK/40C/75%RH/OPEN (Free)	G8-854-16-1	7	20.6	3200	15.5



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Figure 21 (cont.)

Sample	Lot#	Drug C _{max} GR (µgA/mL)	Drug C _{max} FaSSIF (µgA/mL)	Drug AUC _{0-24h} FaSSIF (min*µgA/mL)	Drug C _{24h} (µgA/mL)
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/25C/60%RH/CLOSED	G8-854-17-1	20	38.8	5300	22.4
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/40C/75%RH/CLOSED	G8-854-17-1	19	36.0	4900	20.5
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/25C/60%RH/OPEN	G8-854-17-1	19	39.3	4500	19.3
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/40C/75%RH/OPEN	G8-854-17-1	15	36.8	5200	24.6
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/25C/60%RH/CLOSED (Free)	G8-854-17-1	8	23.9	3200	17.1
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/40C/75%RH/CLOSED (Free)	G8-854-17-1	8	22.4	3200	15.3
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/25C/60%RH/OPEN (Free)	G8-854-17-1	8	24.3	3000	14.5
50 mgA GFB-887 Tablet/mannitol/Ac-Di-Sol, 4 WK/40C/75%RH/OPEN (Free)	G8-854-17-1	5	22.4	3200	15.9

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Figure 22

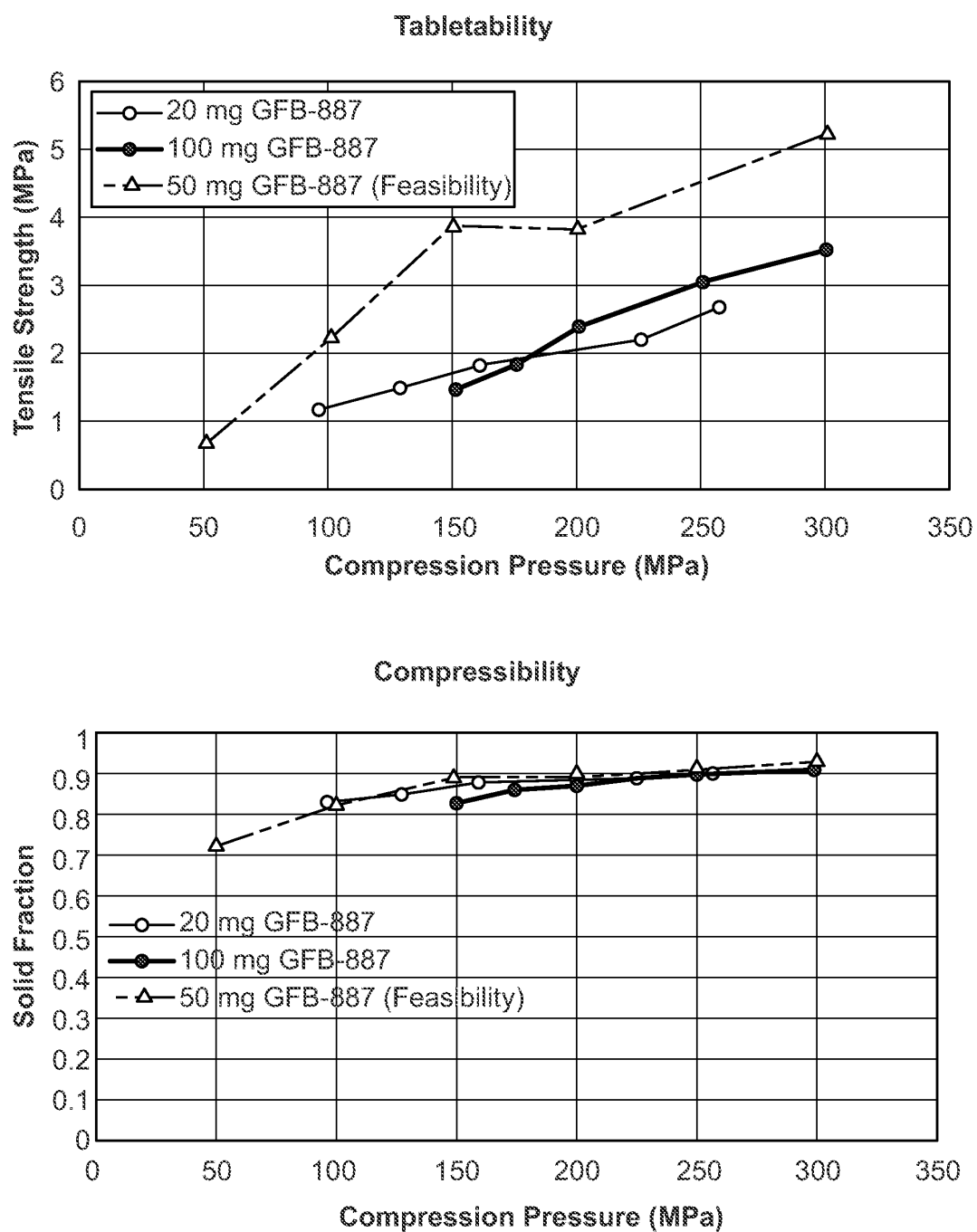


Figure 22 (cont.)

