

FIG. 1
Compound I Form B, XRPD Diffractogram

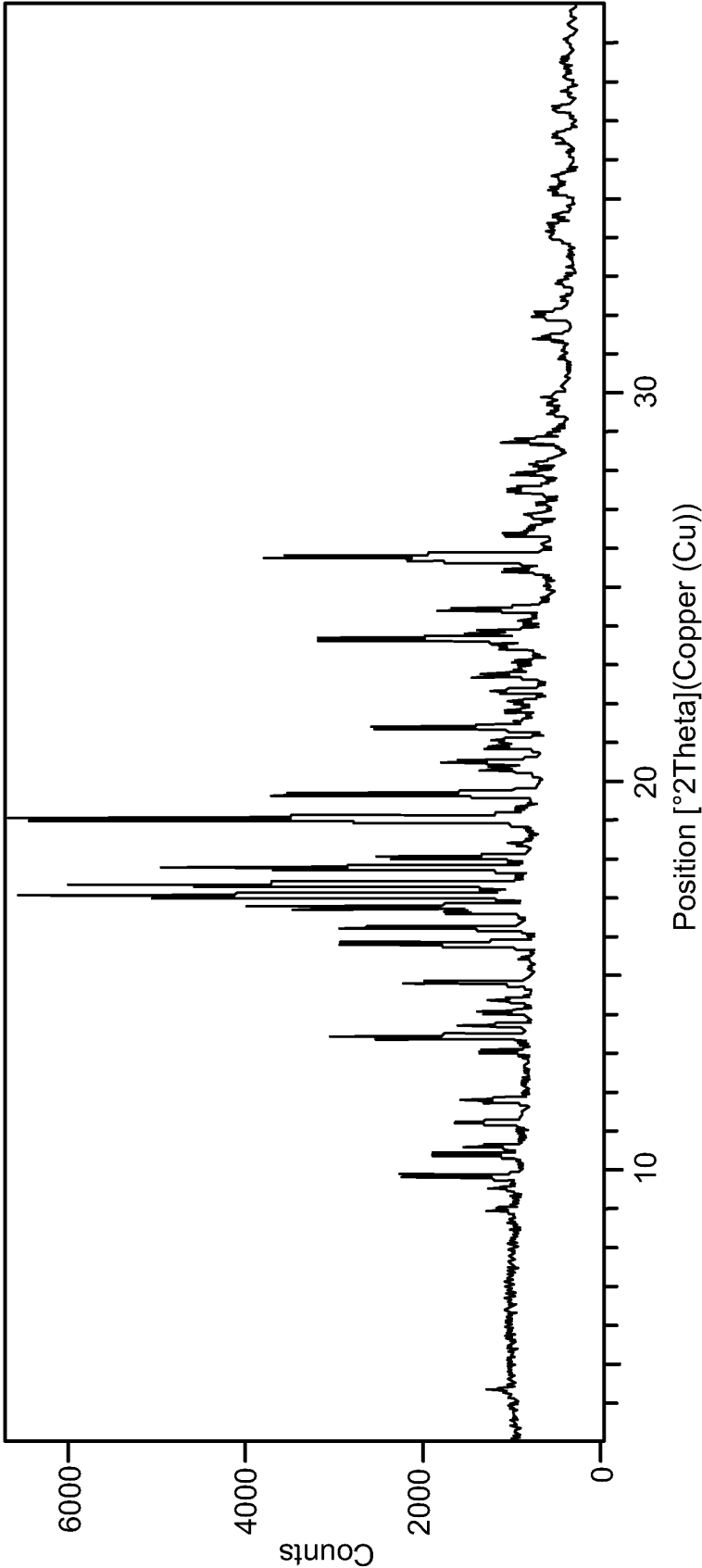


FIG. 2. Compound I Form B, XRPD Peak Table

Angle/ ° 2 θ	Rel. Int. [%]	Angle/ ° 2 θ	Rel. Int. [%]
4.32	2.38	23.60	28.64
8.95	2.56	23.80	6.1
9.51	2.33	24.07	3.82
9.83	10.41	24.36	11.39
10.37	7.7	25.37	7.56
10.58	4.96	25.58	6.27
11.21	5.73	25.74	24.12
11.77	5.49	26.31	5.21
13.01	4.1	26.51	3.4
13.40	21.04	26.78	3.92
13.69	7.35	27.10	3.01
14.03	4.49	27.36	2.53
14.33	4.4	27.84	2.68
14.78	13.64	28.12	5.39
15.43	1.41	28.70	5.42
15.79	24.83	29.41	2.11
16.20	23.89	29.67	2.41
16.56	8.57	29.86	3.22
16.73	35.51	30.85	1.43
17.03	74.86	31.33	2.86
17.32	67.69	31.87	3.29
17.74	55.03	31.99	3.51
18.01	22.65	32.36	1.27
18.38	2.08	32.77	2.39
19.00	100	33.95	4.75
19.62	33.42	34.26	3.51
20.25	6.13	34.49	1.73
20.45	10.29	35.05	1.59
20.83	5.76	35.53	3.27
21.03	7.87	36.39	1.8
21.32	24.22	36.60	3.84
21.76	2.85	37.24	5.15
22.01	5.69	37.72	2.22
22.28	5.32	38.55	2.35
22.67	9.05	39.05	2.32
23.06	3.04		
23.40	2.79		

