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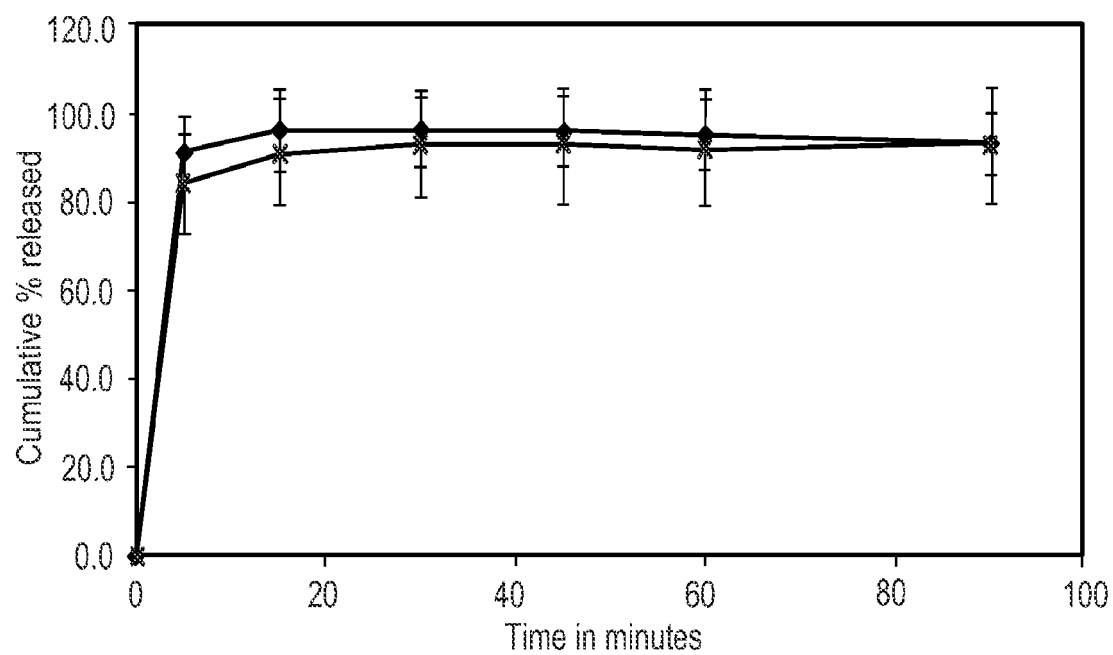


FIG. 1

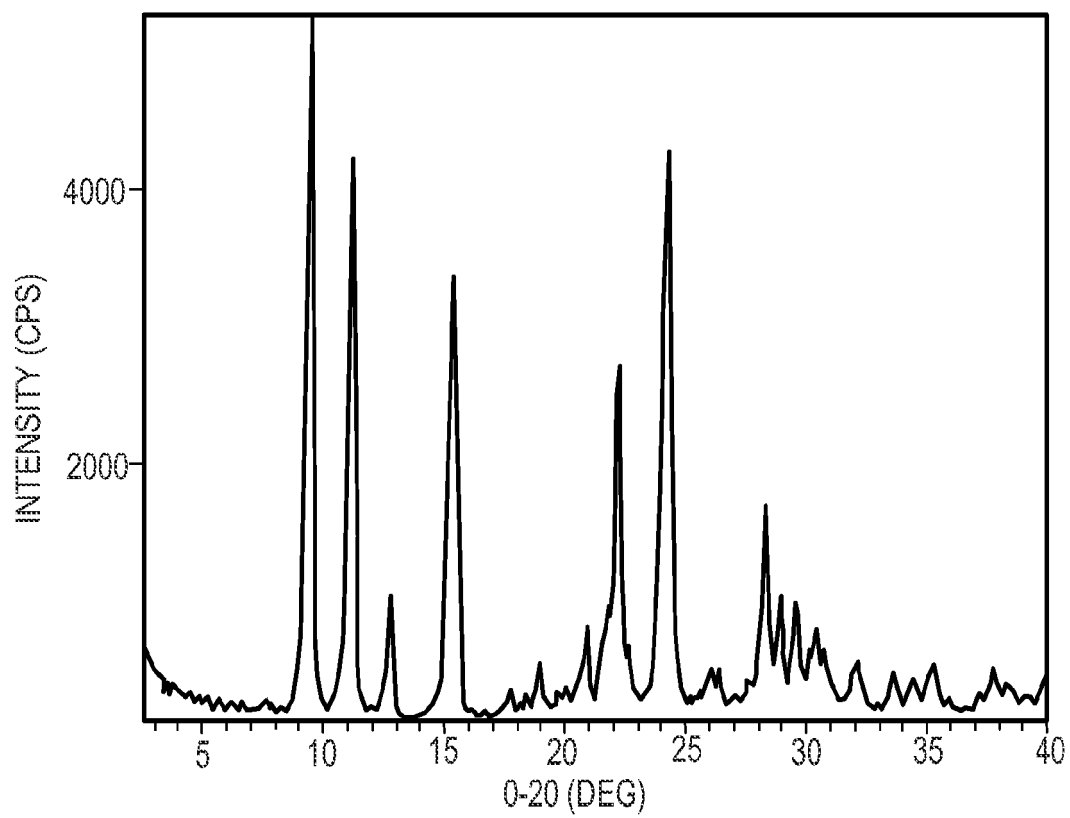


FIG. 2

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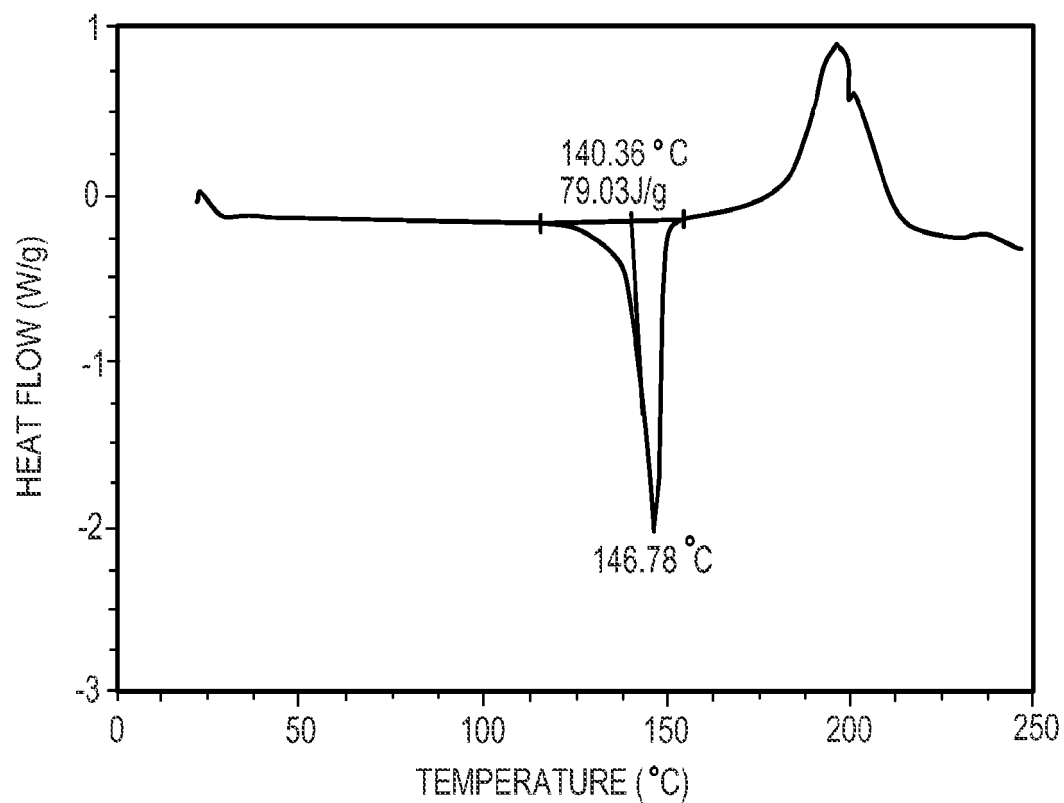