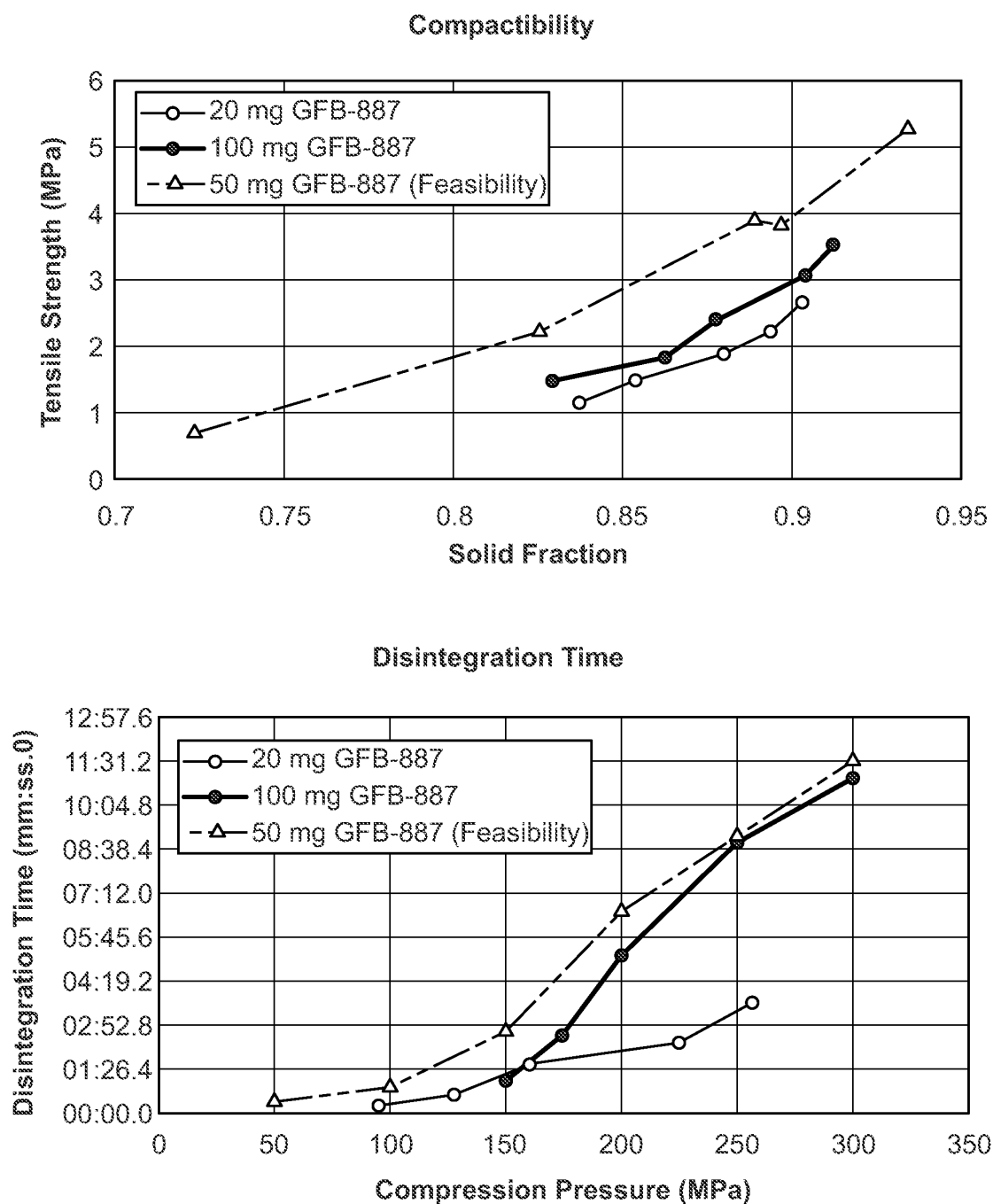
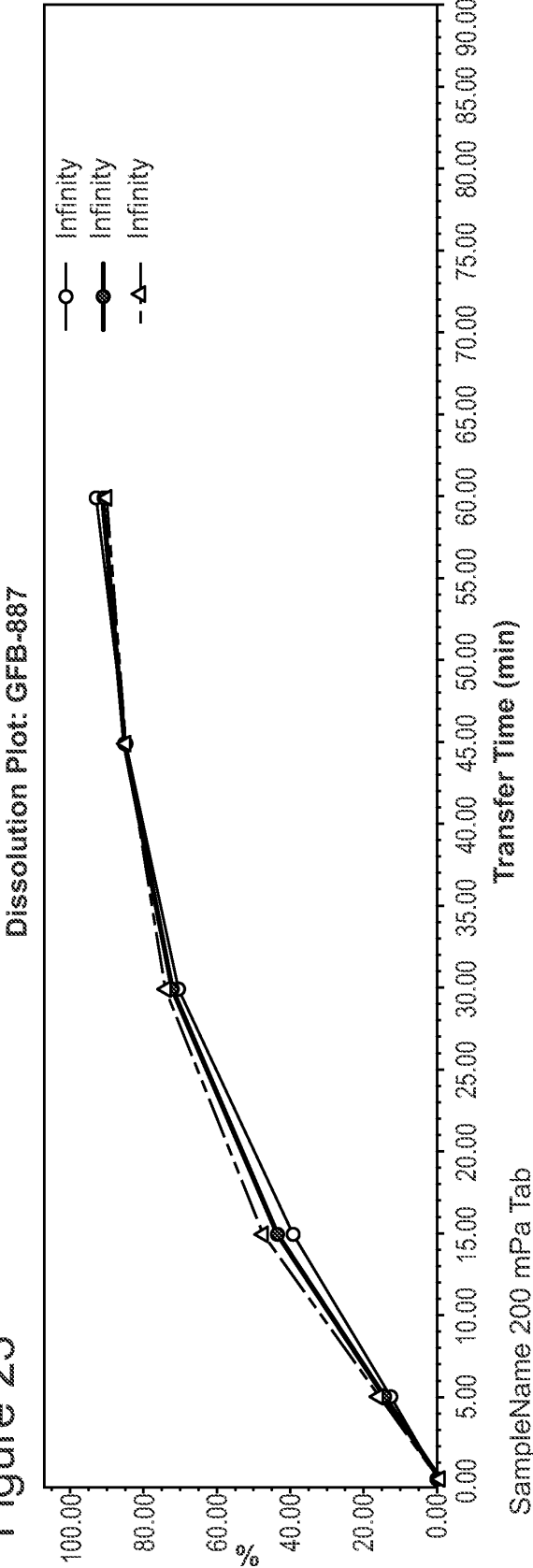