FIG. 3

Compound I Form B, DSC & TGA Thermogram

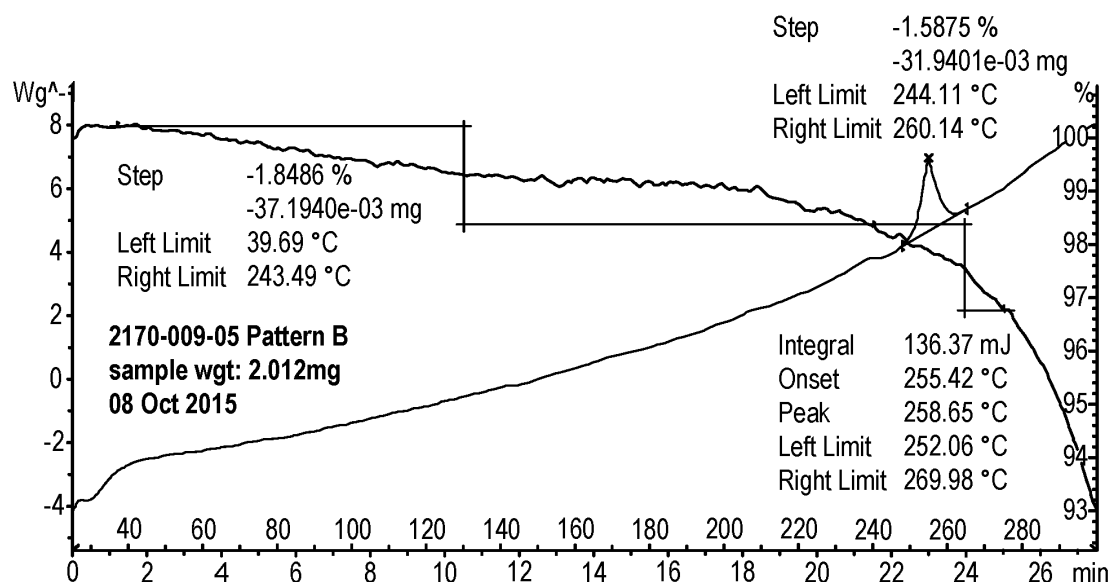


FIG. 4

Dissolution Graph

2-Stage Dissolution – Non-sink Conditions

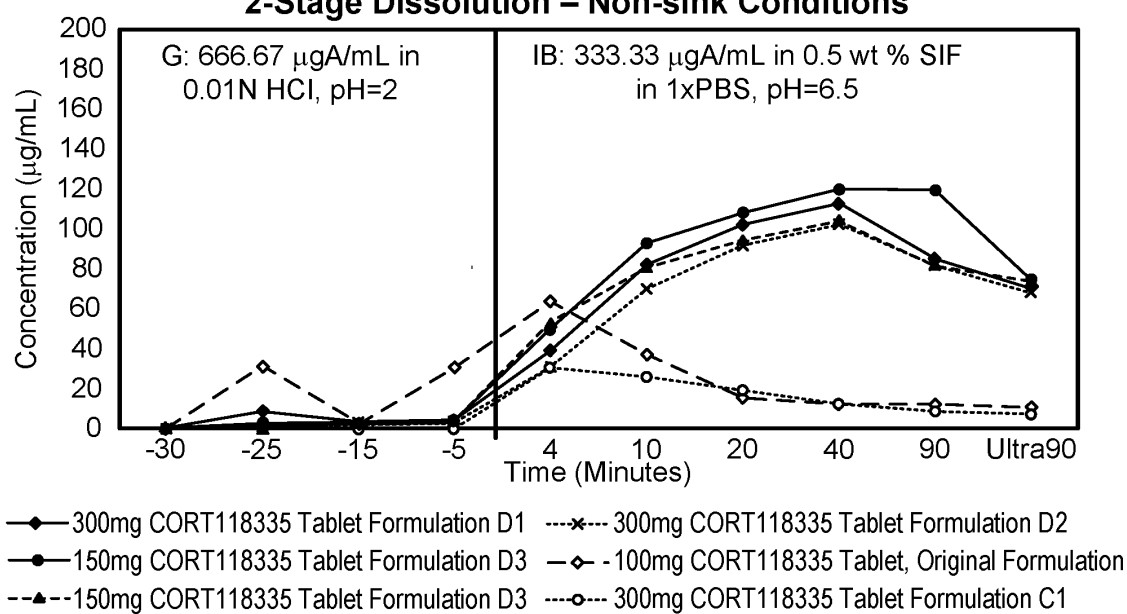


FIG. 5

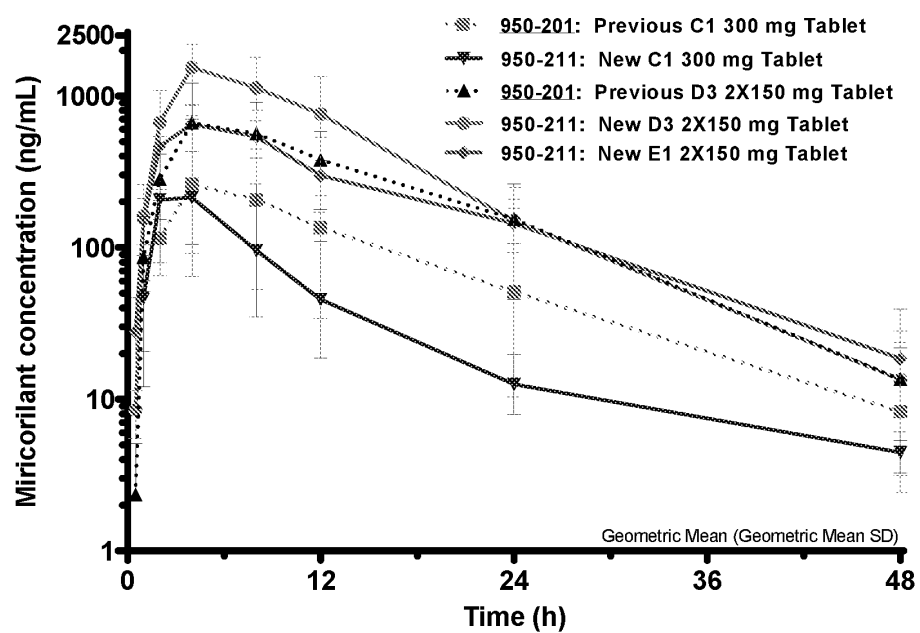


FIG. 6

TREATMENT	SUBJID	AUC0-24 (h*ng/mL)	AUClast (h*ng/mL)	AUCinf (h*ng/mL)	Cmax (ng/mL)	Tmax (h)
New C1 Tablets	1001	1454	1454	1516	228	2
	1002	520	658	745	65	2
	1003	4873	5132	5176	665	2
	1004	2683	2912	2994	401	4
Mean		2382	2539	2608	340	3
CV%		79	77	75	76	40
Geometric Mean		1773	1945	2046	251	2
Geometric CV%		122	109	101	131	36
New D3 Tablets	1001	16988	18244	18295	1750	4
	1002	5093	5716	5794	561	4
	1003	16803	18238	18346	1810	4
	1004	25625	27642	27905	2050	4
Mean		16127	17460	17585	1543	4
CV%		52	52	52	43	0
Geometric Mean		13893	15142	15262	1382	4
Geometric CV%		79	76	76	66	0
New E1 Tablets	1001	7943	8982	9041	646	8
	1002	5242	6256	6460	408	4
	1003	10332	11406	11435	933	4
	1004	8497	10818	11746	652	4
Mean		8003	9366	9670	660	5
CV%		26	25	25	33	40
Geometric Mean		7775	9125	9411	633	5
Geometric CV%		29	28	28	35	36

FIG. 7

Test Article	Treatment Name	Dose (mg)	Animal ID	AUC ₀₋₂₄ (h*ng/mL)	AUC _{last} (h*ng/mL)	AUC _{inf} (h*ng/mL)	AUC _{%exp} (%)	C _{max} (ng/mL)	T _{max} (h)	T _{last} (h)