FIG. 3

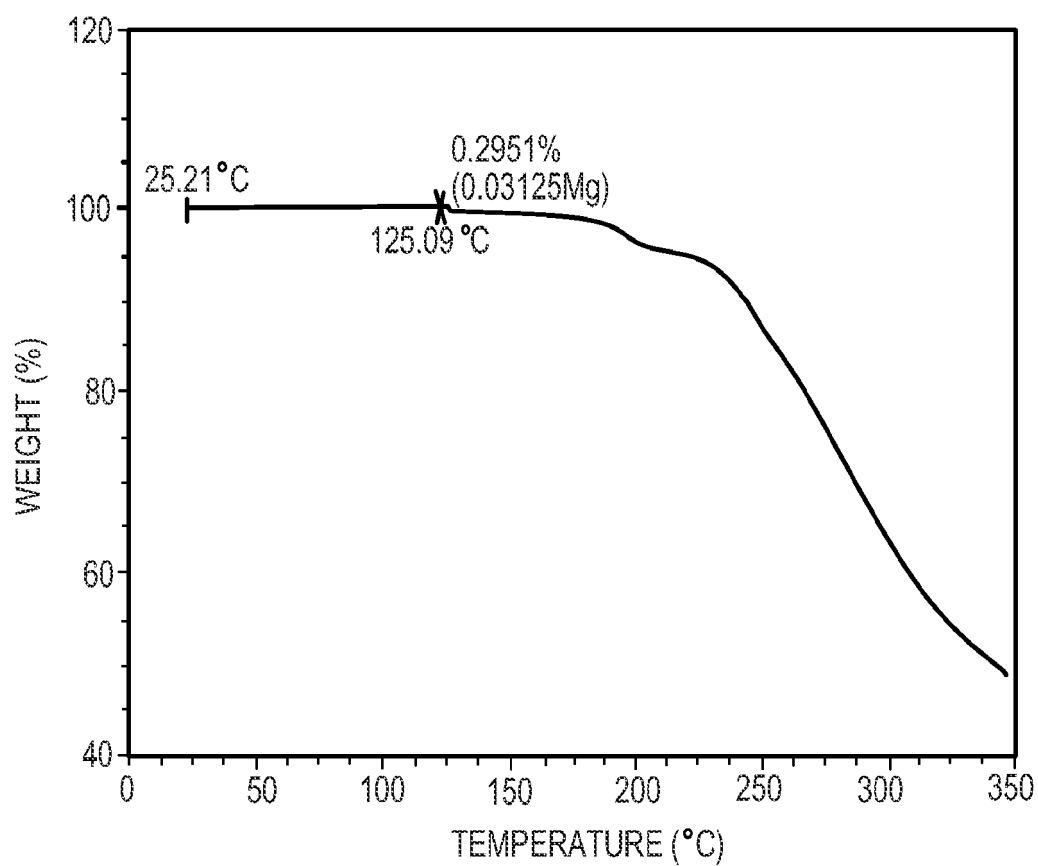


FIG. 4

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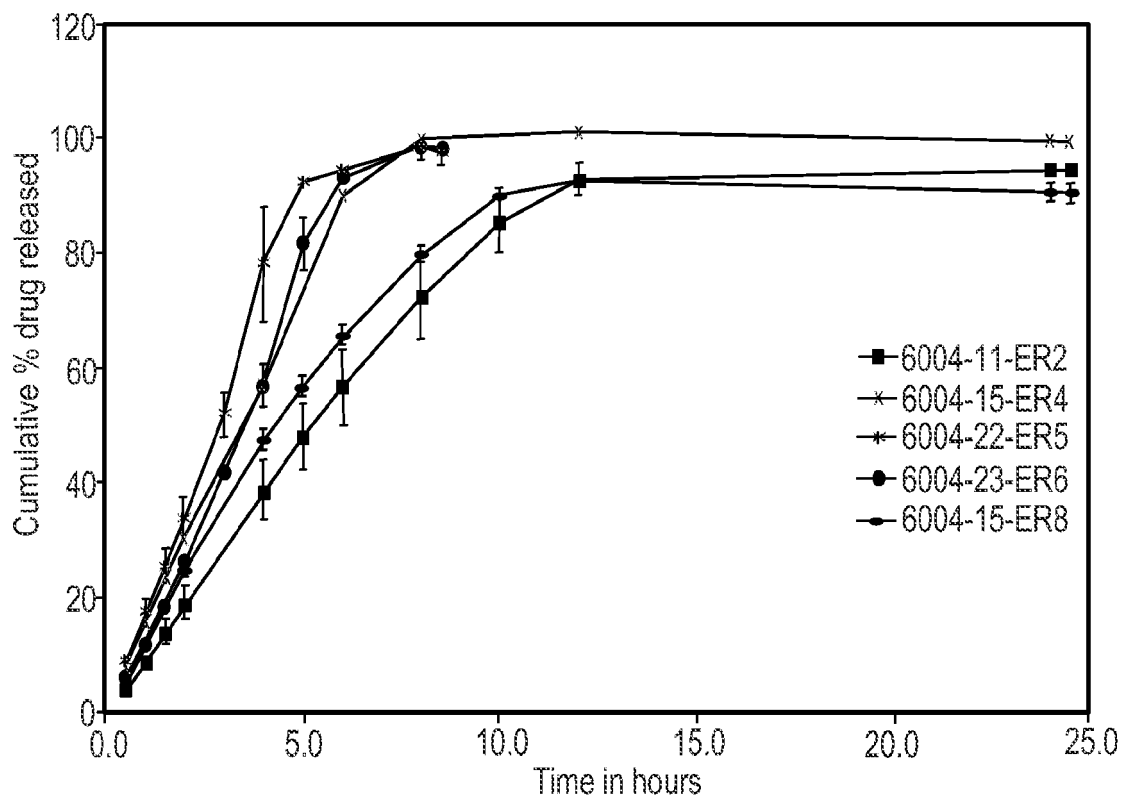


FIG. 5

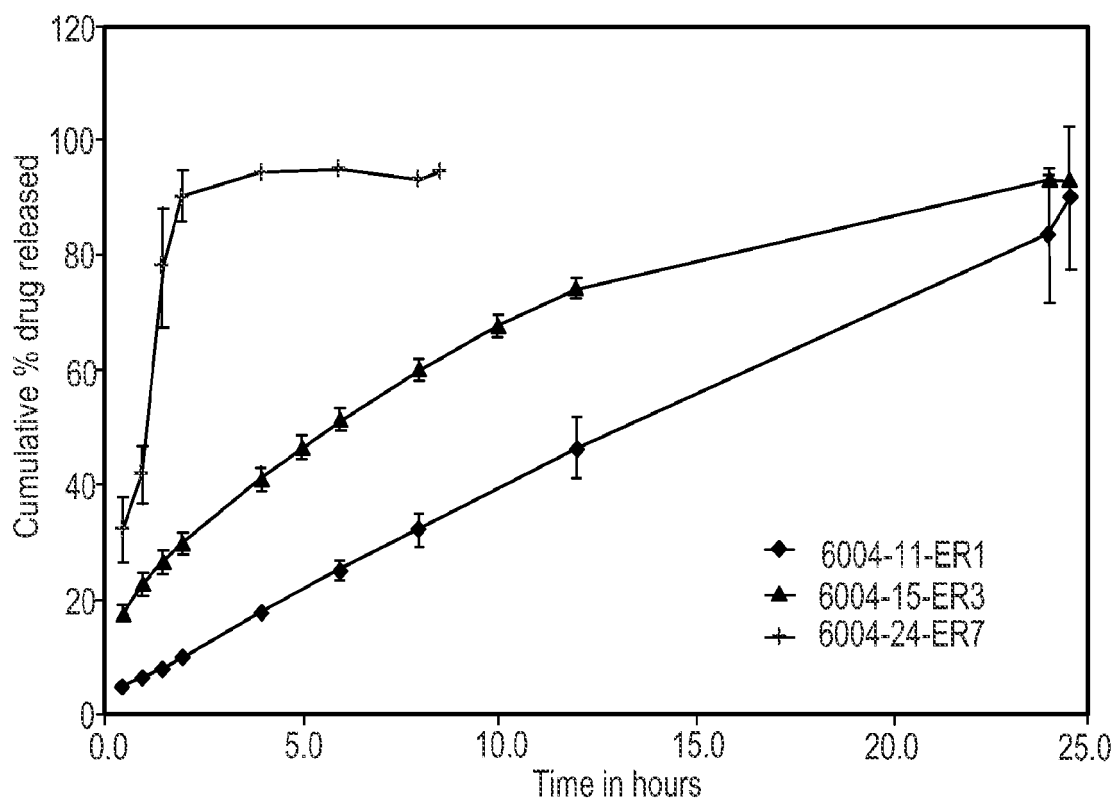


FIG. 6

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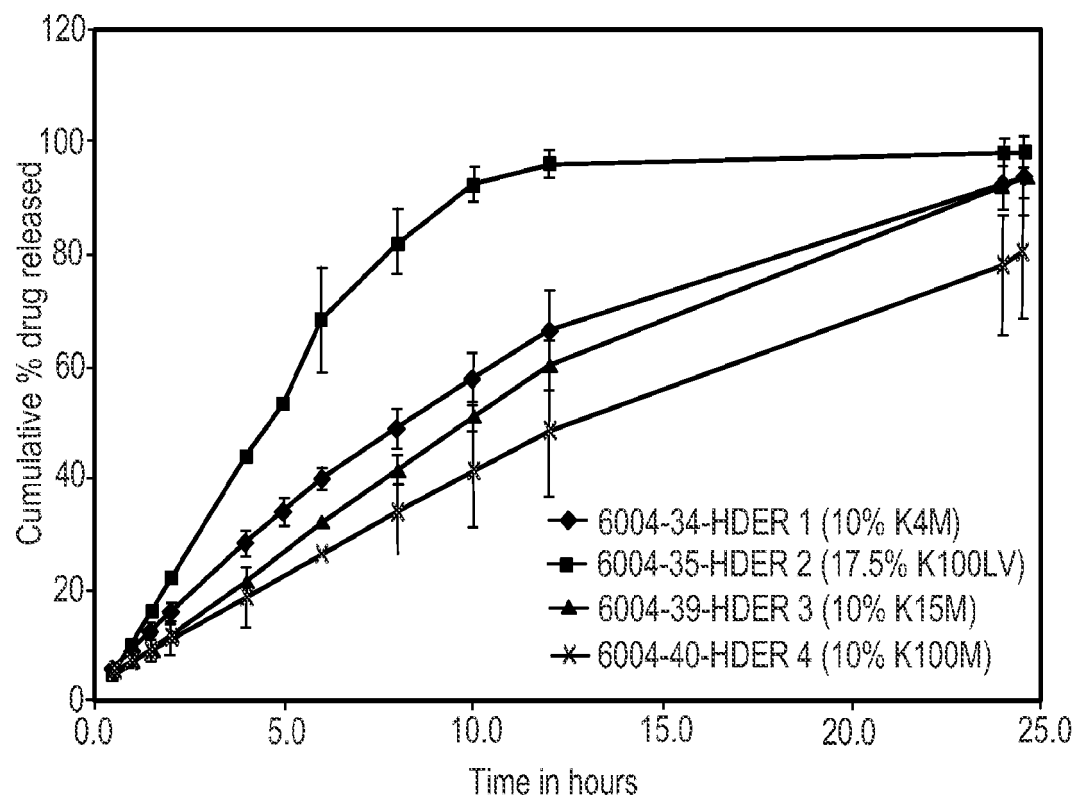


FIG. 7

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METHOCEL Premium product grade	—	K100 Premium LV	K4M Premium	K15M Premium	K100M Premium	E4M Premium	E10M Premium CR
Methoxyl, %	USP	19-24	19-24	19-24	19-24	28-30	28-30
Hydroxypropoxyl, %	USP	7-12	7-12	7-12	7-12	7-12	7-12
USP substitution type	USP/EP	2208	2208	2208	2208	2910	2910
Chlorides, max., %	EP	0.5	0.5	0.5	0.5	0.5	0.5
Apparent viscosity, 2% in water at 20 °C, cP	USP	80-120	3000-5600	11250-21000	80000-120000	3000-5600	7500-14000
Apparent viscosity, 2% in water at 20 °C, mPa's	EP	78-117 [98 Nom]	2308-3755 [2903 Nom]	6138-9030 [7382 Nom]	16922-19267 [18243 Nom]	2308-3755 [2903 Nom]	4646-7070 [5673 Nom]
ID Test A, B, c	USP	Pass	Pass	Pass	Pass	Pass	Pass
ID Test A,B,C,D,E,f	EP	Pass	Pass	Pass	Pass	Pass	Pass
Opalescence of solution	EP	Pass	Pass	Pass	Pass	Pass	Pass
Solution color, yellowness, 1% in water	EP	Pass	Pass	Pass	Pass	Pass	Pass
pH, 1% in water	EP	5.5-8.0	5.5-8.0	5.5-8.0	5.5-8.0	5.5-8.0	5.5-8.0
Loss on drying, max., %	USP/EP	5.0	5.0	5.0	5.0	5.0	5.0
Organic impurities, volatile	USP	Pass	Pass	Pass	Pass	Pass	Pass
Residue in ignition, max., %	USP	1.5	1.5	1.5	1.5	1.5	1.5
Ash, sulfated, mas., %	EP	1.0	1.0	1.0	1.0	1.0	1.0
Heavy metals, as Pb, max., ppm	USP/EP	10	10	10	10	10	10

† The data provided are typical values, intended only as guides, and should not be construed as sales specifications.

FIG. 8

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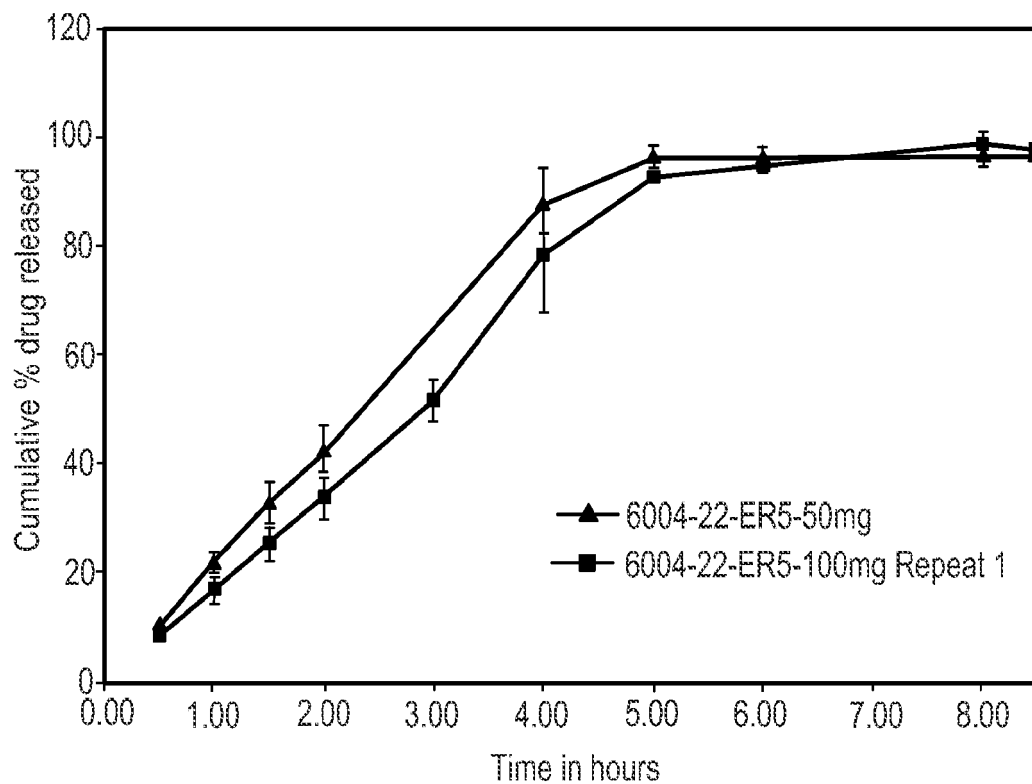