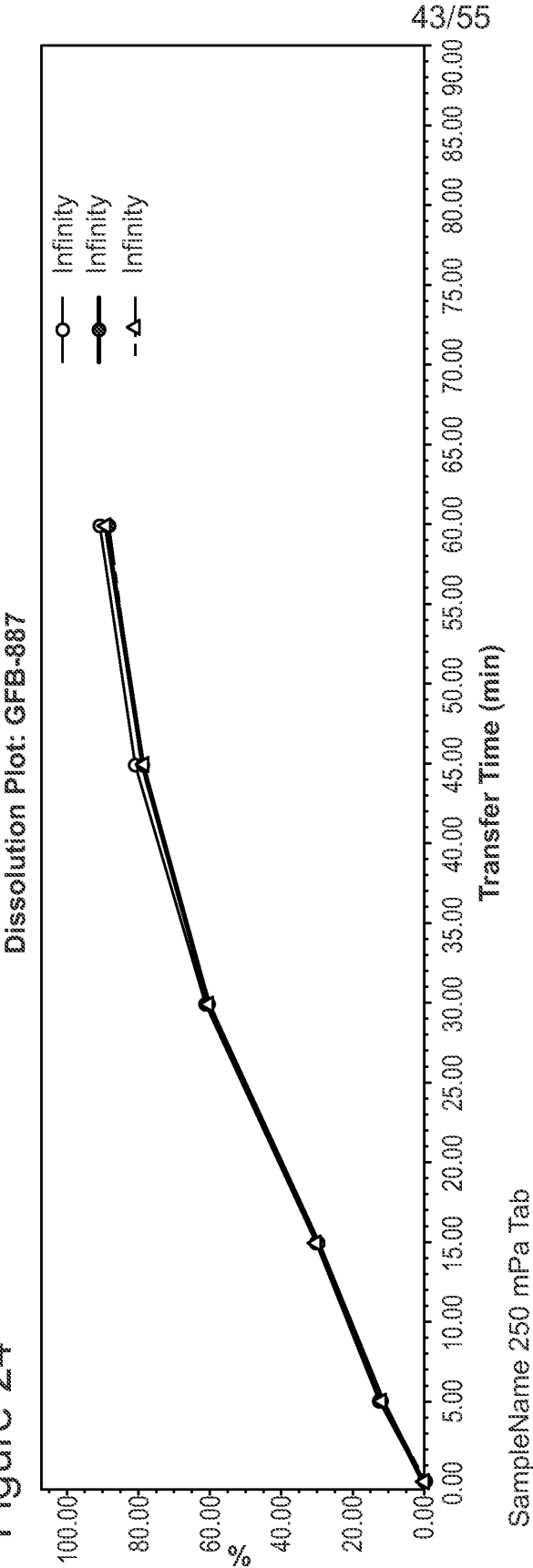
Figure 23



Dissolved Percent for Component GFB-887 Channel: DAD .0.0

	Bath	Vessel	Injection	5.0 min	15.0 min	30.0 min	45.0 min	60.0 min	75.0 min
1	A	1	1	12	40	70	85	93	98
2	A	2	1	16	47	74	85	91	95
3	A	3	1	15	43	72	85	92	95
Mean				14	43	72	85	92	96
Max				16	47	74	85	93	98
Min				12	40	70	85	91	95
%RSD				12.153	8.940	2.327	0.183	1.331	1.687
Std. Dev				1.749	3.872	1.680	0.156	1.221	1.617

Figure 24



Dissolved Percent for Component GFB-887 Channel: DAD .0.0

	Bath	Vessel	Injection	5.0 min	15.0 min	30.0 min	45.0 min	60.0 min	75.0 min
1	A	4	1	12	30	61	81	90	98
2	A	5	1	12	30	61	79	89	97
3	A	6	1	11	29	60	79	89	97
Mean				11	30	61	80	90	97
Max				12	30	61	81	90	98
Min				11	29	60	79	89	97
%RSD				5.163	1.679	0.745	0.991	0.620	0.684
Std. Dev				0.588	0.502	0.453	0.790	0.556	0.665

