WetMill Conpact

Formulation Guide

Fagron lab

This guide contains general information regarding different types of formulations that were previously tested using the WetMill Compact technology.

Compounding Instructions

1. Obtain the appropriate materials necessary to compound the oral liquid formulation according to the yield and concentration provided in the prescription.
2. Label the bottle with the appropriate label and weigh the bottle without the cap. Tare the scale.
3. Place the active ingredients (powder, tablets, or capsules) into the bottle.
4. Add the purified water, USP, to the correct weight.
5. Immediately cap the bottle, swirl the contents gently for about 20 seconds, and then place the bottle in the WetMill Compact. Add counterweight bottle(s) as necessary.
6. Select the milling cycle on the WetMill Compact and press the “Start” button. When the unit signals the end of the cycle, remove the bottle(s) from the unit.
7. Agitate the contents for about 20 seconds by inverting the bottle, swirling the contents, and shaking vigorously. Always ensure that any milled material adhering to the top portion of the bottle is dislodged and re-suspended. Invert the bottle and observe the contents through the upper portion of the bottle. Ensure that there are no large, non-milled particles. If large, non-milled particles are observed, repeat step 6.
8. Uncap the bottle and add SyrSpend powder (SyrSpend® SF PH4 NEO (preserved), SyrSpend® SF PH4 dry, or SyrSpend® SF Alka) to the bottle and shake.
9. Deliver to the patient, remove an aliquot, or unit dose as directed.

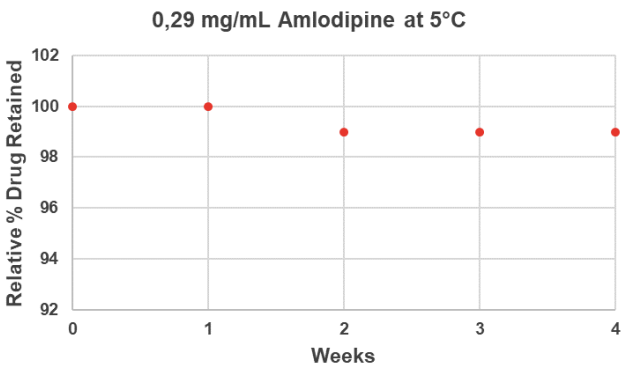
Amlodipine Besylate

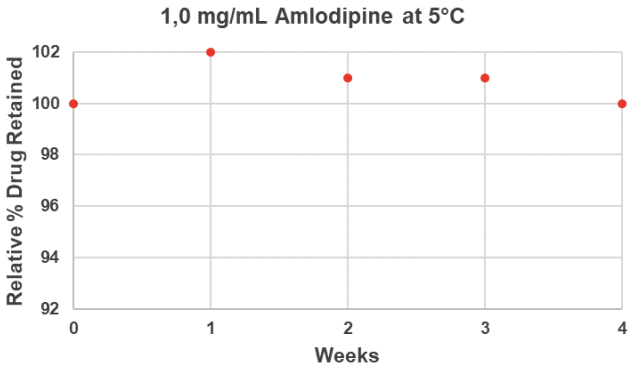
Compounded Formulas - 0.29 and 1 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
0.29	35	5 mg	2	33	70
1	35	5 mg	7	33	70
0.29	70	5 mg	4	66	70
1	70	5 mg	14	66	70
0.29	105	5 mg	6	99	120
1	105	5 mg	21	99	120

Formulas were compounded using amlodipine besylate tablets, containing colloidal silicon dioxide, dibasic calcium phosphate anhydrous, FD&C Blue No. 2 Aluminium Lake, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, and Type A potato sodium starch glycolate.