FIG. 9

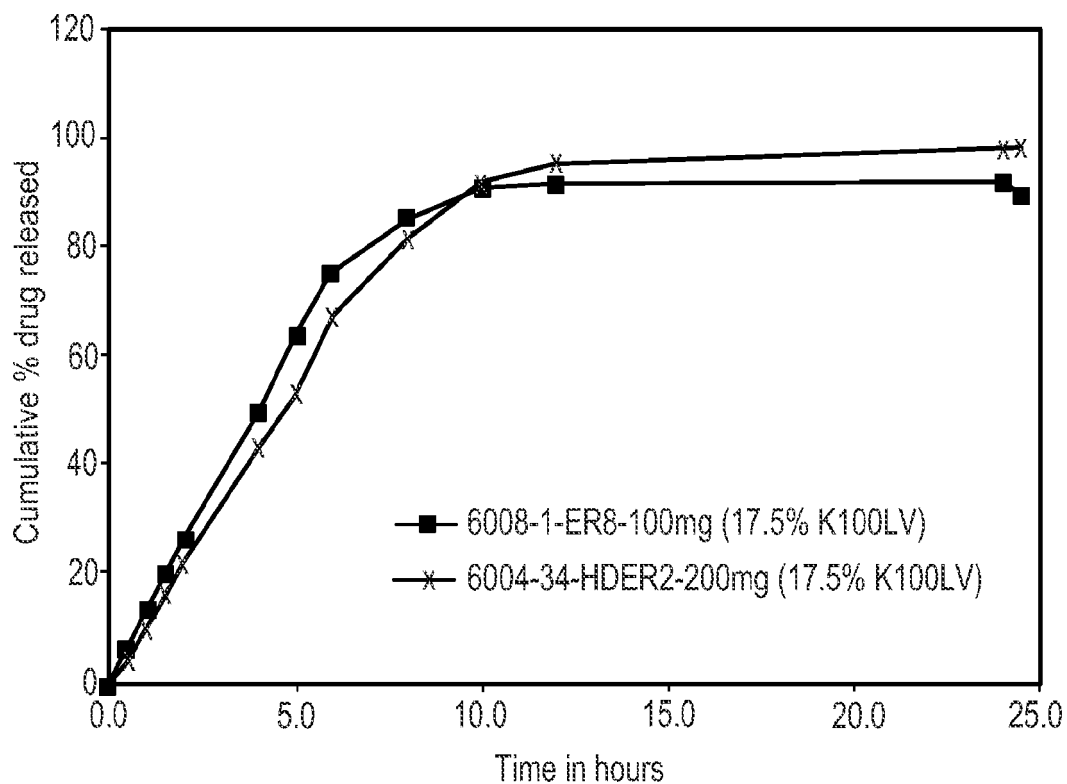


FIG. 10

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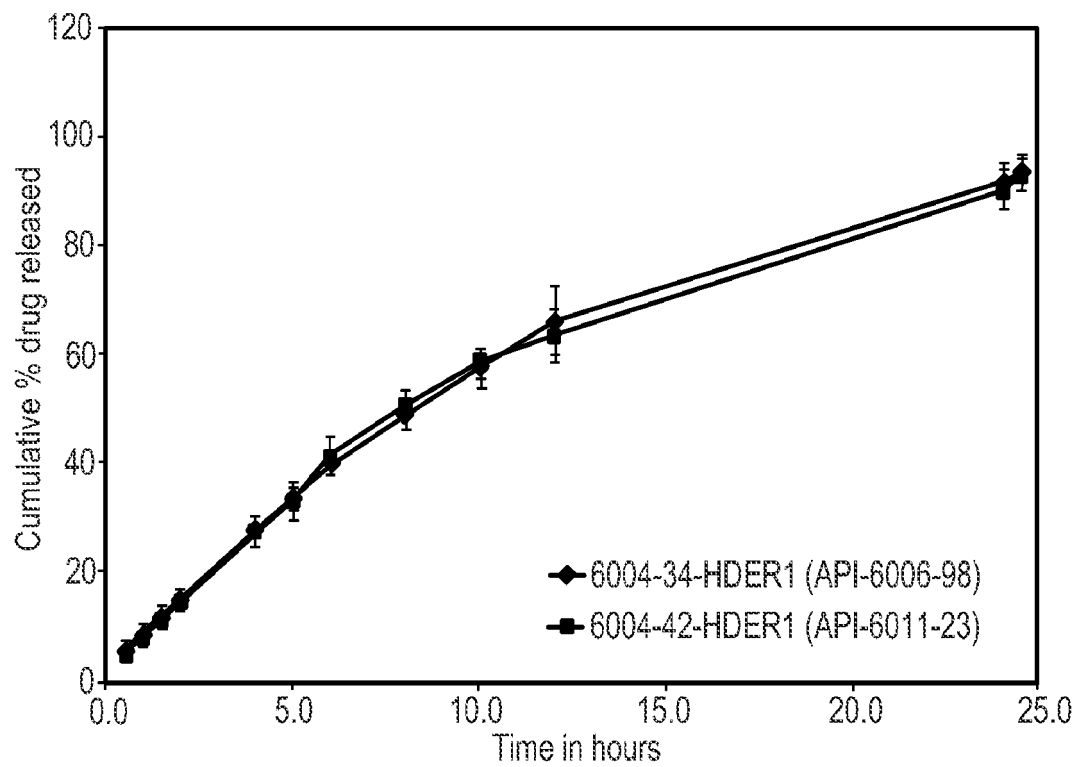


FIG. 11

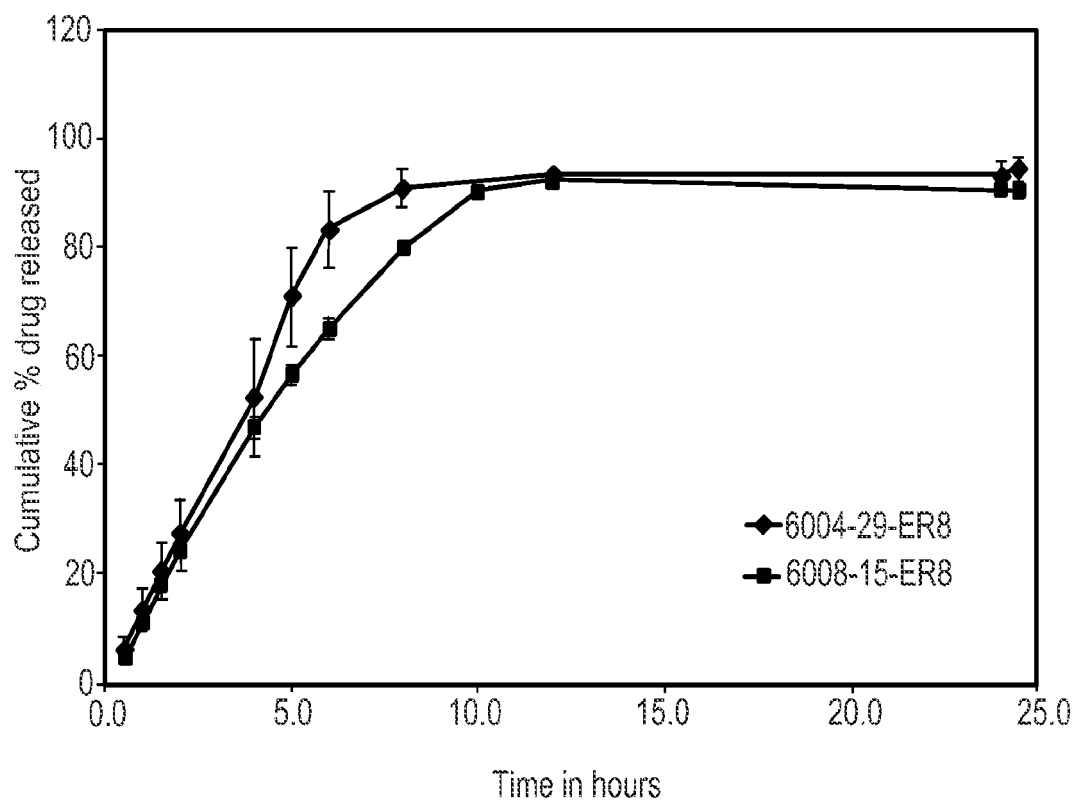


FIG. 12

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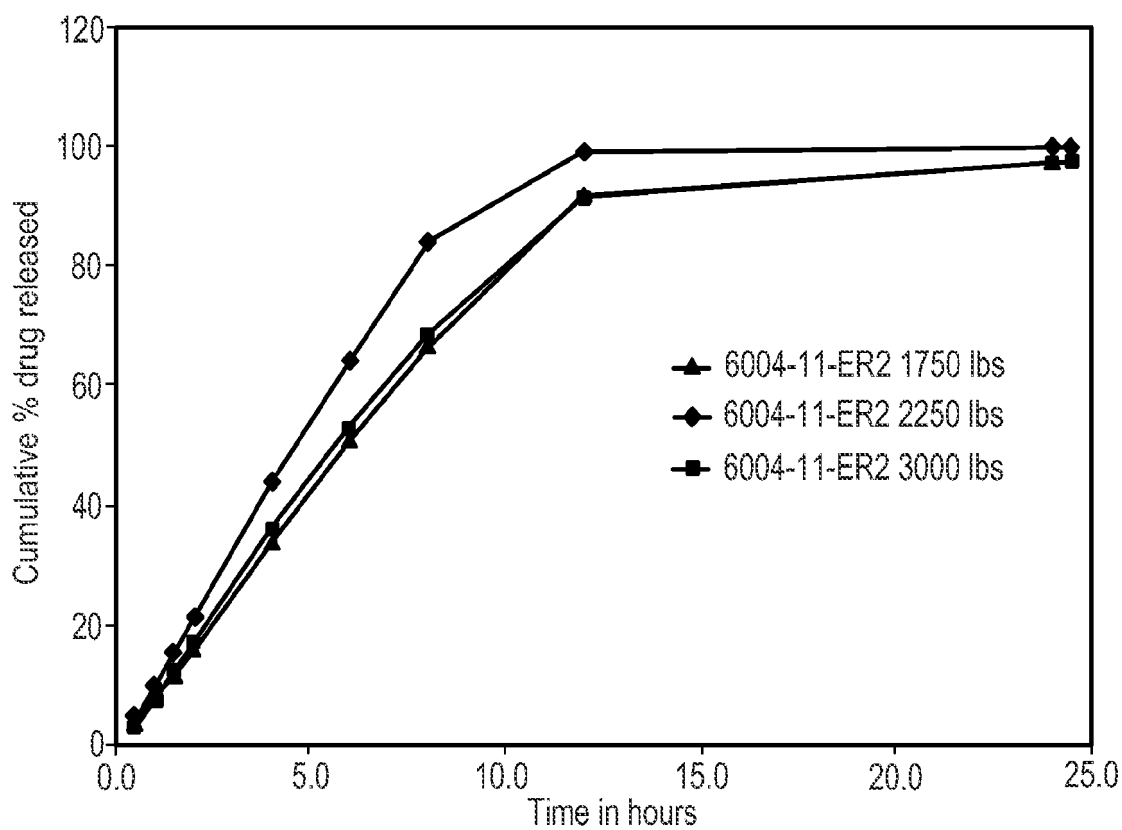