Figure 25

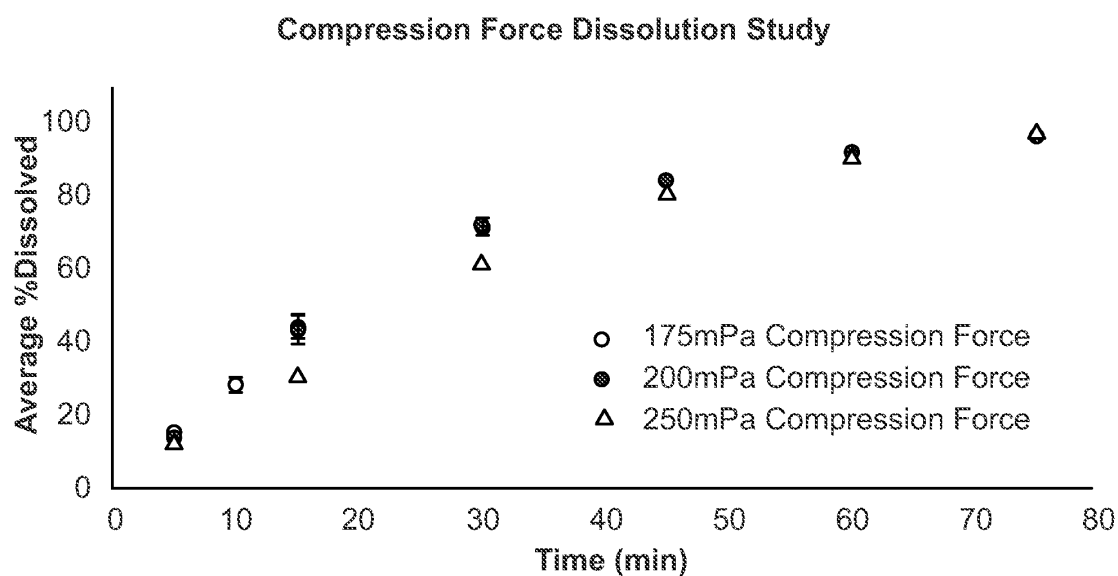


Figure 26

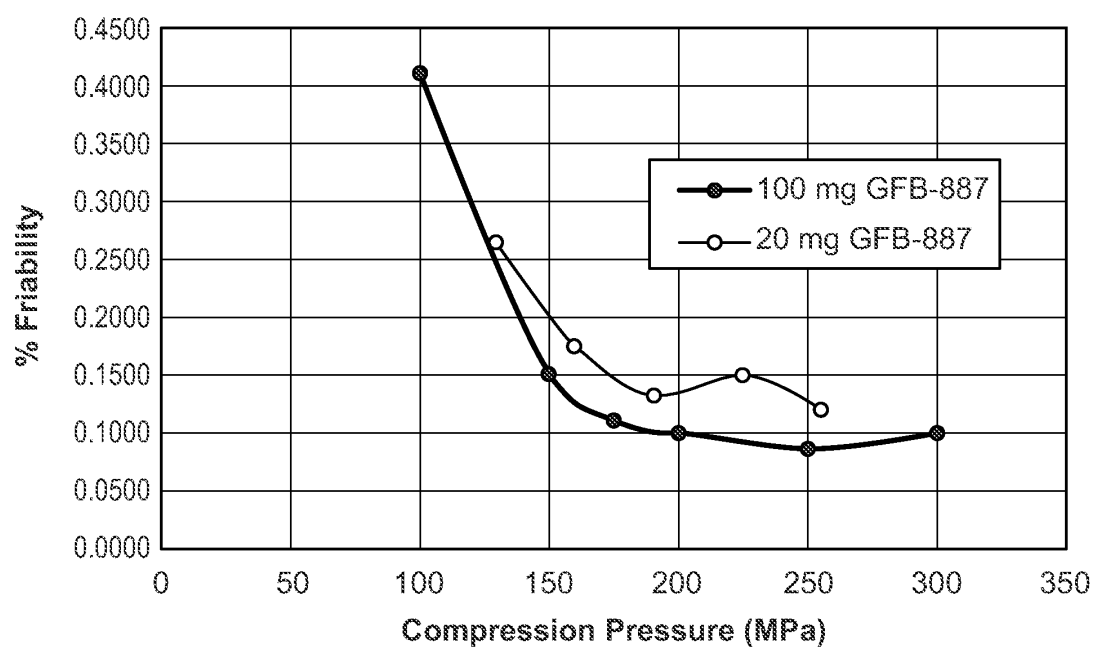


Figure 27