Representative Stability Graphs





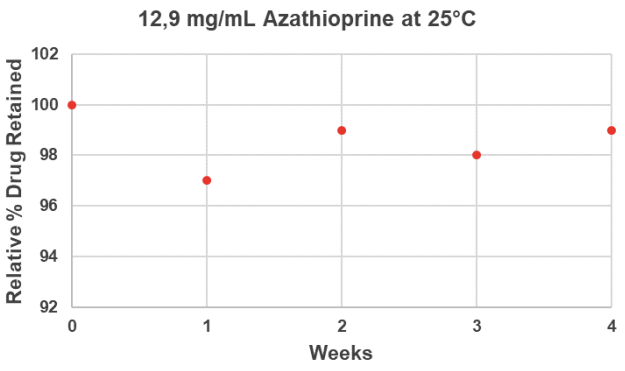
Azathioprine

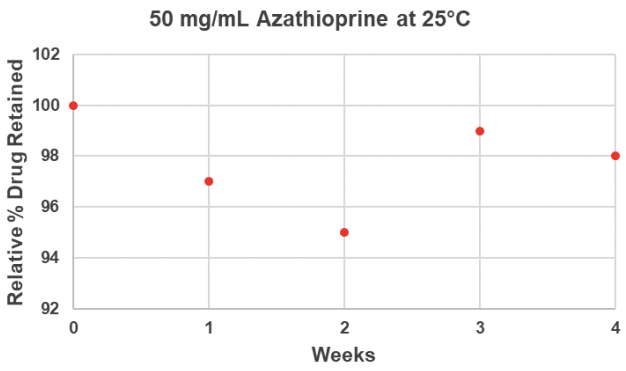
Compounded Formulas - 12.9 and 50 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
12.9	35	50 mg	9	32.8	70
50	35	50 mg	35	34.8	70
12.9	70	50 mg	18	65.6	70
50	70	50 mg	70	69.6	70
12.9	105	50 mg	27	98.4	120
50	105	50 mg	105	104.4	120

Formulas were compounded using 50 mg tablets, containing corn starch, lactose monohydrate, magnesium stearate, povidone, stearic acid.

Representative Stability Graphs





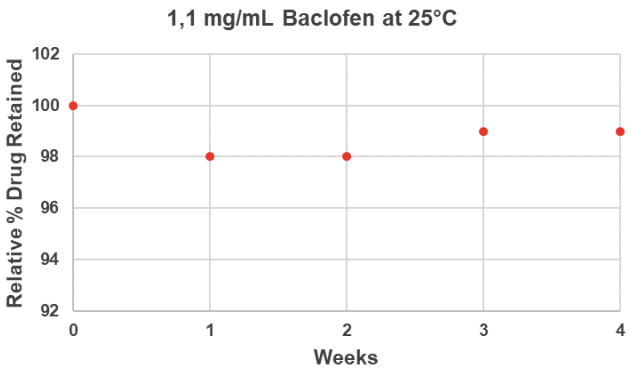
Baclofen

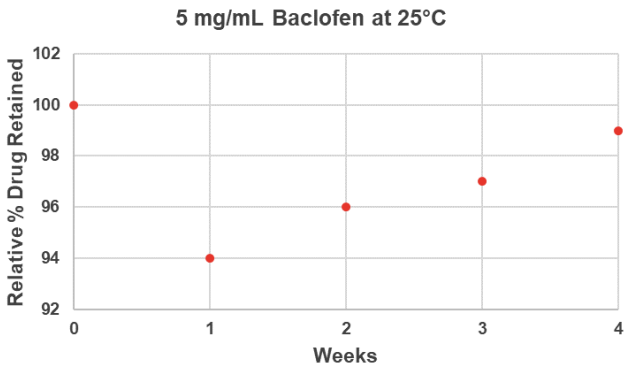
Compounded Formulas - 1.1 and 5 mg/mL

mg/mL	Yield (mL)	Strength	Number	Q.S with Water to (grams)	Bottle Size (mL)
1.1	36	20 mg tablets	2	33.8	70
5	36	API	180 mg	37.4	70
1.1	72	20 mg tablets	4	67.6	120
5	72	API	360 mg	74.8	120
1.1	108	20 mg tablets	6	101.4	120
5	108	API	540 mg	112.2	120

Formulas were compounded using pure API and tablets containing microcrystalline cellulose, corn starch, silicon dioxide, and magnesium stearate.

