

Table 1. Characteristics of Film Forming Polymers

Nonproprietary Names	Viscosity (cps)	Average Molecular Weight (Daltons)
Carboxymethylcellulose Sodium	1500-2500	90000-700000
Hypromellose 3 cps	3	20000
Hypromellose 6 cps	6	31900
Hypromellose 15 cps	15	58300
Hydroxypropyl Cellulose	250-600	80000
Pullulan	100-180	200000-3000000
Povidone K-30	5.5-8.5	5800
Povidone K-90	300-700	130000

Table 2A. Embodiment example 1-17 with only saccharide-based polymers

Category	Formulation No.	Embodiment examples (wt.%)																
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Effective Ingredient	Ondansetron	10.48	10.48	10.48	10	10	10	10	10	10	10	10	10	10	10	10	10	10
Film Forming Polymers (saccharide-based)	CMC Sodium											5	10					
	HPMC 3 cps				17			34	17								8.5	34
	HPMC 6 cps	22.85		15	51	51	59.5			17		8.5	18	37.5	34		59.5	
	HPMC 15 cps	45.55	65					34	51	51	51	59.5	45	20.5				34
	HPMC 50 cps			15														
	HPC														34	34		
Plasticizer	Pullulan		4.50%	5		17	8.5				17					34		
	PEG 6000	20.43		20.43					20	20	20	20	20					20
	PEG 4000						20							20				
	PEG 400			33.4														
	Glycerol		19.38%		20	20		20							20	20	20	
Flavoring agent	Tween 20																	
	Lemon				1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25	1.25
Coloring Agent	Peppermint Oil	0.25		0.25														
	Blue 1 Alumin-lake	0.1	0.1															
Sweetening Agent	Yellow lake(FD&C)		0.25	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
	Sucralose	0.35	0.35	0.35	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65	0.65

Table 2B. Embodiment example 18-23

Category	Formulation No.	Embodiment examples (wt. %)					
		18	19	20	21	22	23
Effective	Ondansetron	10	10	10	10	10	10
Film Forming Polymers (saccharide-based)	CMC Sodium						
	HPMC 3 cps						
	HPMC 6 cps						
	HPMC 15 cps				59.5	42.5	42.5
	HPC	42.5	51	51			
	Pullulan						
Film Forming Polymers (non	Povidone K-30			17	8.5	25.5	25.5
	Povidone K-90	25.5	17				
Plasticizer	PEG 6000						20
	PEG 4000	20	20				
	PEG 400						
	Glycerol			20	20		
	Tween 20					20	
Flavoring agent	Lemon	1.25	1.25	1.25	1.25	1.25	1.25
	Peppermint Oil						
Coloring Agent	Blue 1 Alumin-						
	Yellow	0.1	0.1	0.1	0.1	0.1	0.1
Sweetening Agent	Sucralose	0.65	0.65	0.65	0.65	0.65	0.65