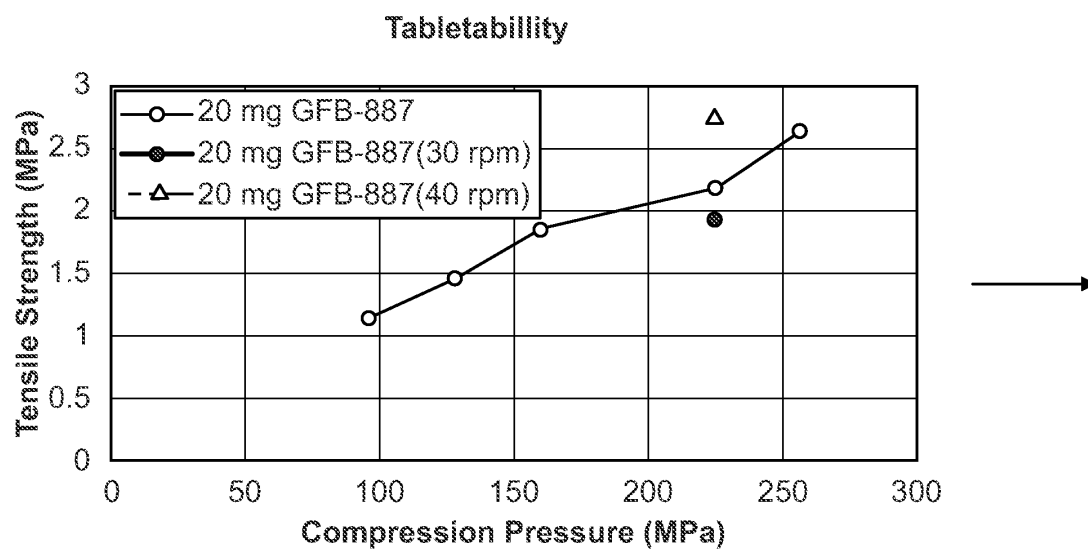


Figure 28

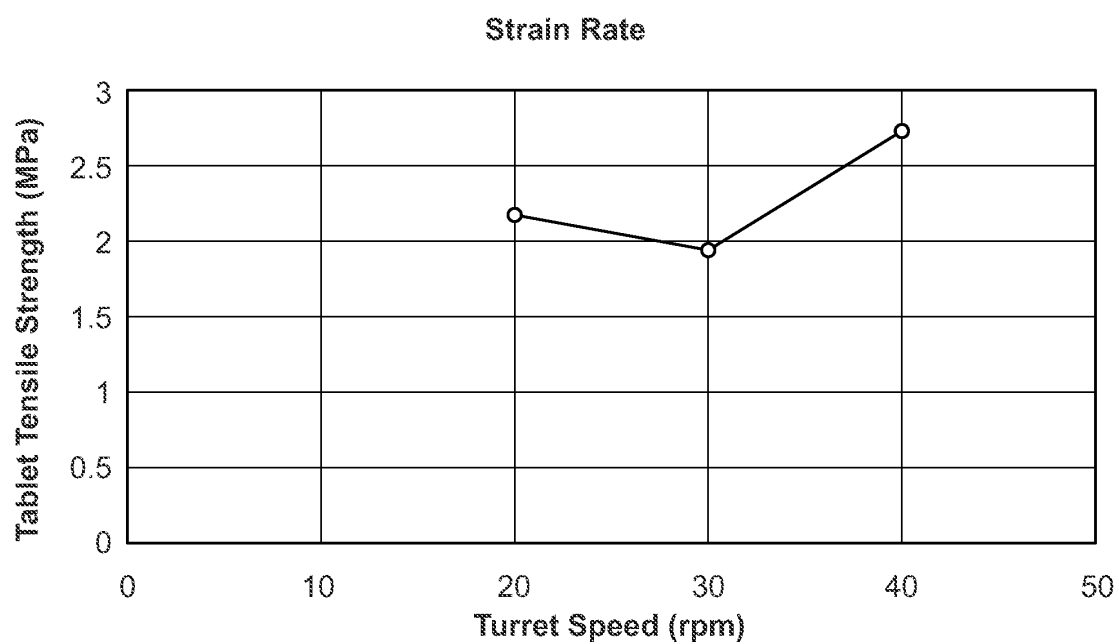


Figure 29