Representative Stability Graphs





Clonidine HCl

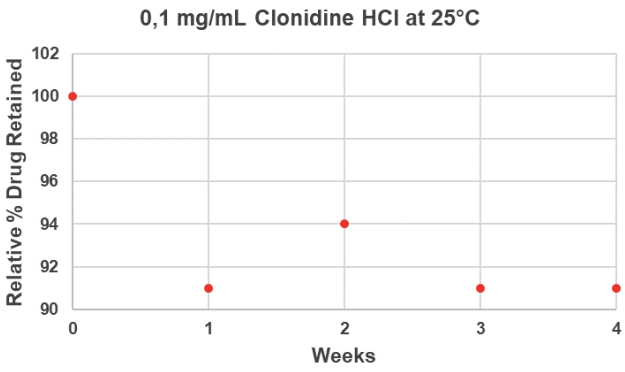
Compounded Formulas - 0.1 and 1 mg/mL

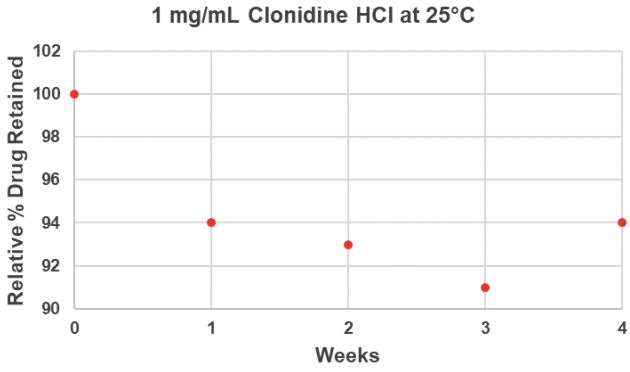
mg/mL	Yield (mL)	Strength	Number	Q.S. with Water to (grams)	Bottle Size (mL)
0.1	36	0.3 mg tablets	12	34.5	70
1	35	API	1 mL of a 35 mg/mL compound	36.4	70
0.1	72	0.3 mg tablets	24	69	120

mg/mL	Yield (mL)	Strength	Number	Q.S. with Water to (grams)	Bottle Size (mL)
1	70	API	2 mL of a 35 mg/mL compound	72.8	70
0.1	108	0.3 mg tablets	36	103.5	120
1	105	API	3 mL of a 35 mg/mL compound	109.2	120

The 0.1 mg/mL formulation was compounded using 0.3 mg clonidine HCl commercial tablets containing colloidal silicon dioxide, corn starch, dibasic calcium phosphate, sodium starch glycolate, glycerine, lactose monohydrate, magnesium stearate, povidone. The 1 mg/mL formulation was compounded using pure API. Formulations were not corrected for HCl percentage.

Representative Stability Graphs





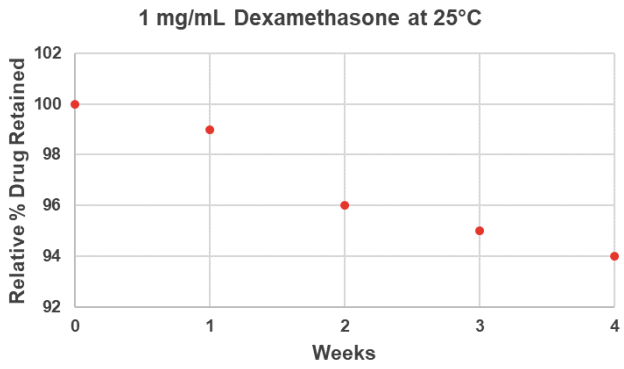
Dexamethasone

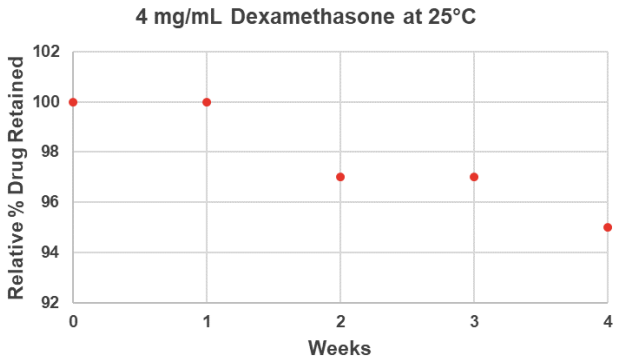
Compounded Formulas - 1 and 4 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
1	36	6 mg	6	34	70
4	36	6 mg	24	34	70
1	72	6 mg	12	68	120
4	72	6 mg	48	68	120
1	108	6 mg	18	102	120
4	108	6 mg	72	102	120

Formulas were compounded using tablets containing lactose monohydrate, magnesium stearate, corn starch, sucrose, and FD&C green nº. 3, cosmetic ochre, D&C Yellow nº 10, FD&C Blue nº 1, FD&C Red nº 3, FD&C Red nº 40, and FD&C Yellow nº 6.