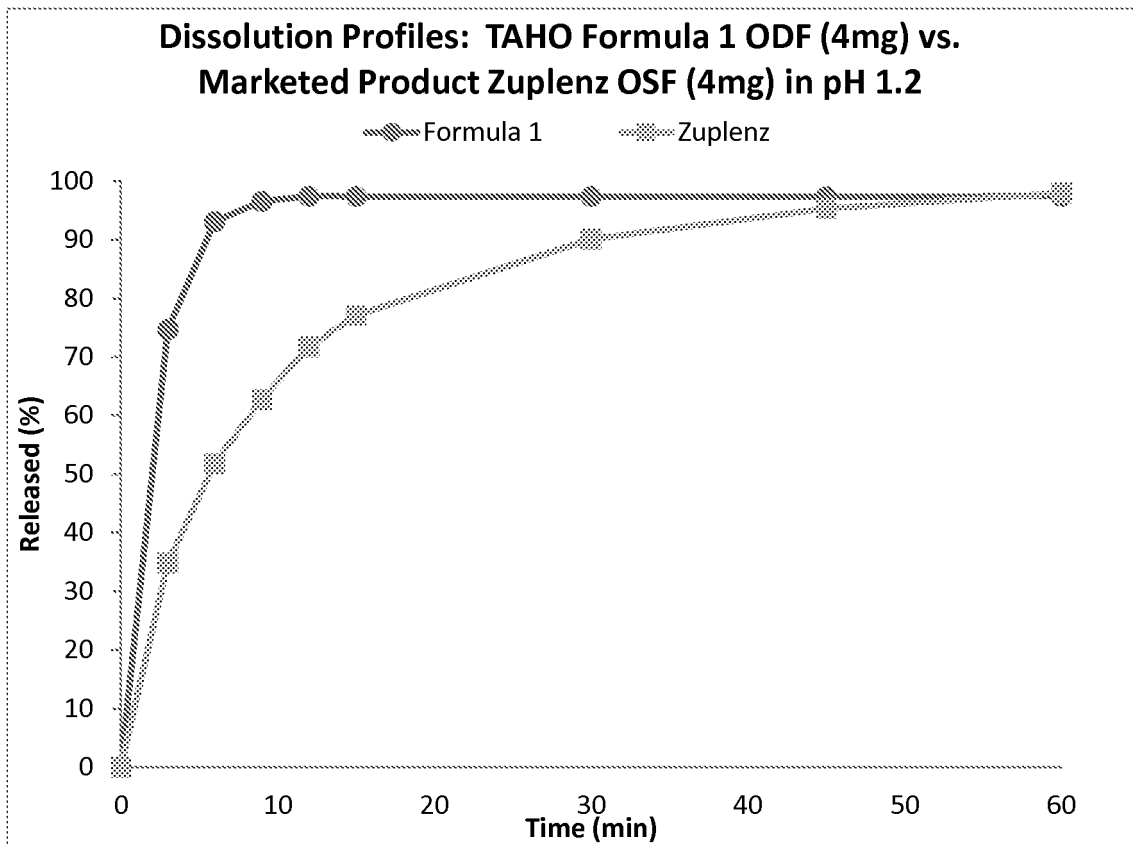


FIGURE 1

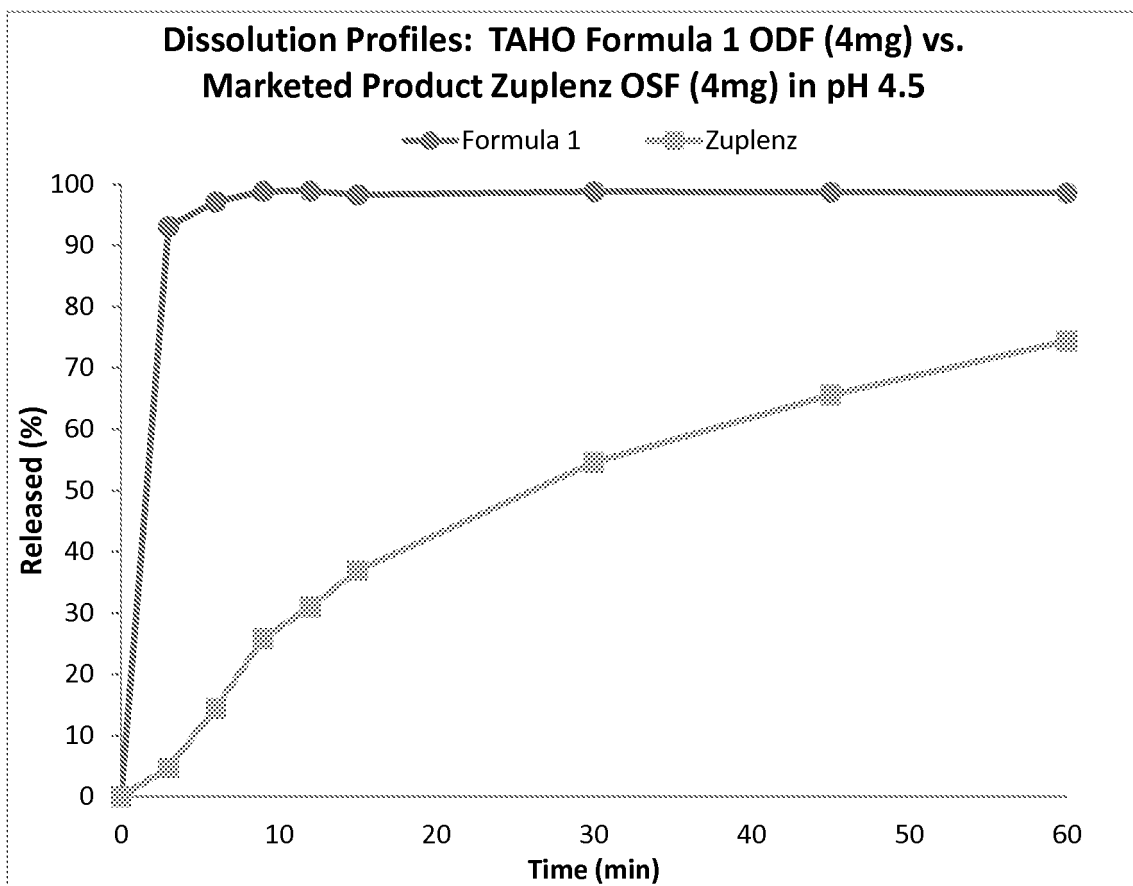


FIGURE 2

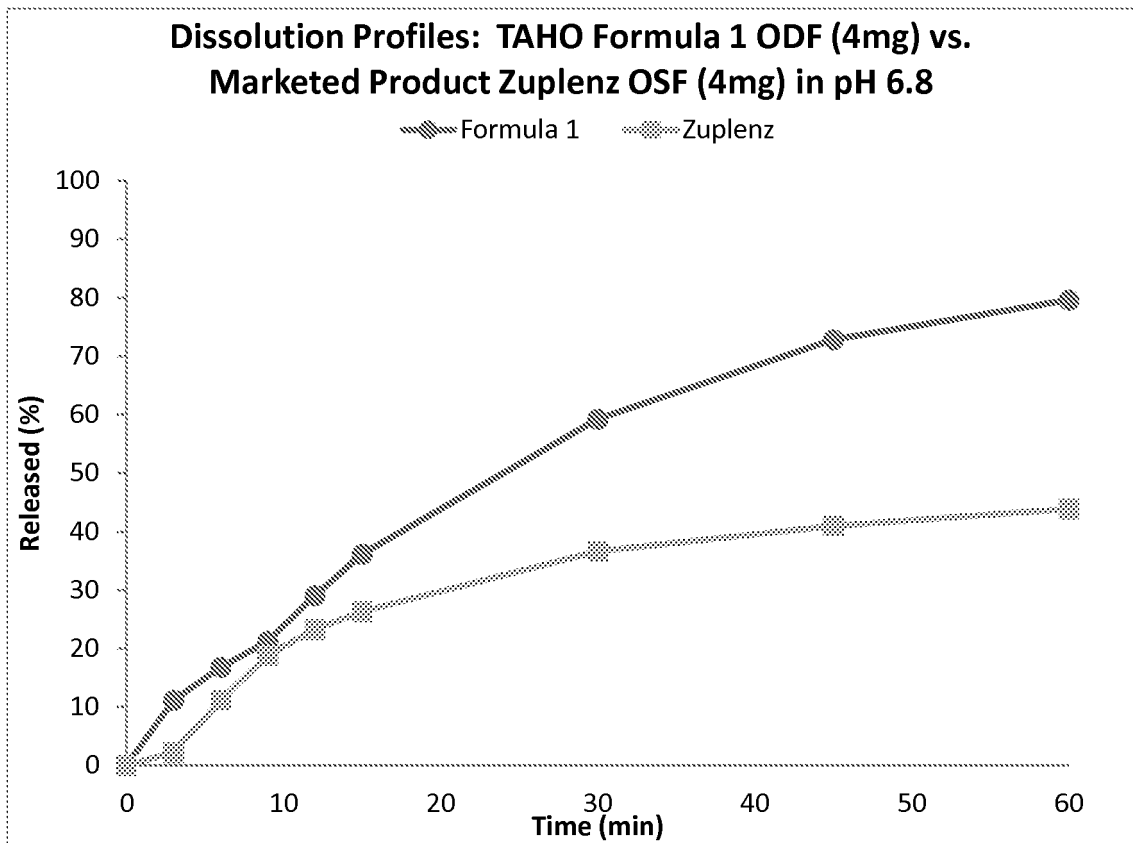


FIGURE 3

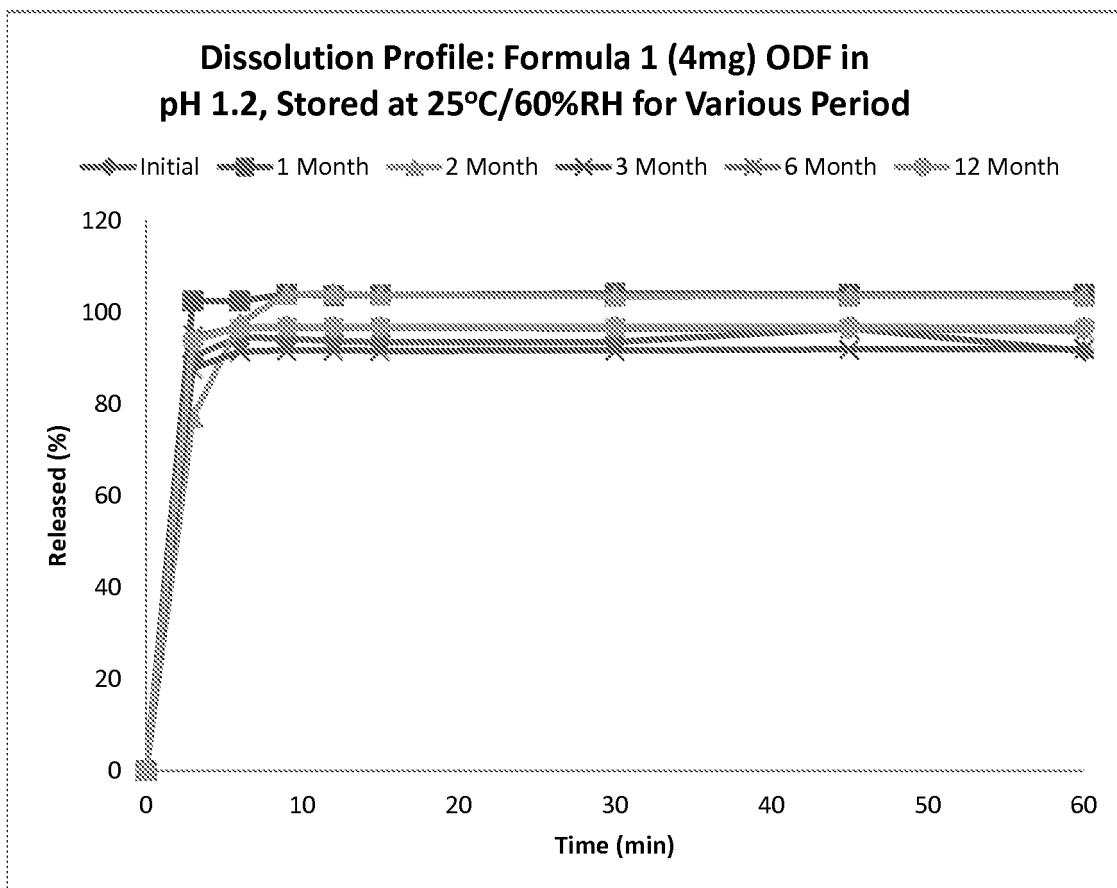


FIGURE 4

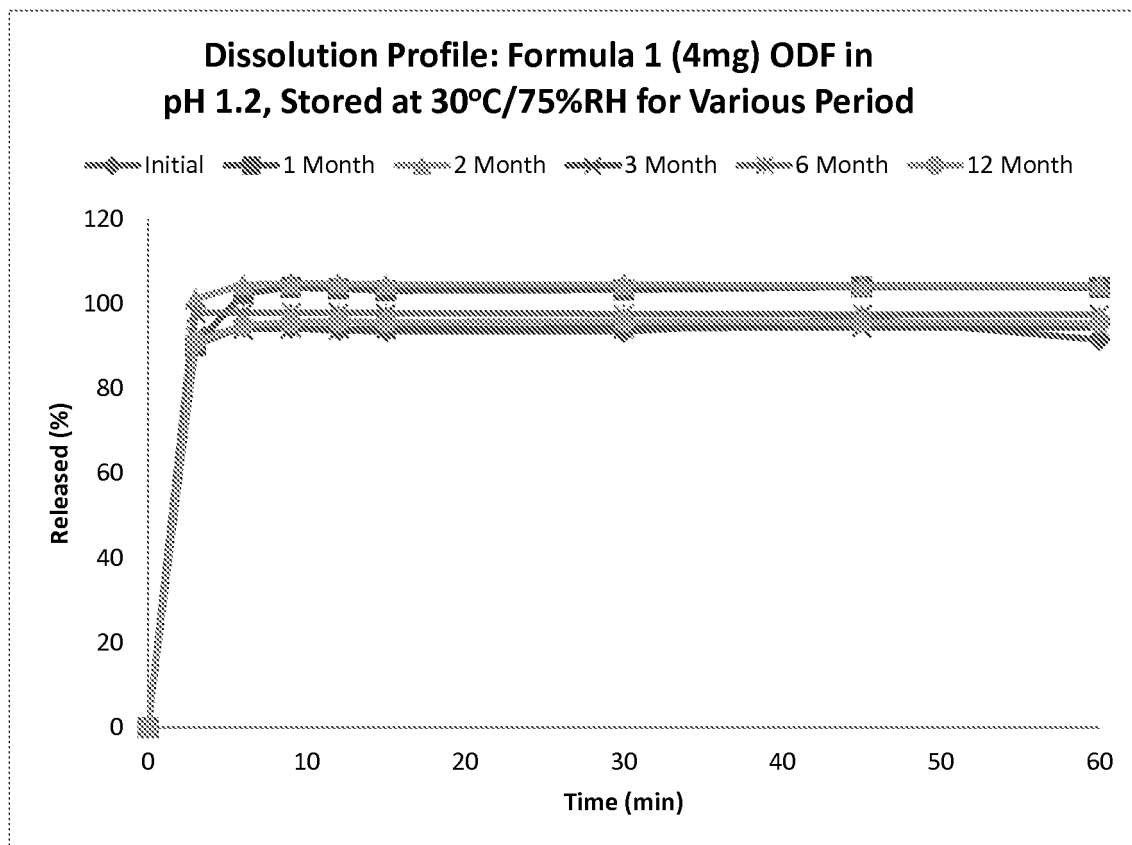


FIGURE 5

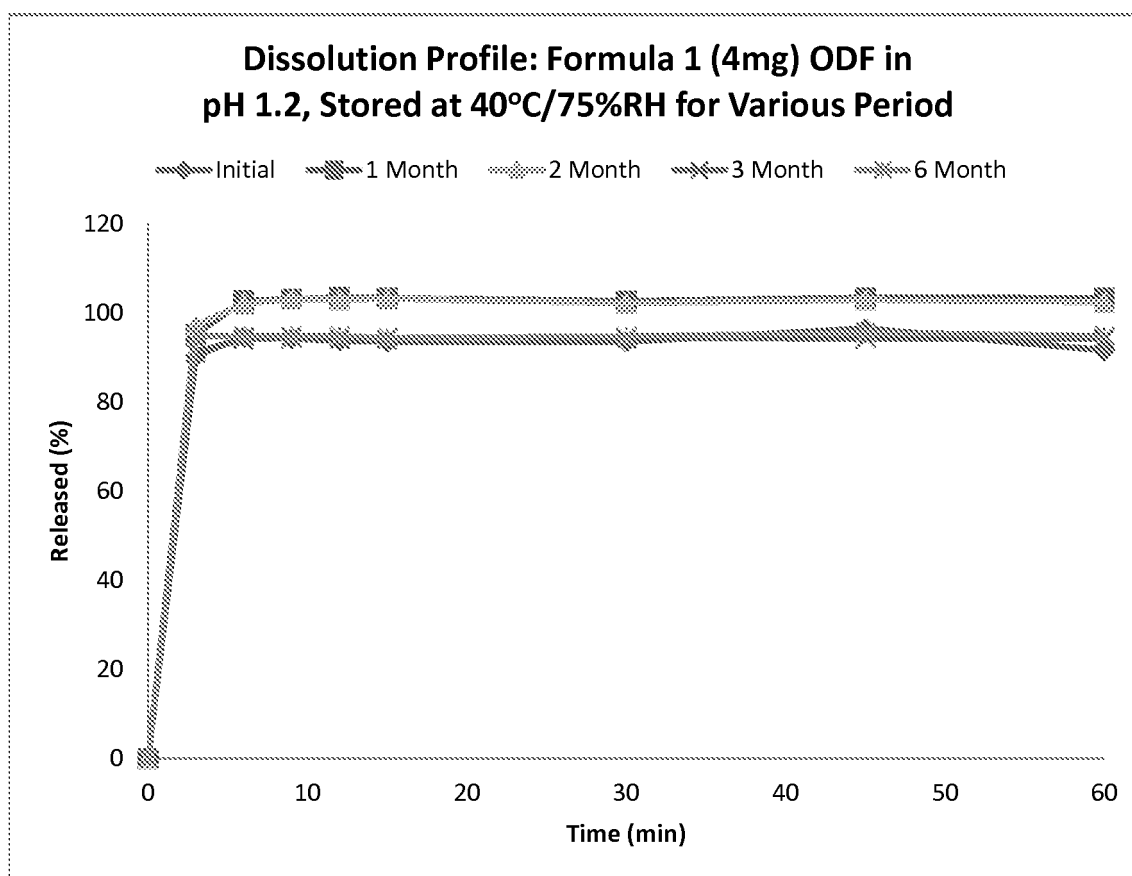


FIGURE 6

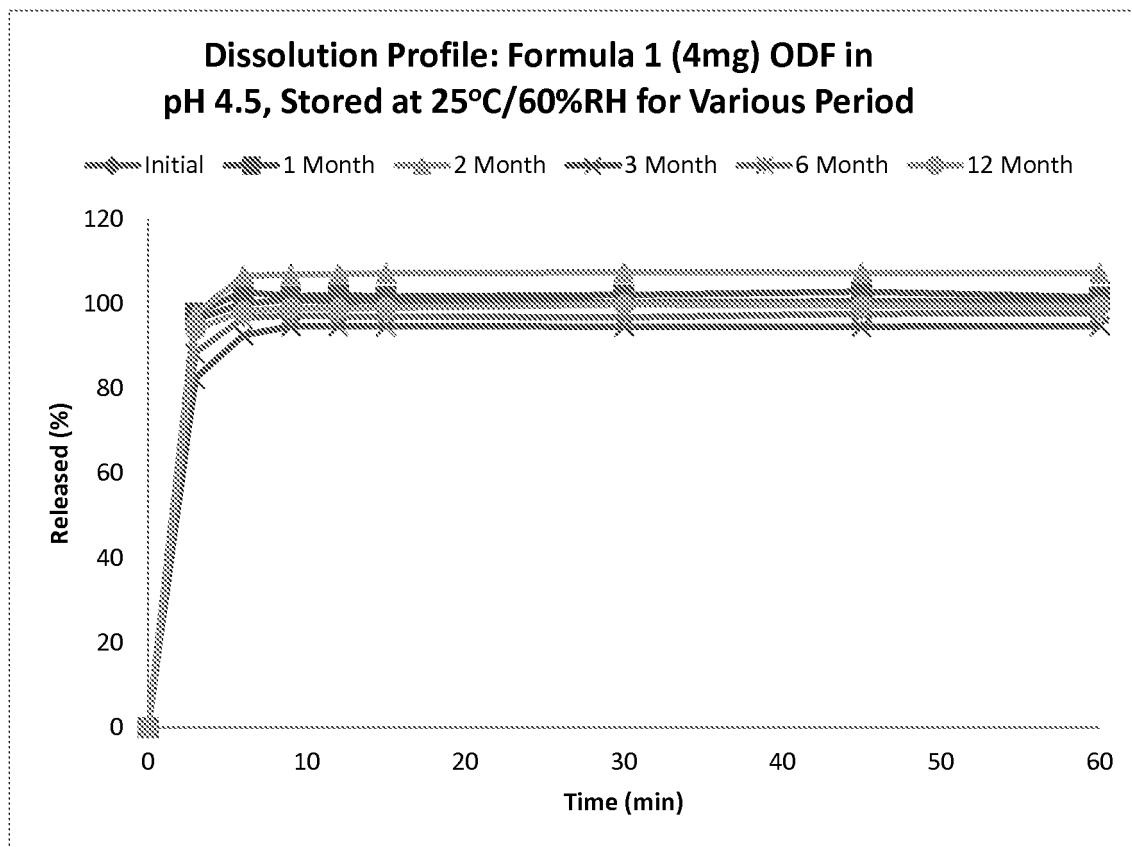


FIGURE 7

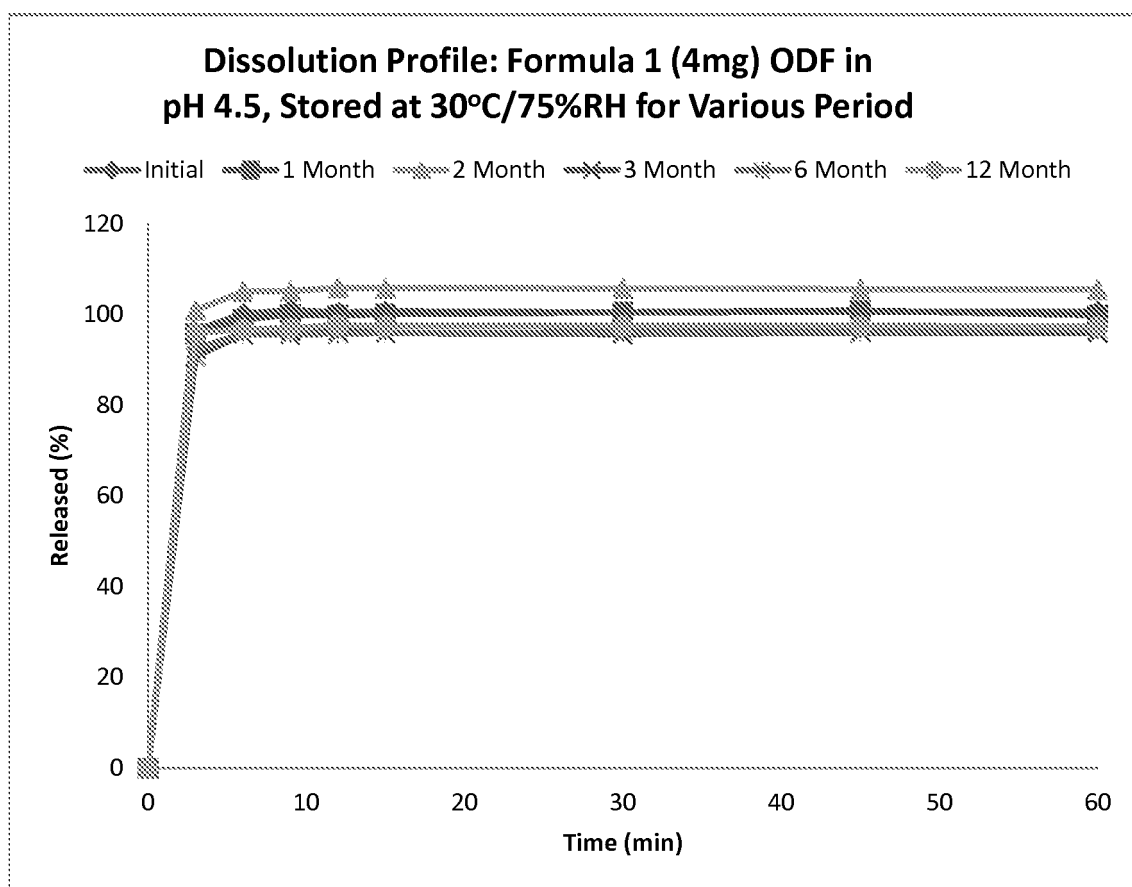


FIGURE 8