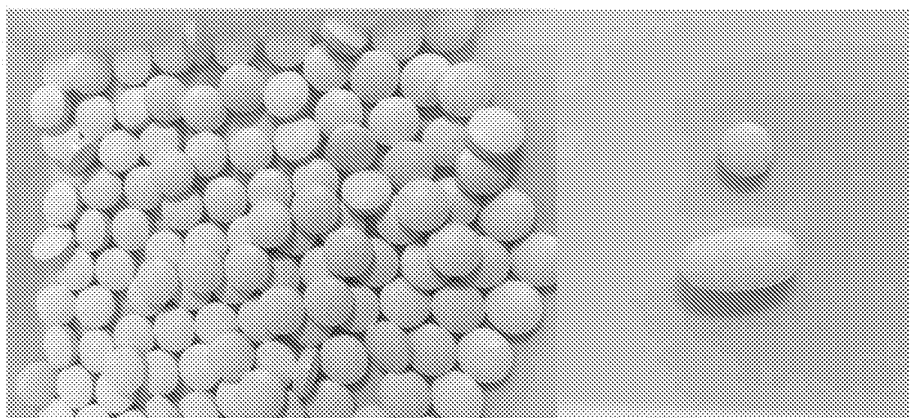
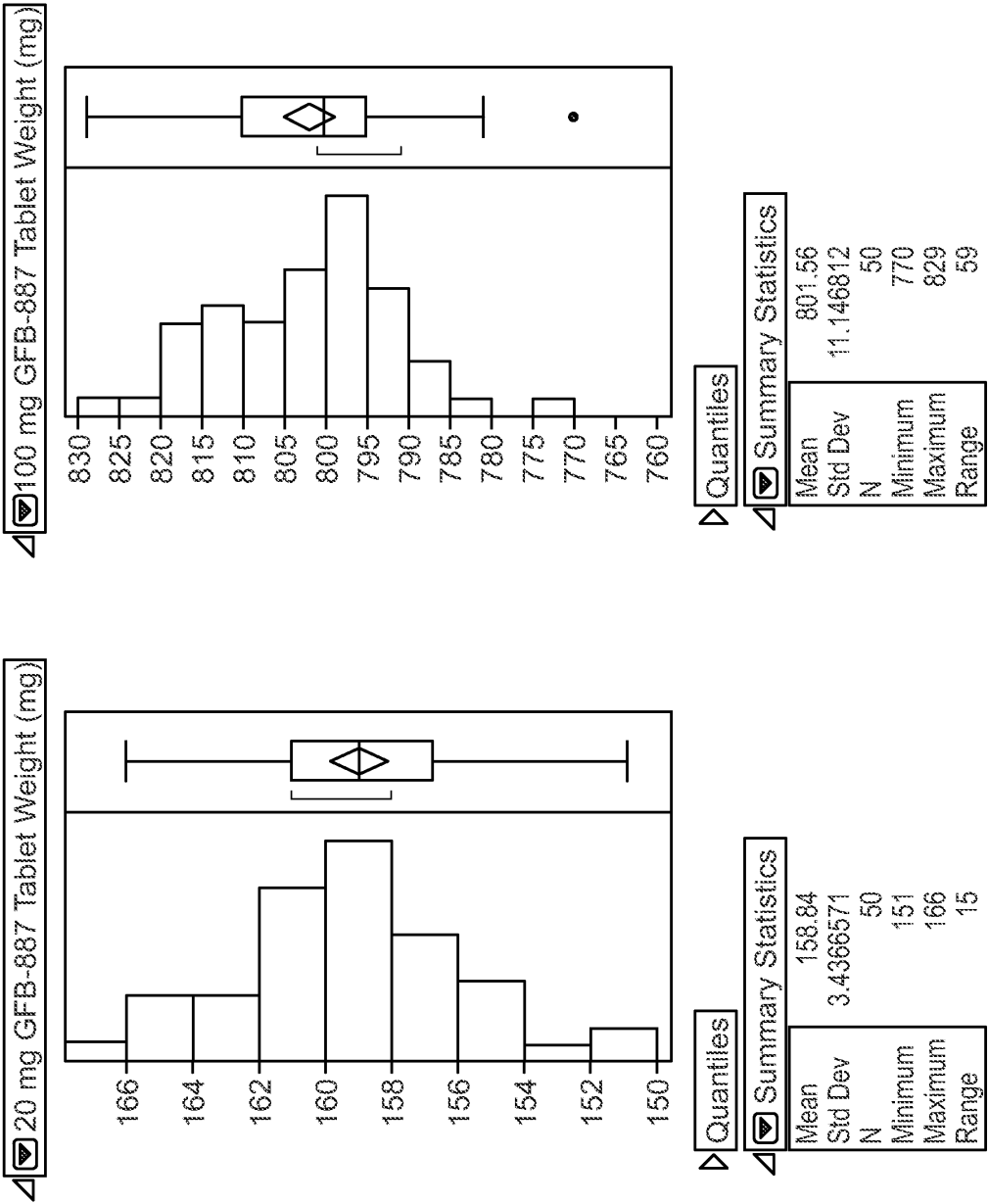
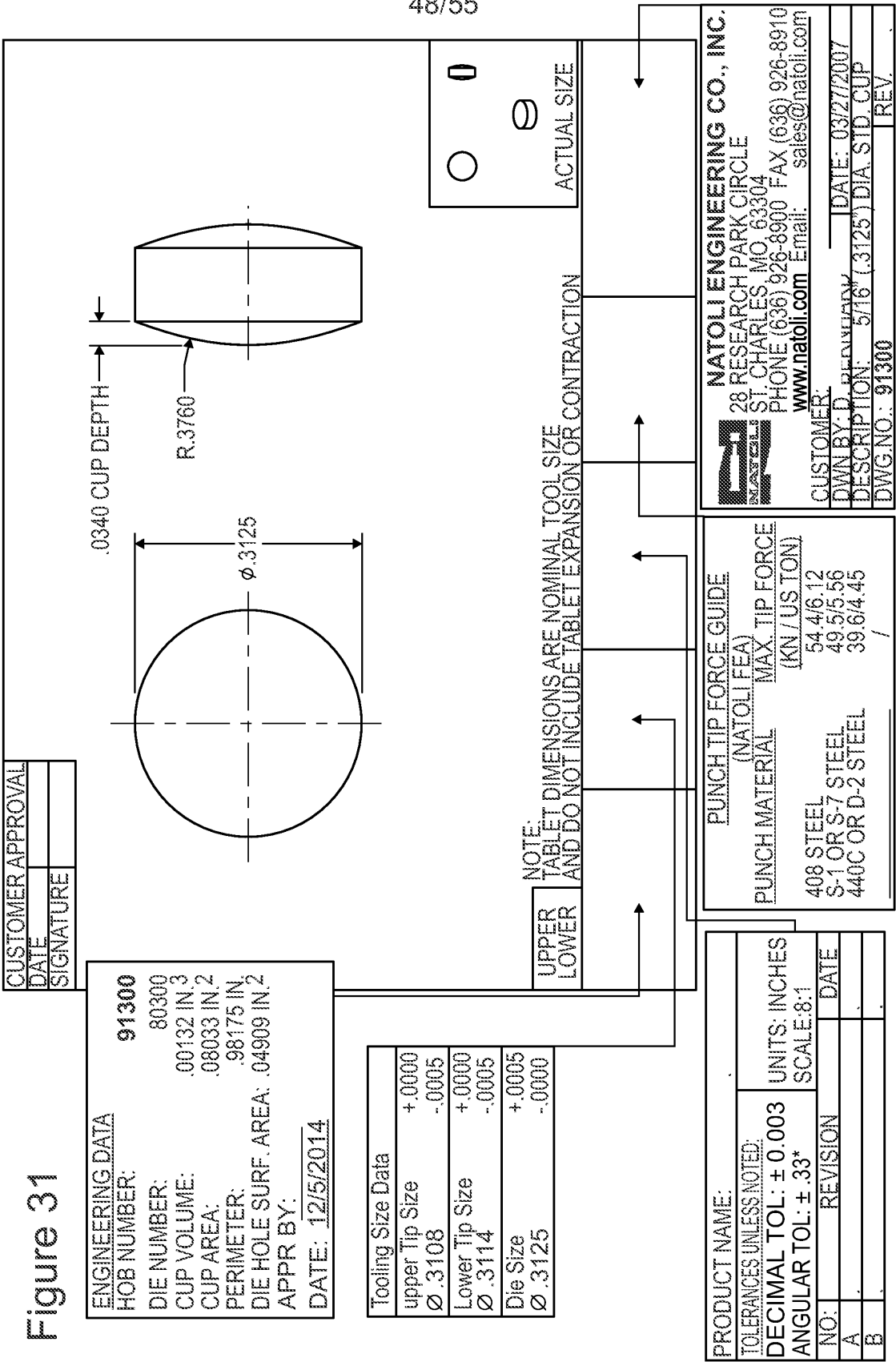