3 X 100 mg immediate release tablets	Original 100 mg tablets	300	1001M	7,983	9,305	9,390	0.90	518	12	48
			1002M	646	646	837	22.80	59	2	24
			1003M	2,174	2,449	2,514	2.60	236	4	48
			1004M	1,924	2,138	2,183	2.00	256	2	48
			Geometric Mean	2,155	2,369	2,563	3.20	207	2	40
			Geometric CV%	137	151	130	238	113	102	36
1 X 300 mg immediate release tablet	Lonza C1 300mg tablet	300	1001M	16,151	20,573	21,173	2.80	1,120	8	48
			1002M	932	1,132	1,178	3.90	86	2	48
			1003M	4,307	4,886	4,966	1.60	408	4	48
			1004M	1,746	1,948	2,002	2.70	237	4	48
			Geometric Mean	3,262	3,859	3,968	2.60	311	4	48
			Geometric CV%	190	200	199	38	147	61	0
1 X 300 mg immediate release tablet	Lonza D2 300mg tablet	300	1001M	9,494	10,646	10,715	0.60	660	4	48
			1002M	5,053	5,774	5,994	3.70	463	4	48
			1003M	3,836	4,565	4,763	4.20	339	4	48
			1004M	3,979	4,458	4,518	1.30	382	4	48
			Geometric Mean	5,202	5,947	6,097	1.90	446	4	48
			Geometric CV%	44	42	41	109	30	0	0
2 X 150 mg immediate release tablets	Lonza D3 150mg tablets	300	1001M	12,685	13,689	13,962	2.00	1,490	4	48
			1002M	6,091	8,142	8,304	2.00	407	4	48
			1003M	8,725	10,373	10,476	1.00	575	8	48
			1004M	5,620	6,178	6,233	0.90	502	4	48
			Geometric Mean	7,846	9,193	9,328	1.30	647	5	48
			Geometric CV%	39	35	35	45	62	36	0