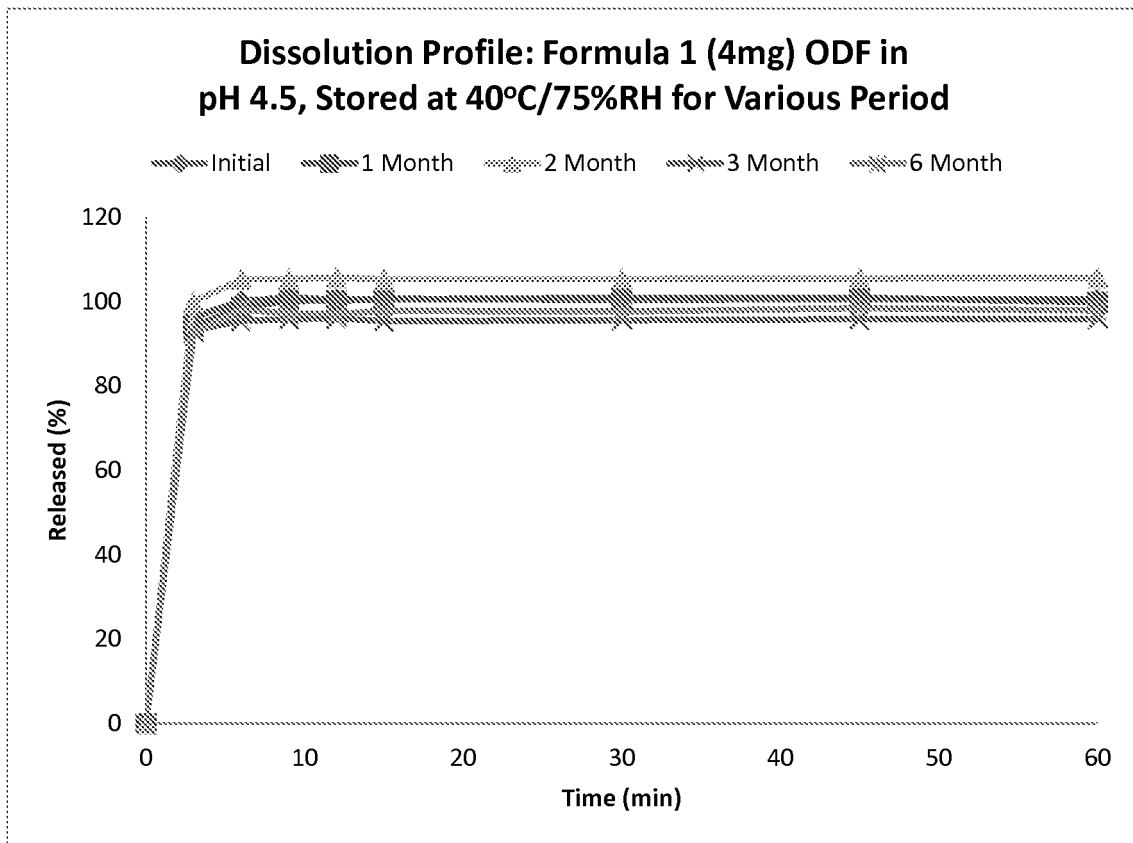


FIGURE 9

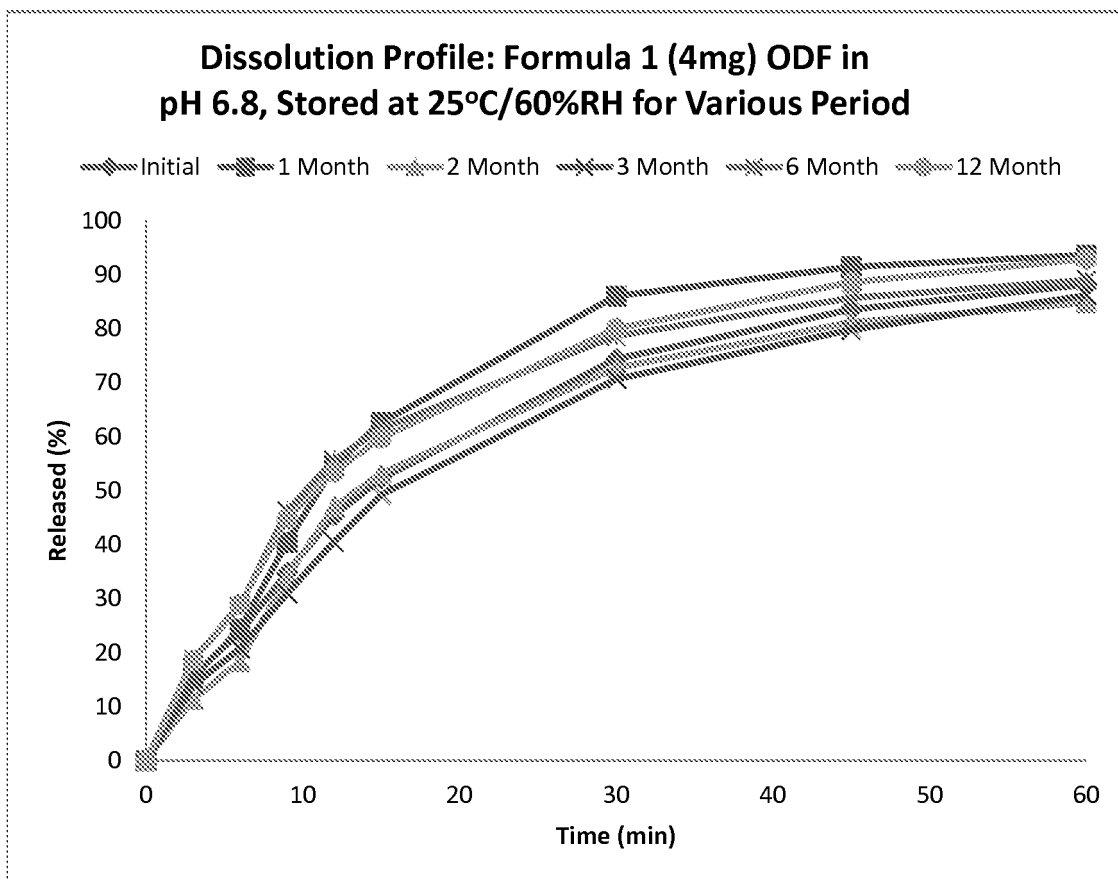


FIGURE 10

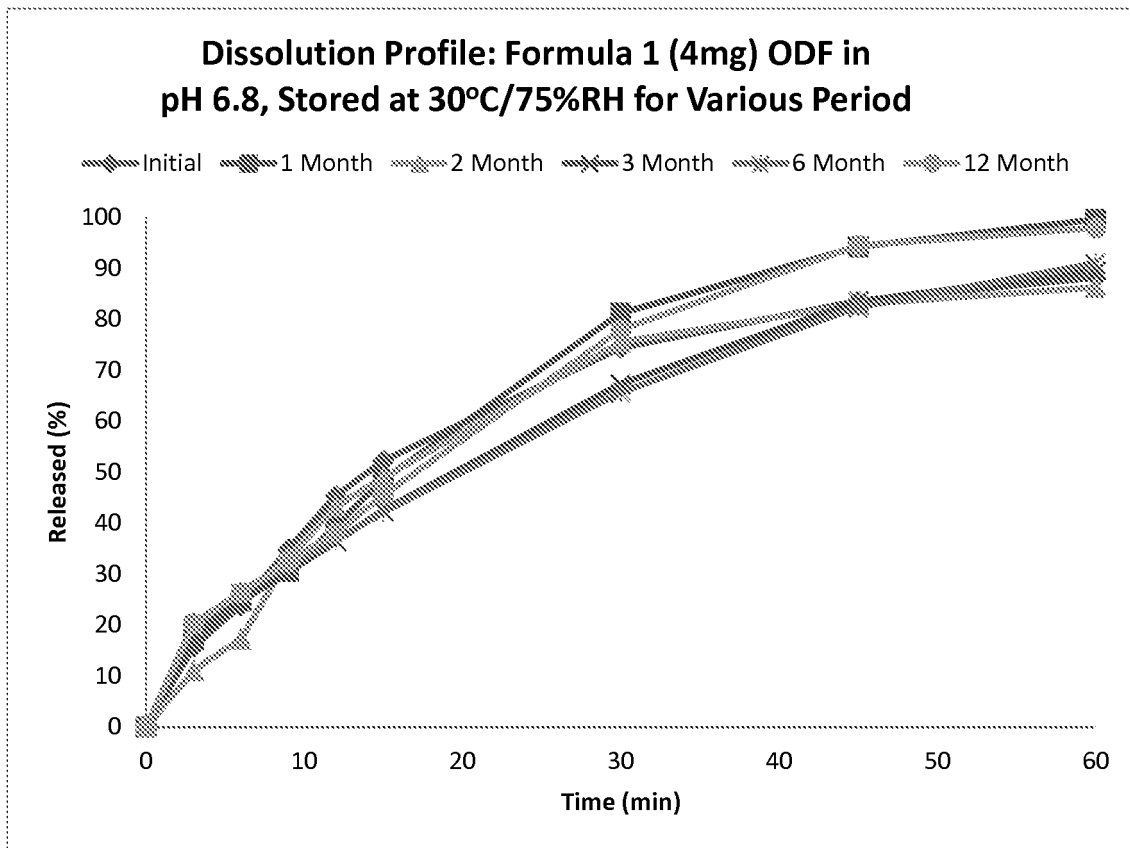


FIGURE 11

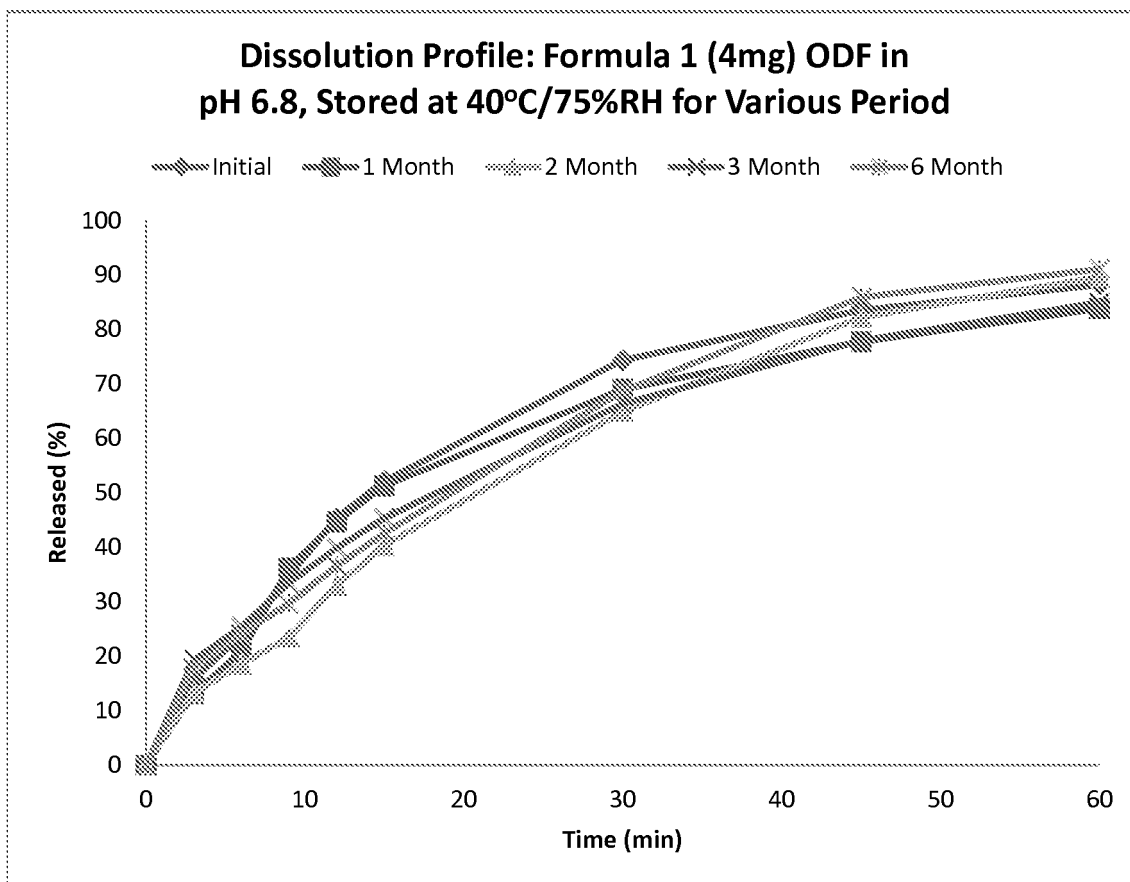


FIGURE 12

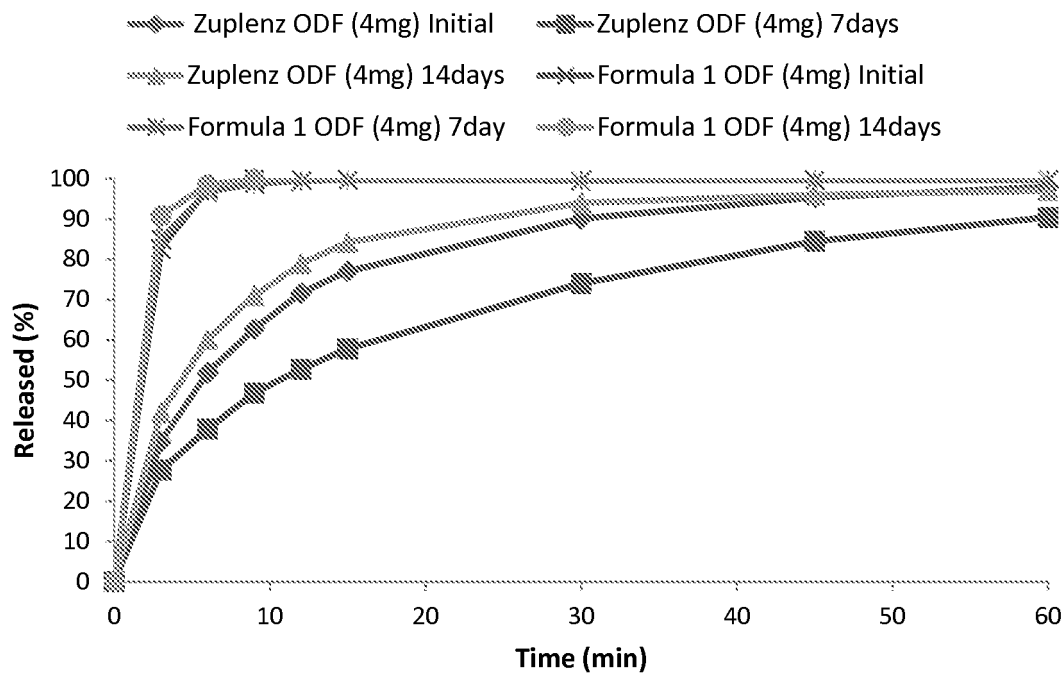
**Dissolution Profiles: Zuplenz OSF vs. TAHO Formula 1
ODF under Stress Condition 60°C/60%RH**

FIGURE 13

Storage Condition	Test Interval	Appearance	Assay	Impurities (% w/w)			