FIG. 13

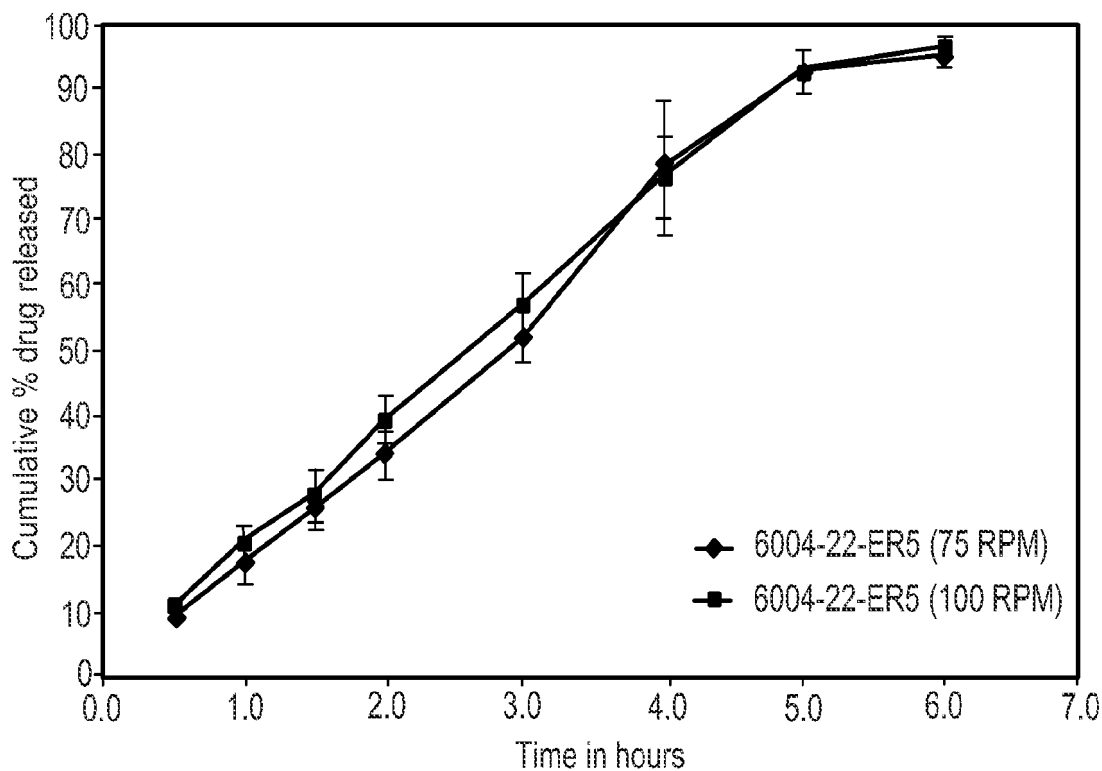


FIG. 14

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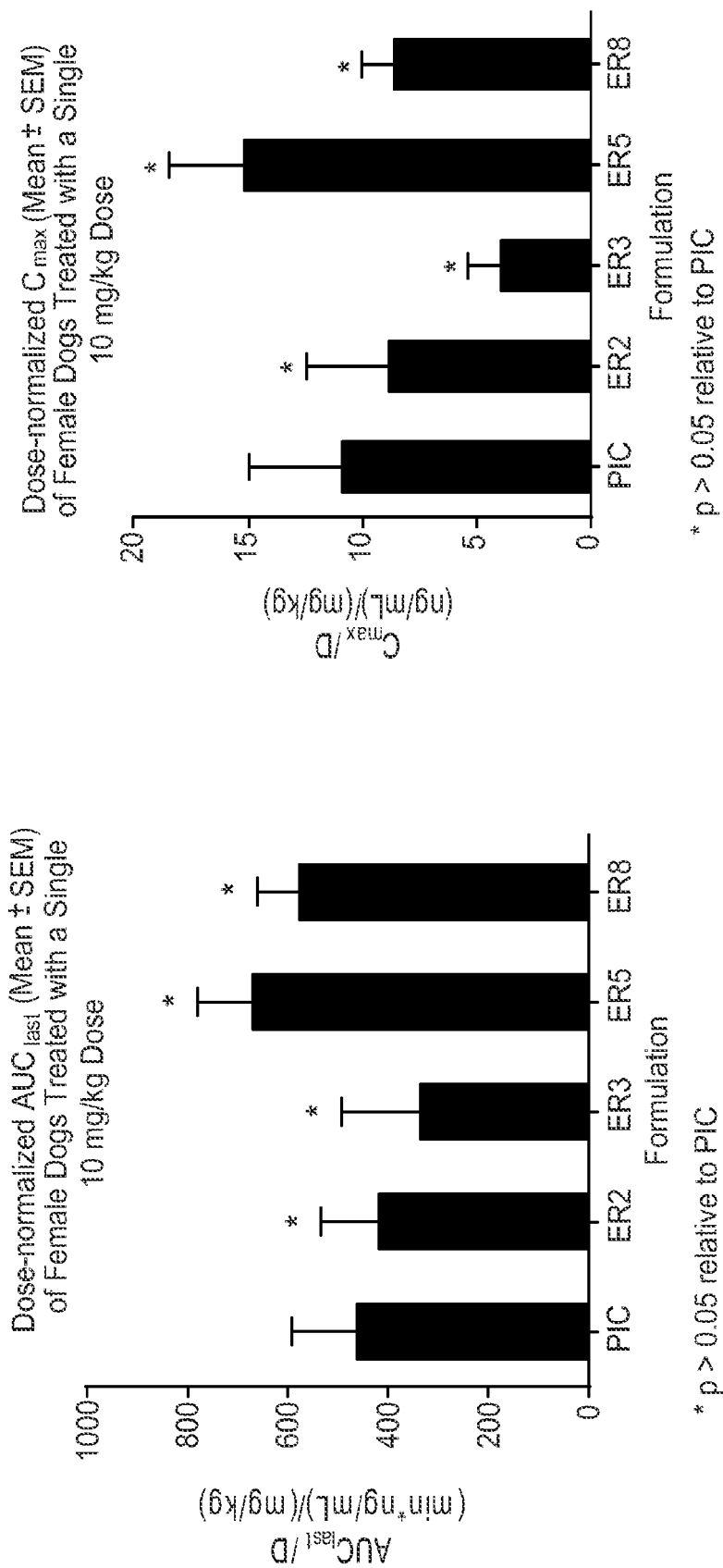


FIG. 15

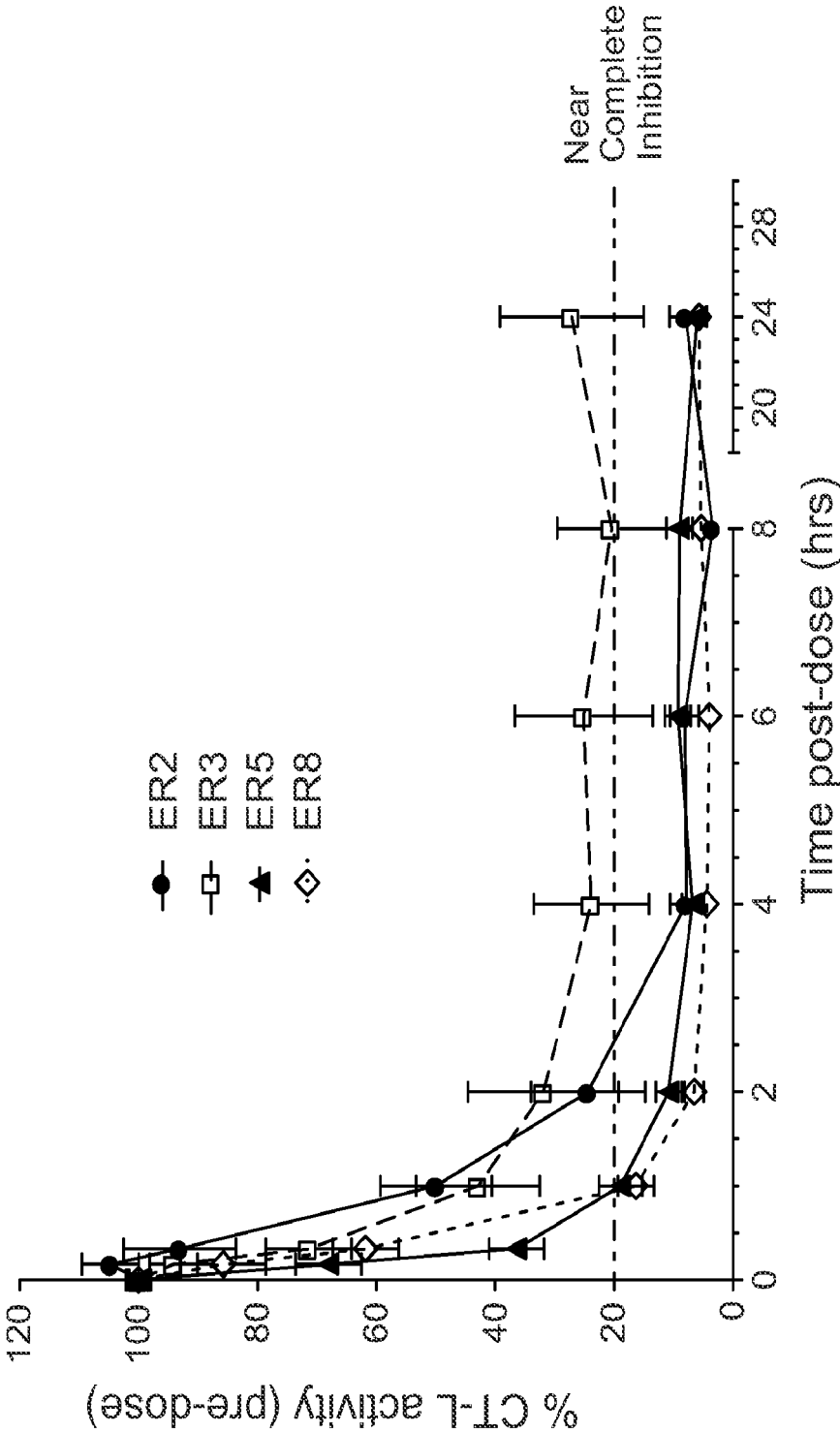
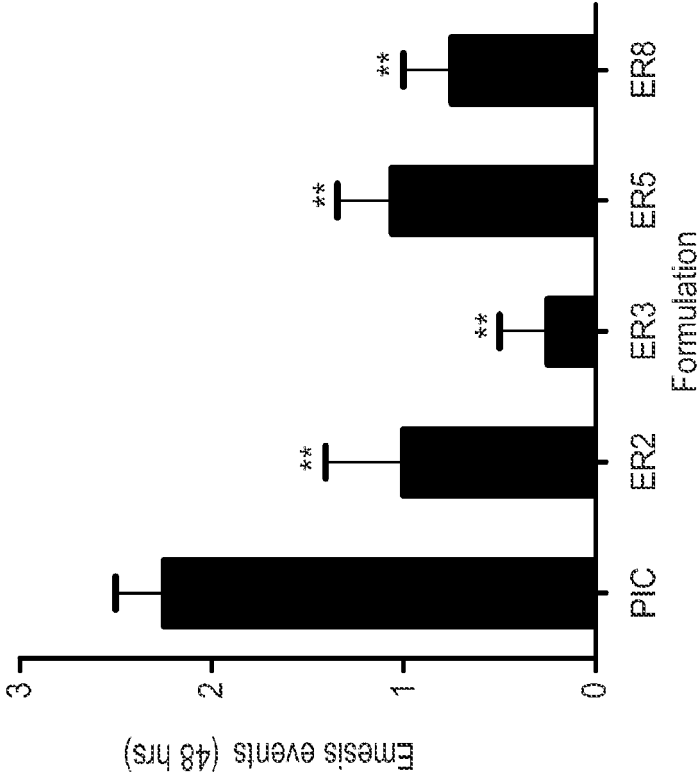
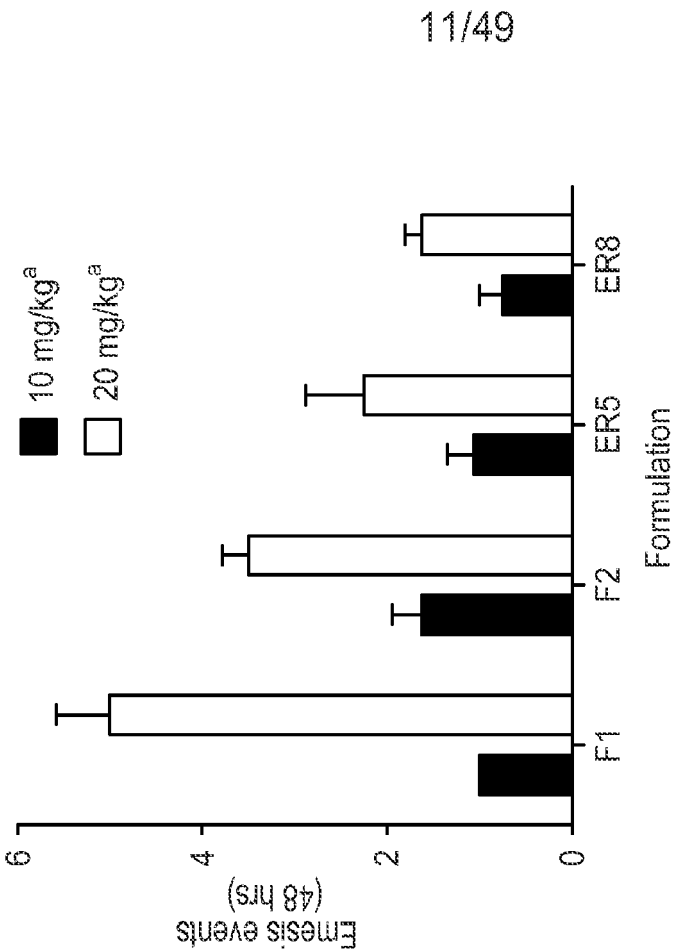