Representative Stability Graphs





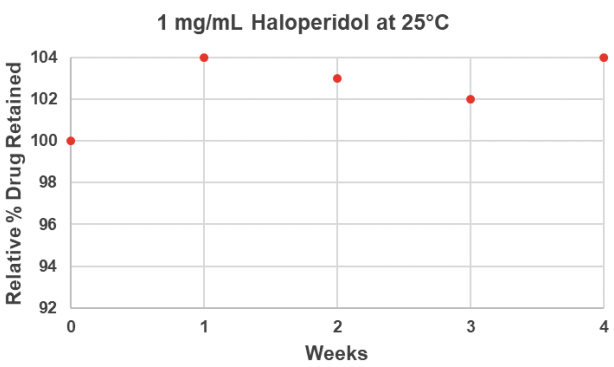
Haloperidol

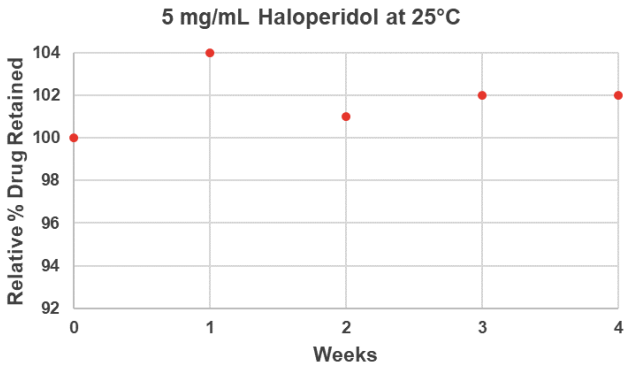
Compounded Formulas - 1 and 5 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
1	35	5 mg	7	33	70
5	36	20 mg	9	34	70
1	70	5 mg	14	66	70
5	72	20 mg	18	68	120
1	105	5 mg	21	99	120
5	108	20 mg	27	102	120

Formulas were compounded using tablets containing calcium stearate, dibasic calcium phosphate dihydrate, povidone (PVP K30), sodium starch glycolate, starch, and colorings as excipients.

Representative Stability Graphs





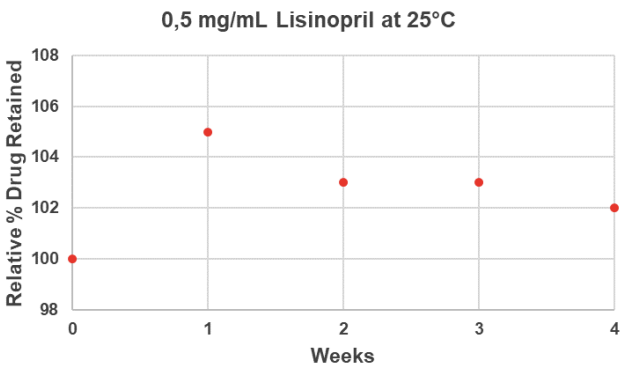
Lisinopril

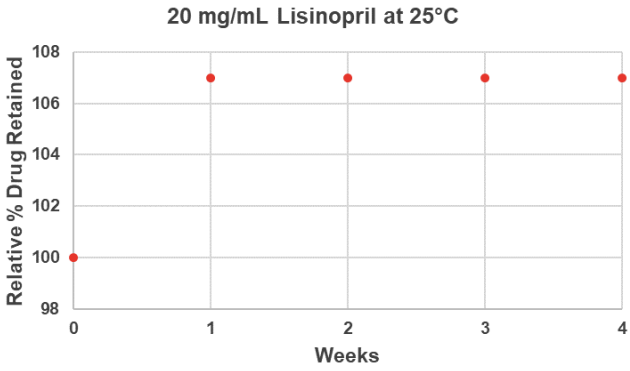
Compounded Formulas - 0.5, 2, and 20 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
0.5	35	2.5 mg	7	32.8	70
2	35	10 mg	7	32.8	70
20	34	40 mg	17	31.7	70
0.5	70	2.5 mg	14	65.6	70
2	70	10 mg	14	65.6	70
20	68	40 mg	34	63.4	70
0.5	105	2.5 mg	21	98.4	120
2	105	10 mg	21	98.4	120
20	102	40 mg	51	95.1	120

Formulas compounded using 2.5 mg tablets, containing corn starch, dibasic calcium phosphate dihydrate, magnesium stearate, mannitol, and talc.
Formulas were also compounded using 10 mg tablets containing silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, dihydrate, magnesium stearate, mannitol, povidone, corn starch, sodium lauryl sulfate.
Formulas were also compounded using 40 mg tablets containing silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, magnesium stearate, mannitol, povidone, corn starch, sodium lauryl sulfate, FD&C Blue nº 2, and FD&C Yellow nº 10.