				RRT 0.79	RRT 0.86	RRT 0.92	RRT 1.48
25°C/60%RH	Initial	3 cm x2 cm film	Pass	0.01	ND	ND	ND
	1 month	3 cm x2 cm film	Pass	0.01	ND	ND	ND
	2 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	3 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	6 month	3 cm x2 cm film	Pass	ND	0.06	ND	0.05
	12 month	3 cm x2 cm film	Pass	ND	ND	0.01	ND
30°C/75%RH	1 month	3 cm x2 cm film	Pass	ND	ND	0.01	ND
	2 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	3 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	6 month	3 cm x2 cm film	Pass	ND	0.05	ND	ND
	12 month	3 cm x2 cm film	Pass	ND	ND	0.01	ND
40°C/75%RH	1 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	2 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	3 month	3 cm x2 cm film	Pass	ND	ND	ND	ND
	6 month	3 cm x2 cm film	Pass	ND	0.08	ND	ND

Pass: expressed normal level

ND: Not detected

Table 3

Sample Name	Storage Condition	Test Interval	Assay	Impurities (% w/w)				
				RRT 0.26	RRT 0.36	RRT 0.6	RRT 0.75	RRT 1.15
Formula 4 ODF 4mg	60°C	Initial	Pass	0.01	ND	ND	ND	ND
		7 days	Pass	0.01	ND	ND	0.01	ND
		14 days	Pass	0.01	ND	ND	0.04	ND
Zuplenz ondansetron OSF 4mg	60°C	Initial	Pass	ND	ND	ND	ND	ND
		7 days	Pass	0.06	ND	0.05	ND	0.05
		14 days	Pass	ND	0.02	0.05	ND	0.08
Remark	ND: Not detected							

Table 4