FIG. 16



** p < 0.03 relative to PIC

FIG. 17A



^a For ER5 and ER8, dogs were dosed with 100 or 200 mg flat dose, which is approximately 10 and 20 mg/kg, respectively.

FIG. 17B

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Table 5: ER Tablet Formulations

ER Formulations	6004-11-ER1		6004-11-ER2		6004-15-ER3		6004-15-ER4	
	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet
Oprozomib	25.00	100.00	25.00	100.00	25.00	100.00	25.00	100.00
Lactose Monohydrate (Grade 316 Fast Flo®)	28.00	112.00	28.00	112.00	35.00	140.00	35.00	140.00
Microcrystalline Cellulose (Avicel® PH102)	20.50	82.00	20.50	82.00	28.50	114.00	28.50	114.00
Sodium Lauryl Sulfate	1.00	4.00	1.00	4.00	1.00	4.00	1.00	4.00
Magnesium Stearate	0.50	2.00	0.50	2.00	0.50	2.00	0.50	2.00
Methocel® K100LV Premium CR	0.00	0.00	25.00	100.00	0.00	0.00	10.00	40.00
Methocel® K4M Premium CR	25.00	100.00	0.00	0.00	10.00	40.00	0.00	0.00
Total	100.00	400.00	100.00	400.00	100.00	400.00	100.00	400.00

FIG. 18

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Table 6: ER Tablet Formulations (Cont.)

ER Formulations	6004-22-ER5		6004-23-ER6		6004-24-ER7		6004-25-ER8	
	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet
Oprozomib	25.00	100.00	25.00	100.00	25.00	100.00	25.00	100.00
Lactose Monohydrate (Grade 315 Fast Flo®)	36.50	146.00	37.50	150.00	36.50	146.00	31.25	125.00
Microcrystalline Cellulose (Avicel® PH102)	30.00	120.00	31.00	124.00	30.00	120.00	24.75	99.00
Sodium Lauryl Sulfate	1.00	4.00	1.00	4.00	1.00	4.00	1.00	4.00
Magnesium Stearate	0.50	2.00	0.50	2.00	0.50	2.00	0.50	2.00
Methocel® K100LV Premium CR	7.00	28.00	5.00	20.00	5.00	20.00	17.50	70.00
Methocel® K4M Premium CR	0.00	0.00	0.00	0.00	2.00	8.00	0.00	0.00
Total	100.00	400.00	100.00	400.00	100.00	400.00	100.00	400.00

FIG. 18(Cont)

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Table 7: ER5 tablet formulation with 50mg strength

6004-22-ER5		
Ingredient	% w/w	mg/Tablet
Oprozomib	25.00	50.00
Lactose Monohydrate (Grade 316 Fast Flo®)	36.50	73.00
Microcrystalline Cellulose (Avicel® PH102)	30.00	60.00
Sodium Lauryl Sulfate	1.00	2.00
Magnesium Stearate	0.50	1.00
Methocel® K100LV Premium CR	7.00	14.00
Total	100.00	200.00

FIG. 18 (CONT)

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Table 8: HDER Tablet Formulations

High Dose ER (HDER) Formulations	6004-34-HDER1		6004-35-HDER2		6004-39-HDER3		6004-40-HDER4	
	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet	% w/w	mg/Tablet
Ingredient								
Oprozomib	40.00	200.00	40.00	200.00	40.00	200.00	40.00	200.00
Lactose Monohydrate (Grade 316 Fast Flo®)	28.50	142.50	21.00	105.00	28.50	142.50	28.50	142.50
Microcrystalline Cellulose (Avicel® PH102)	20.00	100.00	20.00	100.00	20.00	100.00	20.00	100.00
Sodium Lauryl Sulfate	1.00	5.00	1.00	5.00	1.00	5.00	1.00	5.00
Magnesium Stearate	0.50	2.50	0.50	2.50	0.50	2.50	0.50	2.50
Methocel® K100LV Premium CR	0.00	0.00	17.50	87.50	0.00	0.00	0.00	0.00
Methocel® K4M Premium CR	10.00	50.00	0.00	0.00	0.00	0.00	0.00	0.00
Methocel® K15M Premium CR	0.00	0.00	0.00	0.00	10.00	50.00	0.00	0.00
Methocel® K100M Premium CR	0.00	0.00	0.00	0.00	0.00	0.00	10.00	50.00
Total	100.00	500.00	100.00	500.00	100.00	500.00	100.00	500.00

FIG. 18 (CONT)

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Table 12.

		Results										
Lot 6004-47-ERS		Appearance	Assay (%Recovery)	ONX 0912 (Area %)	Impurities (Area %)						Total	
					RRT 0.60	RRT 0.63	RRT 0.70	RRT 0.90	RRT 0.95	RRT 0.97		RRT 1.12
Bulk -Wet Granulation		White solids	71.1	98.9	0.05	-	0.25	0.29	-	0.29	0.12	1.00
		Results										
Lot 6004-47-ERS		Appearance	Assay (%Recovery)	ONX 0912 (Area %)	Impurities (Area %)						Total	
					RRT 0.60	RRT 0.63	RRT 0.70	RRT 0.90	RRT 0.95	RRT 0.97		RRT 1.12
Bulk -Dry Granulation		White solids	100.7	98.8	-	-	0.28	0.29	-	0.29	0.13	0.99
		Results										
Lot 6004-47-ERS		Appearance	Assay (%LC)	ONX 0912 (Area %)	Impurities (Area %)						Total	
					RRT 0.60	RRT 0.63	RRT 0.70 (PR-176)	RRT 0.90	RRT 0.95	RRT 0.97 (PR-487)		RRT 1.12
Timepoint (weeks)	0	White tablets	98.7	98.8	0.05	-	0.27	0.35	-	0.29	0.13	1.08
	2	White round smooth tablets	101.1	99.1	-	-	0.40	0.08	-	0.29	0.13	0.87
	4	White round smooth tablets	100.4	99.1	-	-	0.39	0.10	-	0.29	0.13	0.91
	6	Off-white spotty discoloration round smooth tablets	99.9	98.9	-	-	0.24	0.36	-	0.29	0.12	1.01
	8	Off-white spotty discoloration round smooth tablets	100.2	98.8	-	-	0.25	0.40	-	0.28	0.13	1.07
		Results										
Tablet at 40°C		Appearance	Assay (%LC)	ONX 0912 (Area %)	Impurities (Area %)						Total	
					RRT 0.60	RRT 0.63	RRT 0.70 (PR-176)	RRT 0.90	RRT 0.95	RRT 0.97 (PR-487)		RRT 1.12
Timepoint (weeks)												

FIG. 19

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0	White tablets	98.7	98.8	0.05	-	0.27	0.35	-	0.29	0.13	1.08
2	White round smooth tablets	101.6	99.0	-	-	0.40	0.11	-	0.29	0.13	0.93
4	Off-white round smooth tablets	100.6	98.9	-	-	0.41	0.15	-	0.28	0.14	0.97
6	Off-white spotty discoloration round smooth tablets	98.9	98.7	-	0.05	0.27	0.38	0.05	0.28	0.15	1.14
8	Off-white spotty discoloration round smooth tablets	100.7	98.7	0.05	0.07	0.34	0.42	0.05	0.29	0.15	1.32

Table 13.

Dissolution Study of Stability Samples												
Dissolution (% Released)		Intervals (hours)										
Timepoint (weeks) & Condition	Tablet	0.5	1	1.5	2	4	5	6	8	10	12	24
0	1	12.6	24.8	35.1	45.4	94.5	95.7	95.6	94.9	95.1	95.1	93.6
	2	10.7	21.0	29.7	38.2	89.5	92.8	93.6	93.0	92.6	93.0	91.3
	3	13.7	24.8	34.3	43.8	92.9	93.1	93.6	93.3	93.1	93.2	92.1
	Mean	12.4	23.5	33.0	42.4	92.3	93.8	94.3	93.7	93.6	93.7	92.4
	%RSD	12.5	9.3	8.8	8.9	2.8	1.7	1.2	1.1	1.4	1.2	1.3
4 (25°C)	1	12.6	23.1	33.6	43.0	80.8	95.7	97.7	96.6	96.8	96.5	95.1
	2	12.3	23.2	33.8	43.3	88.9	94.7	95.8	95.1	94.8	95.0	93.3
	3	12.1	23.9	35.3	45.3	90.2	95.4	96.2	95.5	95.0	95.4	93.7
	Mean	12.4	23.4	34.2	43.9	86.6	95.2	96.6	95.7	95.5	95.6	94.0
	%RSD	2.1	1.9	2.7	2.9	5.9	0.5	1.0	0.8	1.2	0.8	1.0
4 (40°C)	1	10.5	20.3	29.5	37.7	65.4	77.6	88.0	90.8	90.8	91.6	91.8
	2	11.7	22.7	33.2	42.6	72.1	87.9	90.2	90.8	90.7	90.8	90.8
	3	NA	NA	30.6	39.7	68.5	81.3	89.6	90.7	90.9	91.3	91.1
	Mean	11.1	21.5	31.1	40.0	68.7	82.2	89.3	90.8	90.8	91.3	91.2
	%RSD	7.3	7.9	6.1	6.2	4.9	6.3	1.2	0.1	0.1	0.4	0.6

FIG. 19 (CONT)

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8 (25°C)	1	11.9	23.4	33.8	43.5	81.6	96.0	97.2	97.1	96.8	96.9	95.3	94.7
	2	12.6	23.7	33.9	43.7	84.4	94.1	95.6	96.0	95.1	95.3	93.3	93.2
	3	11.4	21.9	31.7	41.5	90.0	96.3	96.8	97.2	96.5	96.5	94.7	94.5
	Mean	12.0	23.0	33.2	42.9	85.3	95.5	96.5	96.8	96.1	96.3	94.4	94.1
	%RSD	5.3	4.2	3.8	2.8	5.0	1.3	0.8	0.6	0.9	0.9	1.1	0.9
8 (40°C)	1	11.2	21.9	31.7	40.7	70.0	82.5	87.1	88.2	88.3	88.1	88.1	88.0
	2	9.9	19.6	27.8	35.9	62.5	78.3	83.1	85.3	85.8	85.9	85.8	86.1
	3	14.8	28.7	41.1	51.4	80.6	85.5	85.6	86.1	87.0	86.7	86.1	86.5
	Mean	10.6	20.8	33.5	42.7	71.1	82.1	85.3	86.6	87.0	86.9	86.7	86.9
	%RSD	9.3	8.0	20.3	18.7	12.8	4.4	2.4	1.7	1.4	1.3	1.5	1.1

Table 14.