Figure 30





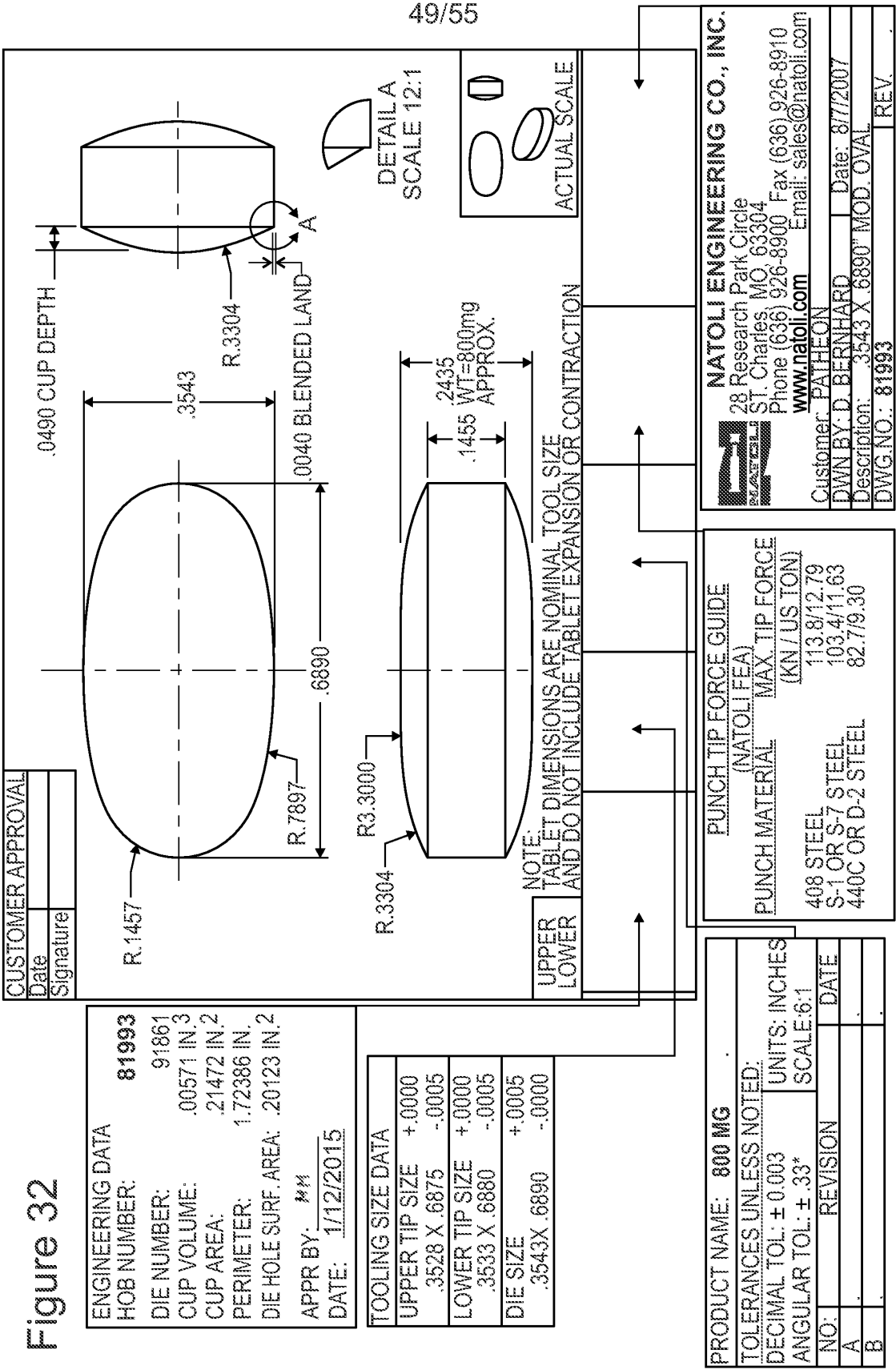


Figure 33

CERTIFICATE OF TESTING



Material Description: GFB-887 Tablets, 20mg
 Patheon Lot #: G8-854-34
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: Room Temperature
 Certificate Rev #: 2
 Page: 1 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Acceptance Criteria	Result	
Appearance (Visual)	AM-0002/ G8-936-32	White to off-white to light brown standard round convex tablet; may or may not be mottled	Biconvex oval tablet, off-white and slightly mottled	
Identification (HPLC, Retention Time Comparison)	AM-0236 (Draft)/ G8-936-26	The retention time of sample conforms to the reference standard	Conforms to Reference - 100%	
Assay (HPLC)	AM-0236 (Draft)/ G8-936-26	90.0% - 110.0% Label Claim	98.7%	
Total Impurities and Related Substances (HPLC)	AM-0236 (Draft)/ G8-936-26	≤3.0%(% area)	0.81%	
Individual Impurities and Related Substances (HPLC) ¹ a. Individual Specified Impurities b. Individual Unspecified Impurities or Related Substances	AM-0236 (Draft)/ G8-936-26	Report Results (RRT and % area)	RRT	%Peak Area
		GDF-9815-IMP1 peak 1: 0.34	0.34	0.18%
		GDF-9815-IMP1 peak 2: 0.36	0.36	0.10%
		GDF-9815-IMP1 Peak 1 (RRT 0.35): ≤0.2%	0.37	<0.05%
		GDF-9815-IMP1 Peak 2 (RRT 0.36): ≤0.5%	0.38	<0.05%
		RRT 0.40: ≤0.2%	0.56	<0.05%
		GDF-9815-IMP4 (RRT 0.85): ≤1.0%	0.66	<0.05%
		RRT 1.02: ≤0.2%	0.80	<0.05%
		RRT 1.10: ≤0.2%	GDF-9815-IMP4: 0.85	0.40%
		RRT 1.48: ≤0.3%	0.91	0.05%
		b. Individual Unspecified Impurities or Related Substances: ≤0.2%	1.02	0.08%
			1.44	<0.05%
			1.50	<0.05%
			1.59	<0.05%