Representative Stability Graphs





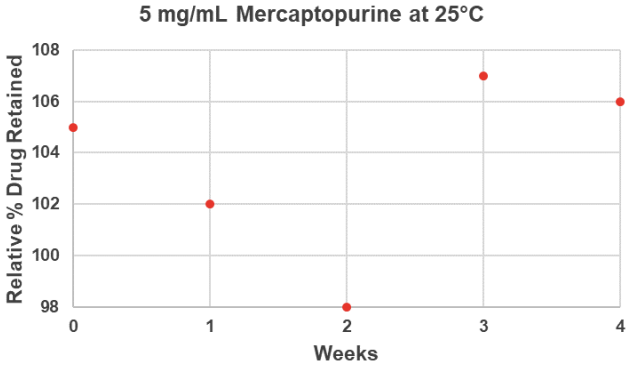
6-Mercaptopurine

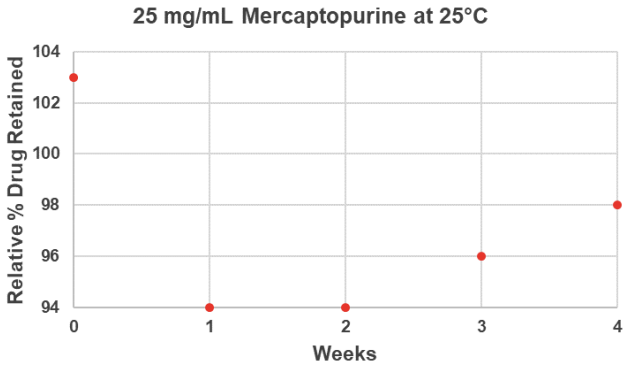
Compounded Formulas - 5 and 25 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
5	40	50 mg	4	37.7	70
25	34	50 mg	17	34	70
5	80	50 mg	8	75.4	120
25	68	50 mg	34	68	70
5	120	50 mg	12	113.1	120
25	102	50 mg	51	102	120

Formulas were compounded using 50 mg Mercaptopurine commercial tablets containing corn starch, lactose monohydrate, magnesium stearate, pregelatinized starch (corn), and sodium lauryl sulfate.

Representative Stability Graphs





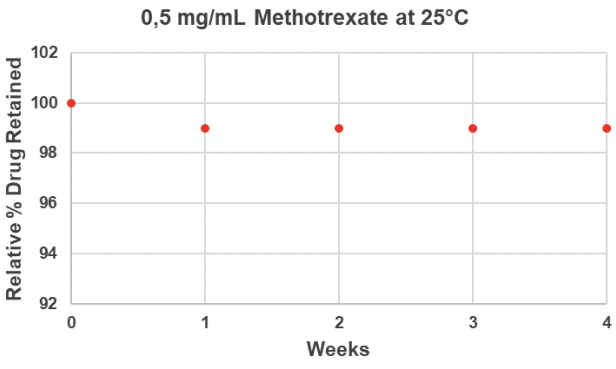
Methotrexate

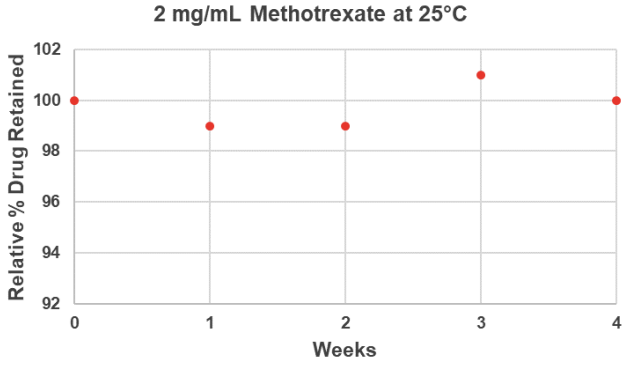
Compounded Formulas - 0.5 and 2 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Sodium Bicarbonate Solution (40 mg/mL)	Q.S with Water to (grams)	Bottle Size (mL)
0.5	35	2.5 mg	7	2 mL	32.8	70
2	35	2.2 mg	28	1.2 mL	32.8	70
0.5	70	2.5 mg	14	4 mL	65.6	70
2	70	2.5 mg	54	2.4 mL	65.6	70
0.5	105	2.5 mg	21	6 mL	98.4	120
2	105	2.5 mg	84	3.6 mL	98.4	120

Formulas were compounded using 2.5 mg tablets, containing colloidal silicon dioxide, FD&C Red nº 40 Aluminium Lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch (corn), sodium carbonate (monohydrate), sodium lauryl sulfate, and sodium starch glycolate.
Before the QS step, sodium bicarbonate is added to the compound using a 40mg/mL solution in water to prevent degradation of the methotrexate. The sodium bicarbonate should be added to increase pH to approximately 6.1. Specific volumes to be added are in the corresponding table. The final pH should be confirmed.