Lot 6004-48-ER8	Results											
	Appearance	Assay (%Recovery)	ONX 0912 (Area %)	Impurities (Area %)								
				RRT 0.60	RRT 0.63	RRT 0.70	RRT 0.90	RRT 0.95	RRT 0.97	RRT 1.12	Total	
Bulk -Wet Granulation	White solids	71.6	98.8	0.05	-	0.26	0.37	-	0.29	0.13	1.10	
Lot 6004-48-ER8	Results											
	Appearance	Assay (%Recovery)	ONX 0912 (Area %)	Impurities (Area %)								
				RRT 0.60	RRT 0.63	RRT 0.70	RRT 0.90	RRT 0.95	RRT 0.97	RRT 1.12	Total	
Bulk -Dry Granulation	White solids	101.3	98.6	0.06	-	0.29	0.45	-	0.29	0.13	1.22	
Lot 6004-48-ER8	Results											
Tablet at 25°C	Appearance	Assay (%LC)	ONX 0912 (Area %)	Impurities (Area %)								
Timepoint (weeks)				RRT 0.60	RRT 0.63	RRT 0.70 (PR-176)	RRT 0.90	RRT 0.95	RRT 0.97 (PR-487)	RRT 1.12	Total	

FIG. 19 (CONT)

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Timepoint (weeks)	Appearance	Assay (%LC)	ONX 0912 {Area %}	Impurities (Area %)								RRT	Total
				RRT 0.60	RRT 0.63	RRT 0.70 (PR-176)	RRT 0.90	RRT 0.95	RRT 0.97 (PR-487)	RRT 1.12			
0	White tablets	98.6	98.4	0.09	0.05	0.27	0.64	-	0.29	0.12	1.45		
2	White round smooth tablets	97.9	99.0	-	-	0.37	0.18	-	0.29	0.13	0.97		
4	White round smooth tablets	98.4	99.0	-	-	0.39	0.20	-	0.29	0.13	1.00		
6	Off-white spotty discoloration round smooth tablets	100.9	98.9	-	-	0.22	0.36	-	0.28	0.13	0.99		
8	Off-white spotty discoloration round smooth tablets	94.6	98.8	0.06	0.05	0.28	0.32	-	0.29	0.13	1.05		

Table 15.

Dissolution (% Released)		Intervals (hours)											
Timepoint (weeks) & Condition	Tablet	0.5	1	1.5	2	4	5	6	8	10	12	24	24.5
0	1	5.3	11.1	16.6	22.4	49.3	58.1	66.8	81.2	90.6	93.5	92.3	91.9
	2	7.3	15.0	22.0	29.1	61.4	71.2	80.4	91.9	92.9	92.8	92.0	91.4
	3	6.3	12.7	18.3	24.6	53.0	62.4	71.1	85.5	93.9	94.3	93.3	92.9
	Mean	6.3	12.9	19.0	25.4	54.6	63.9	72.8	86.2	92.4	93.5	92.5	92.1
	%RSD	15.8	15.3	14.5	13.6	11.4	10.4	9.5	6.2	1.8	0.8	0.7	0.9
4 (25°C)	1	8.5	15.6	22.8	29.6	53.6	63.9	73.3	87.8	97.0	95.8	94.5	93.7

FIG. 19 (CONT)

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	2	7.6	13.9	20.4	26.8	49.1	58.5	67.3	81.5	90.7	94.2	93.0	92.5
	3	7.7	13.6	19.5	25.5	47.5	56.8	65.4	80.0	90.8	94.6	93.8	93.5
	Mean	7.9	14.4	20.9	27.3	50.1	59.7	68.6	83.1	92.8	94.8	93.7	93.2
	%RSD	5.8	7.6	8.1	7.6	6.3	6.2	6.0	5.0	3.9	0.9	0.8	0.7
	1	8.5	15.5	22.4	29.1	52.6	61.9	70.0	84.3	90.9	91.9	91.1	91.1
4 (40°C)	2	7.3	13.6	20.0	26.0	48.1	57.2	65.7	79.4	90.2	92.6	92.4	92.3
	3	7.3	14.5	21.5	28.2	51.7	61.1	70.3	85.2	92.9	93.0	92.6	93.0
	Mean	7.7	14.5	21.3	27.8	50.8	60.0	68.7	83.0	91.3	92.5	92.1	92.1
	%RSD	8.7	6.4	5.6	5.7	4.6	4.2	3.8	3.8	1.5	0.6	0.9	1.0
	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
8 (25°C)	2	8.2	15.8	23.5	30.7	57.1	67.6	77.5	92.0	96.0	96.1	94.8	94.5
	3	5.2	10.8	16.5	22.2	44.4	53.6	62.5	78.1	89.6	95.3	94.3	94.2
	Mean	6.7	13.3	20.0	26.4	50.8	60.6	70.0	85.0	92.8	95.7	94.6	94.3
	%RSD	32.0	26.9	24.8	22.7	17.6	16.4	15.1	11.6	4.9	0.6	0.3	0.2
	1	8.6	15.3	21.6	27.8	48.9	56.9	64.5	77.6	82.2	82.6	82.8	82.7
8 (40°C)	2	5.3	10.2	15.4	20.9	40.8	49.1	56.9	70.4	82.9	87.8	89.0	89.0
	3	5.7	11.5	17.1	22.6	43.6	52.0	59.6	72.9	82.4	87.8	88.2	88.6
	Mean	6.5	12.3	18.0	23.8	44.4	52.7	60.3	73.6	82.5	86.1	86.6	86.8
	%RSD	27.5	21.8	17.6	15.2	9.3	7.5	6.4	5.0	0.4	3.4	3.9	4.0
	1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

FIG. 19 (CONT)

Table 16: Stability Results for Oprozomib Tablets, Lot No. 1, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{RH}$

Bulk Lot No.:	I				Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil
Test Attribute	Appearance	Identification UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content (w/w %)	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: $\leq 10.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Time Point (months)						
Results						
Initial	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard. % Agreement: 100%	99% LC	Total: 0.52% PR-059176 (RRT 0.70): 0.35% RRT 1.12: 0.17%	3% w/w	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g
I	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	99% LC	Total: 0.59% PR-059176 (RRT 0.71): 0.42% RRT 1.11: 0.17%	3% w/w	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S_1 (n = 6): Each tablet is not less than Q + 5%; S_2 (n = 6): Average of 12 tablets ($S_1 + S_2$) is $\geq Q$ and no tablet is $< Q - 15\%$; S_3 (n = 12): Average of 24 tablets ($S_1 + S_2 + S_3$) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20

Bulk Lot No.:		1	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification		Assay (w/w %)	Impurities (area %)	Water Content (w/w %)
		RT UV Spectrum				
						Microbial Limits

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 16: Stability Results for Oprozomib Tablets, Lot No. 1, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$ (cont'd)

Bulk Lot No.:		1	Manufacturer:		Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content (w/w %)	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10 (0% (area %)) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Time Point (months)								
Results								
2	Not scheduled	Not scheduled	Not scheduled	Not scheduled	Not scheduled	NR	Not scheduled	
3	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	100% LC	Total: 0.58% PR-059176 (RRT 0.71); 0.41% RRT 1.11: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 93% Replicate 2: 93% Replicate 3: 92% Replicate 4: 94% Replicate 5: 92% Replicate 6: 93%	Not tested ^b	
6	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	98% LC	Total: 0.46% PR-059176 (RRT 0.70); 0.30% RRT 1.12: 0.16%	3% w/w	Level S ₁ at 8 hours Replicate 1: 93% Replicate 2: 94% Replicate 3: 92% Replicate 4: 93% Replicate 5: 94% Replicate 6: 93%	Not tested ^b	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; NR = Not reported; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopoeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃)

FIG. 20 (CONT)

Bulk Lot No.:		1	Manufacturer:		Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content (w/w %)	Dissolution	Microbial Limits	

is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

Table 17: Stability Results for Oprozomib Tablets, Lot No. 1, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		1				Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification RF UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "3", on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Time Point (months)								Results
Initial	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard. % Agreement: 100%	99% LC	Total: 0.52% PR-059176 (RRT 0.70): 0.35% RRT 1.12: 0.17%	3% w/w	Level S _I at 8 hours Replicate 1: 96% Replicate 2: 96% Replicate 3: 96% Replicate 4: 97% Replicate 5: 95% Replicate 6: 97%	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g	
1	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	98% LC	Total: 0.60% PR-059176 (RRT 0.71): 0.43% RRT 1.11: 0.17%	3% w/w	Level S _I at 8 hours Replicate 1: 95% Replicate 2: 95% Replicate 3: 95% Replicate 4: 93% Replicate 5: 95% Replicate 6: 95%	Not tested ^b	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

Table 17: Stability Results for Oprozomib Tablets, Lot No. 1, Stored at 40 ± 2°C / 75 ± 5% RH (cont'd)

Bulk Lot No.:		1			Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Results								
Time Point (months)								
3	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	97% LC	Total: 0.51% PR-059176 (RRT 0.71): 0.51% RRT 1.11: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 90% Replicate 2: 92% Replicate 3: 92% Replicate 4: 93% Replicate 5: 93% Replicate 6: 93%	Not tested ^b	
6	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard.	98% LC	Total: 0.46% PR-059176 (RRT 0.70): 0.30% RRT 1.12: 0.16%	3% w/w	Level S ₁ at 8 hours Replicate 1: 91% Replicate 2: 91% Replicate 3: 92% Replicate 4: 90% Replicate 5: 91% Replicate 6: 91%	Not tested ^b	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is ≥ Q and no tablet is < Q – 25%
is ≥ Q, not more than 2 tablets are < Q – 15%, and no tablet is < Q – 25%

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 18: Stability Results for Oprozomib Tablets, Lot No. 2, Stored at 25 ± 2°C / 60 ± 5% RH