Stress condition	% Drug Released					
60°C /60% RH Sampling Time (min)	Zuplenz Oral soluble film (4mg)			Formula 1 ODF (4mg)		
	Initial	7days	14days	Initial	7days	14days
3	34.88	27.72	41.93	82.81	84.82	90.79
6	51.84	37.89	60.13	97.39	96.76	98.46
9	62.74	46.81	70.92	99.86	98.76	99.89
12	71.68	52.75	78.91	100.28	99.45	100.05
15	77.09	57.82	84.17	100.41	99.68	100.24
30	90.07	74.04	93.98	100.46	99.51	100.08
45	95.31	84.48	95.97	100.45	99.66	100.29
60	97.99	90.38	96.97	100.35	99.61	100.37

Table 5

Embodiment Examples	Viscosity (cps)	Tension force (N)
1	4000-6000	20-30
4	2500-3000	15-20
5	2000-3000	15-20N
7	2500-3500	15-20N
8	4000-6000	20-30N
9	4000-6000	20-30N
10	2500-4000	40-50N
11	4000-6000	40-50N
12	6000-10000	40-50N
16	2500-4000	15-20N
19	3000-4500	25-30N
20	2500-4000	20-30N
21	3000-5000	10-20N
22	2500-3500	5-15N
23	2500-3000	10-20N
Zuplenz OSF	NA	3-20N

Table 6