Representative Stability Graphs





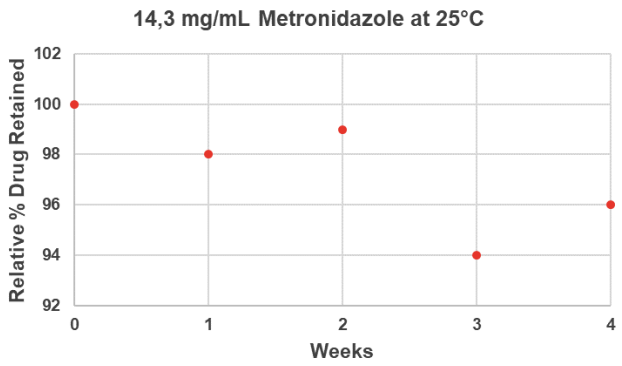
Metronidazole

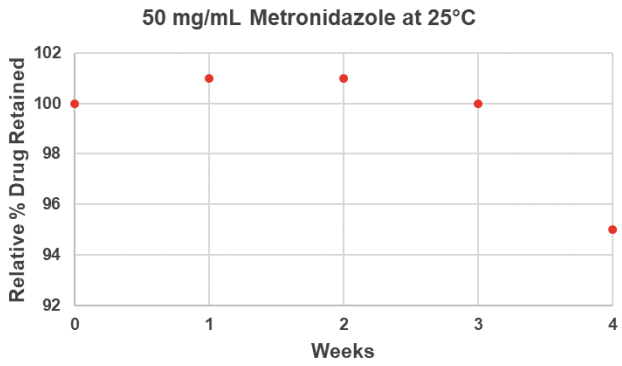
Compounded Formulas - 14.3 and 50 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
14.3	35	250 mg	2	32.8	70
50	35	250 mg	7	32.8	70
14.3	70	250 mg	4	65.6	70
50	70	250 mg	14	65.6	70
14.3	105	250 mg	6	98.4	120
50	105	250 mg	21	98.4	120

Formulas were compounded using tablets containing silicified microcrystalline cellulose, crospovidone, colloidal silicon dioxide and hydrogenated cottonseed oil.

Representative Stability Graphs





Rifampin

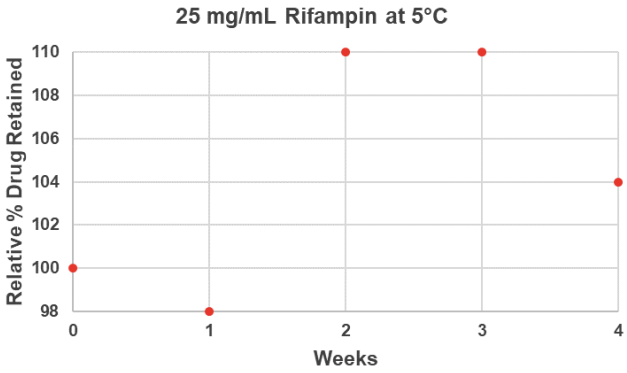
Compounded Formulas - 25 and 60 mg/mL

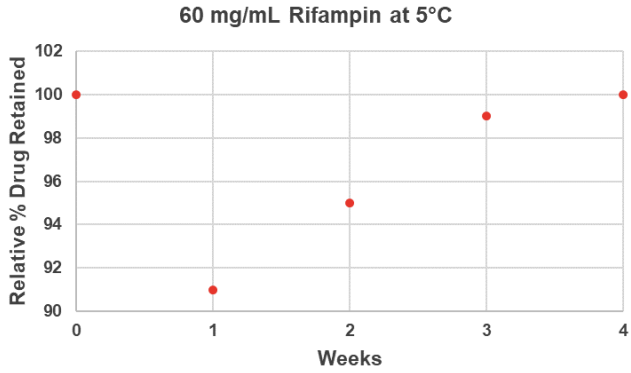
mg/mL	Yield (mL)	Capsule Strength	Capsule Number	Amount of Simethicone (0.2%w/w) (mL)	Q.S with Water to (grams)	Bottle Size (mL)
25	36	300 mg	3	0.08	37.4	70
60	35	300 mg	7	0.07	36.4	70
25	72	300 mg	6	0.16	74.8	120
60	70	300 mg	14	0.14	72.8	70

mg/mL	Yield (mL)	Capsule Strength	Capsule Number	Amount of Simethicone (0.2%w/w) (mL)	Q.S with Water to (grams)	Bottle Size (mL)
25	108	300 mg	9	0.24	112.2	120
60	105	300 mg	21	0.21	109.2	120