Bulk Lot No.:	2	Packaging:					Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Time Point (months)	Results						
Initial	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard. % Agreement: 100%	98% LC	Total: 0.51% PR-059176 (RRT 0.76): 0.34% RRT 1.12: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 95% Replicate 2: 94% Replicate 3: 95% Replicate 4: 96% Replicate 5: 98% Replicate 6: 93%	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g
1	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard.	100% LC	Total: 0.59% PR-059176 (RRT 0.71): 0.43% RRT 1.11: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 92% Replicate 2: 91% Replicate 3: 95% Replicate 4: 93% Replicate 5: 93% Replicate 6: 92%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is ≥ Q and no tablet is < Q – 15%; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is ≥ Q, not more than 2 tablets are < Q – 15%, and no tablet is < Q – 25%

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 18: Stability Results for Oprozomib Tablets, Lot No. 2, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$ (cont'd)

Bulk Lot No.:		2				Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Time Point (months)	Results							
2	Not scheduled	Not scheduled	Not scheduled	Not scheduled	Not scheduled	Level S ₁ at 8 hours Replicate 1: 94% Replicate 2: 92% Replicate 3: 93% Replicate 4: 95% Replicate 5: 93% Replicate 6: 93%	Not scheduled	
3	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard.	97% LC	Total: 0.78% PR-059176 (RRT 0.71): 0.61% RRT 1.11: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 90% Replicate 2: 92% Replicate 3: 91% Replicate 4: 92% Replicate 5: 89% Replicate 6: 93%	Not tested ^b	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S – stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq$ Q, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 18: Stability Results for Oprozomib Tablets, Lot No. 2, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$ (cont'd)

Bulk Lot No.:		2	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Results							
Time Point (months)							
6	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard.	96% LC	Total: 0.47% PR-059176 (RRT 0.71): 0.30% RRT 1.12: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 92% Replicate 2: 91% Replicate 3: 93% Replicate 4: 93% Replicate 5: 93% Replicate 6: 93%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 19: Stability Results for Oprozomib Tablets, Lot No. 2, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		2	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Time Point (months)							
Initial				Results			
	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard. % Agreement: 100%	98% LC	Total: 0.51% PR-059176 (RRT 0.70): 0.34% RRT 1.12: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 95% Replicate 2: 94% Replicate 3: 95% Replicate 4: 96% Replicate 5: 98% Replicate 6: 93%	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g
1	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard.	98% LC	Total: 0.61% PR-059176 (RRT 0.71): 0.44% RRT 1.12: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 91% Replicate 2: 93% Replicate 3: 92% Replicate 4: 93% Replicate 5: 92% Replicate 6: 93%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

Table 19: Stability Results for Oprozomib Tablets, Lot No. 2, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$ (cont'd)

Bulk Lot No.:	2	Packaging:			Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: $\leq 10.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Time Point (months)							
				Results			
3	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard. % Agreement: 100%	98% LC	Total: 0.61% PR-059176 (RRT 0.71): 0.43% RRT 1.11: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 89% Replicate 2: 91% Replicate 3: 91% Replicate 4: 87% Replicate 5: 88% Replicate 6: 87%	Not tested ^b
6	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard.	97% LC	Total: 0.48% PR-059176 (RRT 0.70): 0.31% RRT 1.12: 0.17%	3% w/w	Level S ₁ at 8 hours Replicate 1: 91% Replicate 2: 90% Replicate 3: 89% Replicate 4: 87% Replicate 5: 88% Replicate 6: 88%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq$ Q, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability

FIG. 20 (CONT)

Table 20: Stability Results for Oprozomib Tablets, Lot No. 3, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$

Bulk Lot No.:		3	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil			
Test Attribute	Appearance	Identification RT	Assay (w/w %)	Impurities (area %)	Water Content (w/w %)	Hardness	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of Escherichia coli
Time Point (months)								
Results								
Initial	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	102% LC	Total: 0.58% PR-059176 (RRT 0.70): 0.31% RRT 0.97: 0.10% RRT 1.12: 0.17%	3% w/w	Mean: 16.4 kP RSD: 7.0% Range: 15.0-18.1 kP	Level S1 at 8 hours Replicate 1: 96% Replicate 2: 97% Replicate 3: 96% Replicate 4: 97% Replicate 5: 97% Replicate 6: 96%	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g
1	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	100% LC	Total: 0.68% PR-059176 (RRT 0.71): 0.51% RRT 1.11: 0.17%	2% w/w	Mean: 16.0 kP RSD: 8.9% Range: 14.0-18.2 kP	Level S1 at 8 hours Replicate 1: 94% Replicate 2: 98% Replicate 3: 96% Replicate 4: 95% Replicate 5: 95% Replicate 6: 95%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S – stage of testing; USP – United States Pharmacopoeia; UV – ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20 (CONT)

Bulk Lot No.: 3		Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil				
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits

^b Test is performed at release and end of stability

FIG. 20 (CONT)

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Table 20: Stability Results for Oprozomib Tablets, Lot No. 3, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{RH}$ (cont'd)

Bulk Lot No.:		3	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil			
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of Escherichia coli
Results								
Time Point (months)								
2	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	100% LC	Total: 1.4% PR-059176 (RRT 0.70): 0.89% RRT 0.72: 0.14% RRT 0.78: 0.16% RRT 0.97: 0.10% RRT 1.12: 0.17%	3% w/w	Mean: 16.2 kP RSD: 5.4% Range: 14.7-17.2 kP	Level S1 at 8 hours Replicate 1: 96% Replicate 2: 94% Replicate 3: 95% Replicate 4: 95% Replicate 5: 96% Replicate 6: 96%	Not tested ^b
3	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	101% LC	Total: 0.62% PR-059176 (RRT 0.70): 0.45% RRT 1.12: 0.17%	2% w/w	Mean: 16.5 kP RSD: 4.7% Range: 15.1-17.6 kP	Level S1 at 8 hours Replicate 1: 98% Replicate 2: 96% Replicate 3: 94% Replicate 4: 94% Replicate 5: 94% Replicate 6: 94%	Not tested ^b

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$, and no tablet is $< Q - 25\%$ is $\geq$ Q, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20 (CONT)

Bulk Lot No.: 3				Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits

^b Test is performed at release and end of stability

FIG. 20 (CONT)

Table 21: Stability Results for Oprozomib Tablets, Lot No. 3, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		3	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil				
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with “S” on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Results									
Time Point (months)									
Initial	White, round biconvex tablet, debossed with “1” on one side	Conforms to reference standard	102% LC	Total: 0.58% PR-059176 (RRT 0.70): 0.31% RRT 0.97: 0.10% RRT 1.12: 0.17%	3% w/w	Mean: 16.4 kP RSD: 7.0% Range: 15.0–18.1 kP	Level S1 at 8 hours Replicate 1: 96% Replicate 2: 97% Replicate 3: 96% Replicate 4: 97% Replicate 5: 97% Replicate 6: 96%	1. <100 CFU/g 2. <10 CFU/g 3. Absent in 1 g	
I	White, round biconvex tablet, debossed with “1” on one side	Conforms to reference standard	101% LC	Total: 0.61% PR-059176 (RRT 0.71): 0.43% RRT 1.11: 0.17%	2% w/w	Mean: 16.4 kP RSD: 3.9% Range: 15.6–17.7 kP	Level S1 at 8 hours Replicate 1: 96% Replicate 2: 94% Replicate 3: 95% Replicate 4: 94% Replicate 5: 93% Replicate 6: 96%	Not tested ^b	

Abbreviations: ABC = Analytical Bio-Chemistry Laboratories; CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

FIG. 20 (CONT)

Bulk Lot No.:		3			Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil			
Test Attribute		Appearance	Identification RT UV Spectrum		Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is ≥ Q and no tablet is < Q – 25%
is ≥ Q, not more than 2 tablets are < Q – 15%, and no tablet is < Q – 25%

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 21: Stability Results for Oprozomib Tablets, Lot No. 3, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$ (cont'd)

Bulk Lot No.:		3	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil						
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits			
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>			
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: $\leq 16.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>			
Results											
Time Point (months)											
2	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	99% LC	Total: 0.96% PR-059176 (RRT 0.70): 0.79% RRT 1.12: 0.17%	3% w/w	Mean: 15.9 kP RSD: 6.1% Range: 14.5-17.2 kP	Level S1 at 8 hours Replicate 1: 96% Replicate 2: 93% Replicate 3: 91% Replicate 4: 93% Replicate 5: 98% Replicate 6: 94%	Not tested ^b			
3	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	101% LC	Total: 0.61% PR-059176 (RRT 0.71): 0.43% RRT 1.11: 0.17%	2% w/w	Mean: 15.9 kP RSD: 6.0% Range: 14.3-17.5 kP	Level S1 at 8 hours Replicate 1: 94% Replicate 2: 94% Replicate 3: 92% Replicate 4: 93% Replicate 5: 93% Replicate 6: 96%	Not tested ^b			

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopoeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃)

FIG. 20 (CONT)

Bulk Lot No.:		3				Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum		Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits	

is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$
^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 22: Stability Results for Oprozomib Tablets, Lot No. 4, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$

Bulk Lot No.:		4	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil				
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: $\leq 10.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Results									
Time Point (months)									
Initial	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	99% LC	Total: 0.37% PR-059176 (RRT 0.70); 0.37%	3% w/w	Mean: 17.6 kP RSD: 5.0% Range: 16.0-18.4 kP	Level S1 at 8 hours Replicate 1: 99% Replicate 2: 98% Replicate 3: 95% Replicate 4: 97% Replicate 5: 95% Replicate 6: 98%	< 100 CFU/g < 10 CFU/g Absent in 1 g	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq$ Q, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

^b Test is performed at release and end of stability.

FIG. 20 (CONT)

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Table 23: Stability Results for Oprozomib Tablets, Lot No. 4, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		4	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil			
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardness	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	90%-110% of label claim	1. Total impurities: $\leq 10.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Results								
Time Point (months)								
Initial	White, round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	99% LC	Total: 0.37% PR-059176 (RRT 0.70): 0.37%	3% w/w	Mean: 17.6 kP RSD: 5.0% Range: 16.0-18.4 kP	Level S1 at 8 hours Replicate 1: 99% Replicate 2: 98% Replicate 3: 95% Replicate 4: 97% Replicate 5: 95% Replicate 6: 98%	< 100 CFU/g < 10 CFU/g Absent in 1 g

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20 (CONT)

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Table 24: Stability Results for Oprozomib Tablets, Lot No. 5, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$

Bulk Lot No.:		5	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil			
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Hardn ess	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3535	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "1" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤10.0% (area %) 2. Report impurities ≥0.10% (area %)	≤5%	Report results	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Results								
Time Point (months)								
Initial	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	100% LC	Total: 0.37% PR-059176 (RRT 0.70); 0.37%	3% w/w	Mean: 20.3 kP RSD: 2.3% Range: 19.7–20.9 kP	Level S1 at 8 hours Replicate 1: 95% Replicate 2: 95% Replicate 3: 95% Replicate 4: 96% Replicate 5: 96% Replicate 6: 96%	< 100 CFU/g 10 CFU/g Absent in 1 g

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20 (CONT)

Table 25: Stability Results for Oprozomib Tablets, Lot No. 5, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		5				Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits	
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>	
Specification	White to off-white round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>	
Results								
Time Point (months)								
Initial	White, round biconvex tablet, debossed with "3" on one side	Conforms to reference standard	100% LC	Total: 0.37% PR-059176 (RRT 0.70): 0.37%	3% w/w	Level S1 at 8 hours Replicate 1: 95% Replicate 2: 95% Replicate 3: 95% Replicate 4: 96% Replicate 5: 96% Replicate 6: 96%	< 100 CFU/g 10 CFU/g Absent in 1 g	

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq$ Q and no tablet is < Q – 15%; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq$ Q, not more than 2 tablets are < Q – 15%, and no tablet is < Q – 25%

FIG. 20 (CONT)