Figure 33 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: GFB-887 Tablets, 20mg
 Patheon Lot #: G8-854-34
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: Room Temperature
 Certificate Rev #: 2
 Page: 2 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Acceptance Criteria	Result		
				Mean % LC	AV
Uniformity of Dosage (HPLC)	AM-0236 (Draft)/ USP<905>/ G8-936-50	Meet USP <905> criteria (Report acceptance Value [AV])	Beginning	98.0	5.7
			Middle	96.9	5.5
			End	93.3	14.5
Dissolution	AM-0235 (Draft)/ USP<711>/ G8-936-38	Report Results (Average and %RSD of %Dissolved at each time point)	Timepoint (min)	Dissolved %	%RSD
			5	15	13
			10	33	22
			15	48	11
			30	71	4
			45	84	3
			60	91	2
			75	96	3
Water Content (KF)	AM-0233 (Draft)/ USP<921>/ G8-936-30	NMT 7% (wt%)	1.54%		

Figure 33 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: GFB-887 Tablets, 20mg
Patheon Lot #: G8-854-34
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: Room Temperature
Certificate Rev #: 2
Page: 3 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Revision History:

Revision #	Change	Date
00	New document	08Mar2019
01	Omit RRT 1.76 SSF peak	14May2019
02	Update SEM Figure Title	09May2019

Prepared By/Date:



Ashley Moon
I am the author of this
document
2019.05.09 13:35:14-07'00'

Reviewed By/Date:



Kevin Carman
I am approving this
document
2019.05.09 13:45:17-07'00'

Figure 34



CERTIFICATE OF TESTING

Material Description: GFB-887 Tablets, 100mg
 Patheon Lot #: G8-854-36
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: Room Temperature
 Certificate Rev #: 2
 Page: 1 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Acceptance Criteria	Result	
Appearance(Visual)	AM-0002/ G8-936-32	White to off-white to light brown standard round convex tablet; may or may not be mottled	Biconvex oval tablet, off-white and slightly mottled	
Identification (HPLC, Retention Time Comparison)	AM-0236 (Draft)/ G8-936-26	The retention time of ample conforms to the reference standard	Conforms to Reference - 100%	
Assay (HPLC)	AM-0236 (Draft)/ G8-936-26	90.0%-110.0% Label Claim	99.2%	
Total Impurities and Related Substances (HPLC)	AM-0236 (Draft)/ G8-936-26	≤3.0%(% area)	0.81%	
Individual Impurities and Related Substances (HPLC) ¹ a. Individual Specified Impurities b. Individual Unspecified Impurities or Related Substances	AM-0236 (Draft)/ G8-936-26	Report Results (RRT and % area)	RRT	%Peak Area
		a. Individual Specified Impurities or Related Substances	GDF-9815-IMP1 peak 1: 0.34	0.18%
		GDF-9815-IMP1 Peak 2: 0.36	GDF-9815-IMP1 peak 2: 0.36	0.10%
		GDF-9815-IMP1 Peak 1 (RRT 0.35): ≤0.2%	0.37	<0.05%
		GDF-9815-IMP1 Peak 2 (RRT 0.36): ≤0.5%	0.38	<0.05%
		RRT 0.40: ≤0.2%	0.56	<0.05%
		GDF-9815-IMP4 (RRT 0.85): ≤1.0%	0.66	<0.05%
		RRT 1.02: ≤0.2%	0.80	<0.05%
		RRT 1.10: ≤0.2%	GDF-9815-IMP4: 0.85	0.40%
		RRT 1.48: ≤0.3%	0.91	0.05%
		b. Individual Unspecified Impurities or Related Substances: ≤0.2%	1.02	0.08%
			1.44	<0.05%
			1.50	<0.05%
			1.59	<0.05%

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 www.patheon.com

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Figure 34 (cont.)



CERTIFICATE OF TESTING

Material Description: GFB-887 Tablets, 100mg
 Patheon Lot #: G8-854-36
 Date of Manufacture: 12Dec2018
 Expiration/Review Date: NA
 Storage: Room Temperature
 Certificate Rev #: 2
 Page: 2 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Test	Procedure/LNB Ref.	Acceptance Criteria	Result		
				Mean % LC	AV
Uniformity of Dosage (HPLC)	AM-0236 (Draft)/ USP<905>/ G8-936-50	Meet USP<905> criteria (Report acceptance Value [AV])	Beginning	98.9	2.0
			Middle	98.8	3.7
			End	95.4	7.1
Dissolution	AM-0235 (Draft)/ USP<711>/ G8-936-38	Report Results (Average and %RSD of %Dissolved at each time point)	Timepoint (min)	Dissolved %	%RSD
			5	15	8
			10	28	7
			15	44	8
			30	71	3
			45	84	2
			60	91	2
			75	96	2
Water Content (KF)	AM-0233 (Draft)/ USP<921>/ G8-936-30	NMT 7% (wt%)	1.47%		

Figure 34 (cont.)

ThermoFisher
SCIENTIFIC

CERTIFICATE OF TESTING

Material Description: GFB-887 Tablets, 100mg
Patheon Lot #: G8-854-36
Date of Manufacture: 12Dec2018
Expiration/Review Date: NA
Storage: Room Temperature
Certificate Rev #: 2
Page: 3 of 3

Note: Contains a new drug for investigational use only in laboratory research animals, or for *in vitro* tests. Not for use in humans.

Revision History:

Revision #	Change	Date
00	New document	08Mar2019
01	Omit RRT 1.76 SSF peak	14May2019
02	Updated Material Description	09May2019

Prepared By/Date:



Ashley Moon
I am the author of this
document
2019.05.09 13:38:25-07'00'

Reviewed By/Date:



Kevin Carman
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2019.05.09 13:44:32-07'00'