Formulas were compounded using 300 mg capsules containing corn starch, silicon dioxide, talc, magnesium stearate, gelatine, titanium dioxide, D&C red nº 28, FD&C red nº 40, FD&C blue nº 1, shellac, alcohol, ferrosoferric oxide, butyl alcohol, propylene glycol, methyl alcohol, aluminum oxide, FD&C blue nº 2, D&C yellow nº 10.

Representative Stability Graphs





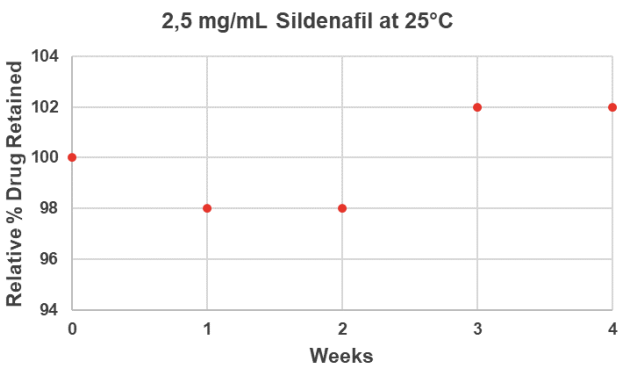
Sildenafil

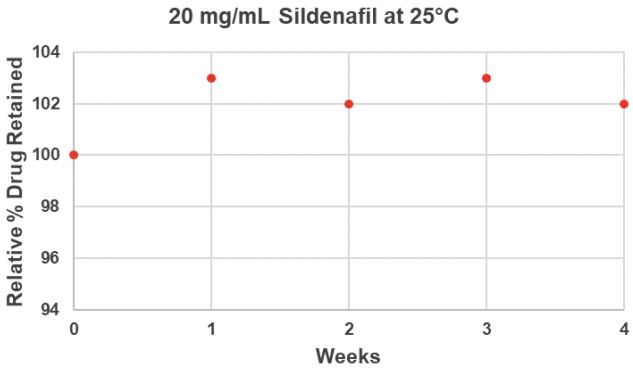
Compounded Formulas - 2.5 and 20 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S. with Water too (grams)	Bottle Size (mL)
2.5	40	20 mg	5	38.2	70
20	35	20 mg	35	33.0	70
2.5	80	20 mg	10	76.4	120
20	70	20 mg	70	66.0	70
2.5	120	20 mg	15	114.6	120
20	105	20 mg	105	99.0	120

Formulas were compounded using 20 mg sildenafil commercial tablets containing microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, mag. stearate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol, and titanium dioxide.