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Table 26: Stability Results for Oprozomib Tablets, Lot No. 6, Stored at $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{ RH}$

Bulk Lot No.:		6			Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil	
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: ≤ 10.0% (area %) 2. Report impurities ≥ 0.10% (area %)	≤ 5%	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Results							
Time Point (months)							
Initial	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	102% LC	Total: 0.39% PR-059176 (RRT 0.70); 0.39%	3% w/w	Level S1 at 8 hours Replicate 1: 98% Replicate 2: 99% Replicate 3: 98% Replicate 4: 99% Replicate 5: 98% Replicate 6: 97%	< 100 CFU/g < 10 CFU/g Absent in 1 g

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopoeia; UV = ultraviolet

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is $\geq Q$ and no tablet is $< Q - 15\%$; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is $\geq Q$, not more than 2 tablets are $< Q - 15\%$, and no tablet is $< Q - 25\%$

FIG. 20 (CONT)

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Table 27: Stability Results for Oprozomib Tablets, Lot No. 6, Stored at $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{ RH}$

Bulk Lot No.:		6	Packaging:		Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits
Method No.	PM-QS 6.7	M-3104	M-3104	M-3104	M-2815	M-3106	STP 09.4754; USP <61> and <62>
Specification	White to off-white round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	90%–110% of label claim	1. Total impurities: $\leq 10.0\%$ (area %) 2. Report impurities $\geq 0.10\%$ (area %)	$\leq 5\%$	1. Q = 75% 2. At 8 hours, conforms to the acceptance criteria in Footnote a.	1. Total aerobic microbial count: NMT 1000 CFU/g 2. Total combined yeast/mold: NMT 100 CFU/g 3. Absence of <i>Escherichia coli</i>
Results							
Time Point (months)							
Initial	White, round biconvex tablet, debossed with "5" on one side	Conforms to reference standard	102% LC	Total: 0.39% PR-059176 (RRT 0.70): 0.39%	3% w/w	Level S1 at 8 hours Replicate 1: 98% Replicate 2: 99% Replicate 3: 98% Replicate 4: 99% Replicate 5: 98% Replicate 6: 97%	< 100 CFU/g < 10 CFU/g Absent in 1 g

Abbreviations: CFU/g = colony forming units per gram; CRC = child-resistant cap; HDPE = high density polyethylene; LC = label claim; NMT = not more than; Q = amount of dissolved active ingredient expressed as a percentage of the labeled content of the dosage unit; RH = relative humidity; RRT = relative retention time; RT = retention time; S = stage of testing; USP = United States Pharmacopoeia; UV = ultraviolet

FIG. 20 (CONT)

Bulk Lot No.:		6				Packaging:	Finished Product: 30 count in white, opaque 75 cc HDPE bottles, 38 mm CRC, desiccant, polyester coil		
Test Attribute	Appearance	Identification RT UV Spectrum	Assay (w/w %)	Impurities (area %)	Water Content, (w/w %)	Dissolution	Microbial Limits		

^a S₁ (n = 6): Each tablet is not less than Q + 5%; S₂ (n = 6): Average of 12 tablets (S₁ + S₂) is ≥ Q and no tablet is < Q – 15%; S₃ (n = 12): Average of 24 tablets (S₁ + S₂ + S₃) is ≥ Q, not more than 2 tablets are < Q – 15%, and no tablet is < Q – 25%

FIG. 20 (CONT)

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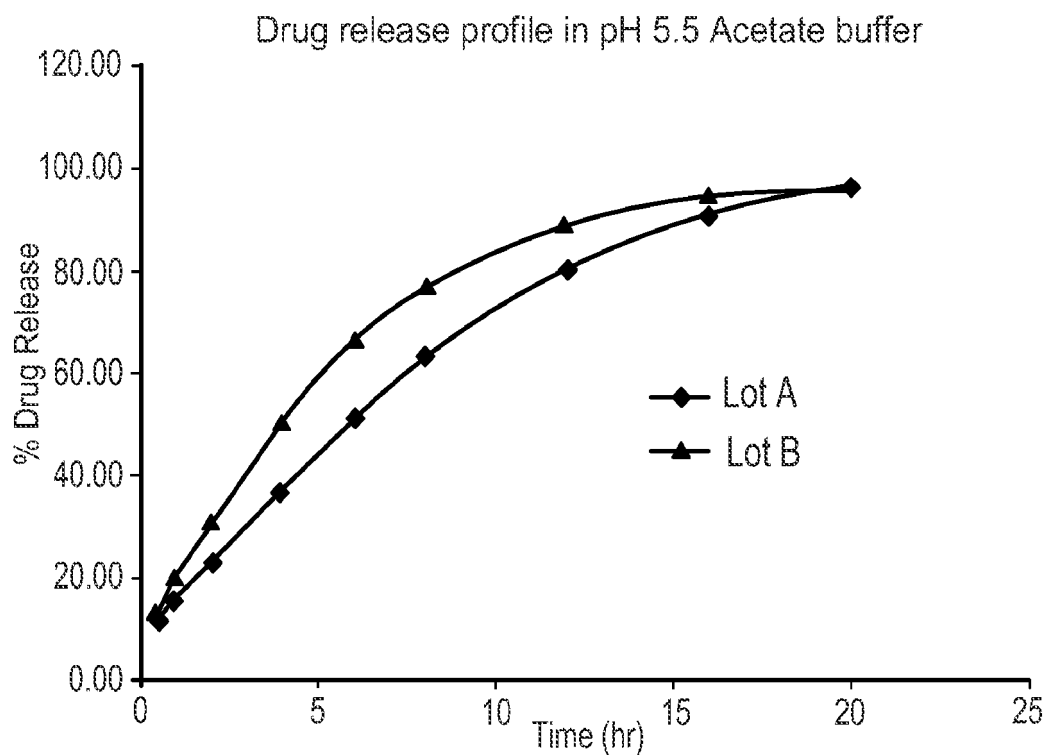


FIG. 21

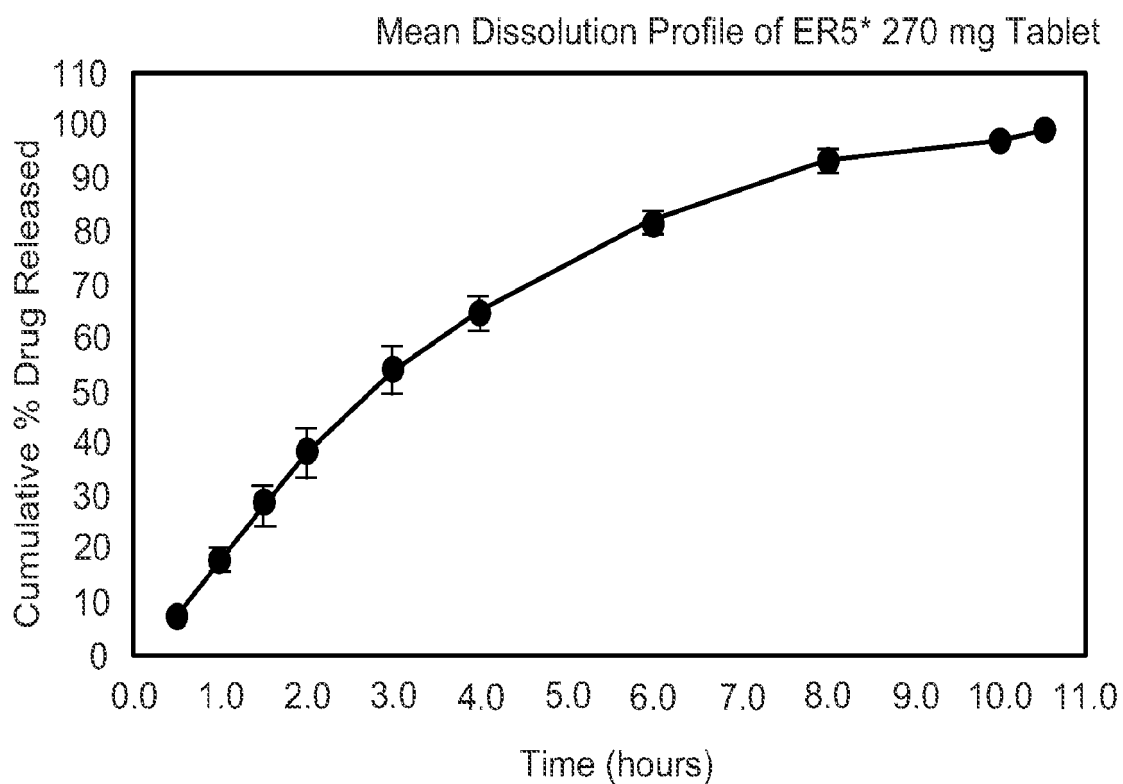


FIG. 24

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Table 29.

ER5	
Ingredient	% w/w
OPZ	25.00
Sodium Lauryl Sulfate	1.00
Magnesium Stearate	0.50
Avicel PH102	30.00
Lactose 316	36.50
Methocel K100LV CR	7.00
Core Total	100.00
Coating	
Opadry II 85F18422	3.00
Total	103.00

Table 30.

ER9	
Ingredient	% w/w
OPZ	25.00
Sodium Lauryl Sulfate	1.00
Magnesium Stearate	0.50
Avicel PH101	16.12
Lactose 312	48.83
Methocel K100LV CR	8.55
Core Total	100.00
Coating	
Opadry II 85F18422	3.00
Total	103.00

FIG. 22

49/49

Run #	Lot #	OPZ	SLS	Magnesium Stearate	HPMC	MCC	Lactose	MCC:Lactose	Core Total	H2O for Granulation
1	6008-166	25.00	1.00	0.50	15.00	14.52	43.98	0.33	100.00	33.50
2	6008-167	25.00	1.00	0.50	15.00	14.52	43.98	0.33	100.00	33.50
3	6008-168	25.00	1.00	0.50	15.00	38.27	20.23	1.89	100.00	34.15
4	6008-169	25.00	1.00	0.50	5.00	51.38	17.13	3.00	100.00	30.00
5	6008-170	25.00	1.00	0.50	9.85	40.24	23.41	1.72	100.00	38.50
6	6008-171	25.00	1.00	0.50	10.00	46.61	16.89	2.76	100.00	31.00
7	6008-172	25.00	1.00	0.50	10.95	36.61	25.94	1.41	100.00	30.00
8	6008-173	25.00	1.00	0.50	15.00	14.52	43.98	0.33	100.00	40.00
9	6008-174	25.00	1.00	0.50	5.00	17.00	51.50	0.33	100.00	30.00
10	6008-175	25.00	1.00	0.50	5.00	51.38	17.13	3.00	100.00	30.00
11	6008-176	25.00	1.00	0.50	15.00	43.88	14.63	3.00	100.00	30.00
12	6008-177	25.00	1.00	0.50	5.00	39.96	28.54	1.40	100.00	36.00
13	6008-178	25.00	1.00	0.50	11.00	46.88	15.63	3.00	100.00	35.97
14	6008-179	25.00	1.00	0.50	5.00	51.38	17.13	3.00	100.00	40.00
15	6008-180	25.00	1.00	0.50	15.00	43.88	14.63	3.00	100.00	30.00
16	6008-181	25.00	1.00	0.50	6.00	49.42	18.08	2.73	100.00	35.00
17	6008-182	25.00	1.00	0.50	8.55	16.12	48.83	0.33	100.00	40.00
18	6008-183	25.00	1.00	0.50	5.00	17.00	51.50	0.33	100.00	30.00
19	6008-184	25.00	1.00	0.50	15.00	39.25	19.25	2.04	100.00	40.00
20	6008-185	25.00	1.00	0.50	5.00	51.38	17.13	3.00	100.00	40.00

FIG. 23