Representative Stability Graphs





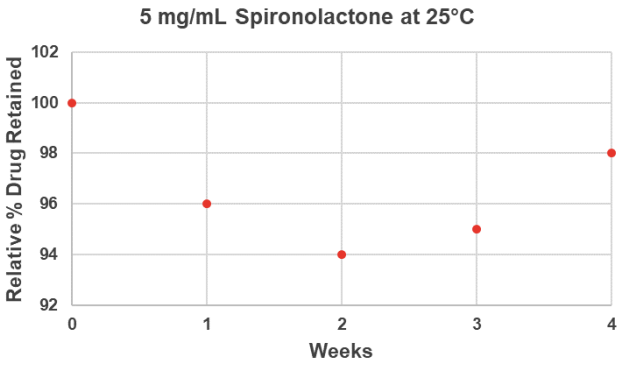
Spironolactone

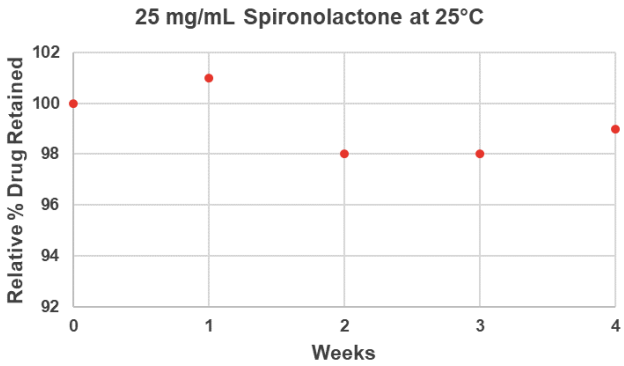
Compounded Formulas - 5 and 25 mg/mL

mg/ml	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
5	35	25 mg	7	32.8	70
25	36	100 mg	9	35	70
5	70	25 mg	14	65.6	70
25	72	100 mg	18	70	120
5	105	25 mg	21	98.4	120
25	108	100 mg	27	105	120

The 5 mg/mL suspensions were compounded using 25 mg immediate-release tablets, containing anhydrous lactose, silicon dioxide, crospovidone (15 MPA.S AT 5%), docusate sodium, sodium benzoate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate type A potato, peppermint.
The 25 mg/mL suspensions were compounded using 100 mg immediate-release tablets containing calcium sulfate, corn starch, hypromellose, magnesium stearate, povidone, titanium dioxide, ferric oxide red, ferric oxide yellow, ferrosoferric oxide, polyethylene glycols, peppermint.

Representative Stability Graphs





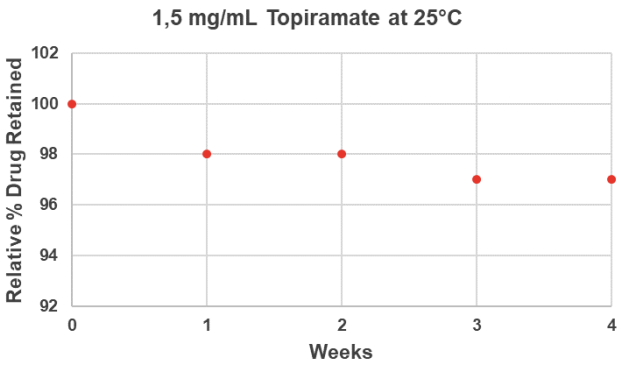
Topiramate

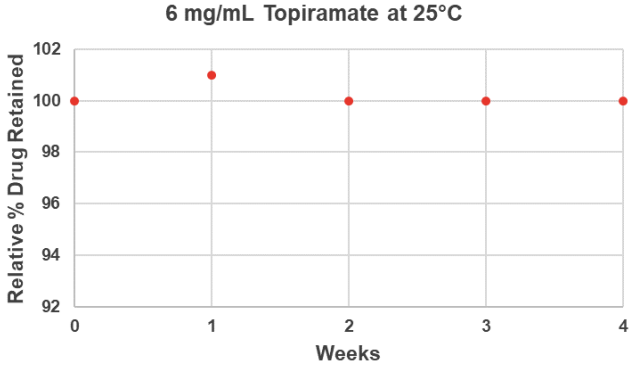
Compounded Formulas - 1.5 and 6 mg/mL

mg/mL	Yield (mL)	Tablet Strength	Tablet Number	Q.S with Water to (grams)	Bottle Size (mL)
1.5	33.3	25 mg	2	31.2	70
6	37.5	25 mg	9	35.6	70
1.5	66.6	25 mg	4	62.4	70
6	75	25 mg	18	71.2	120
1.5	100	25 mg	6	93.6	120
6	112.5	25 mg	27	106.8	120

Formulas were compounded using tablets containing hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, sodium starch glycolate, and titanium dioxide.

Representative Stability Graphs





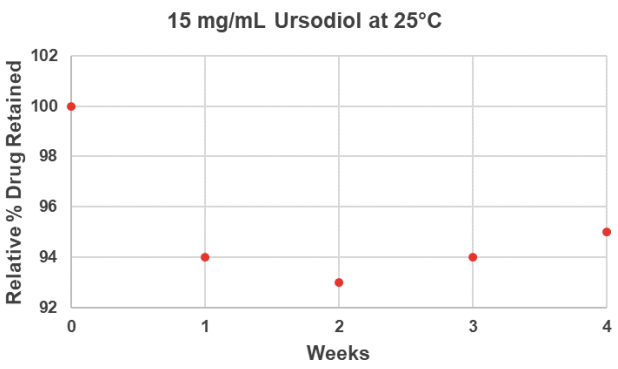
Ursodiol

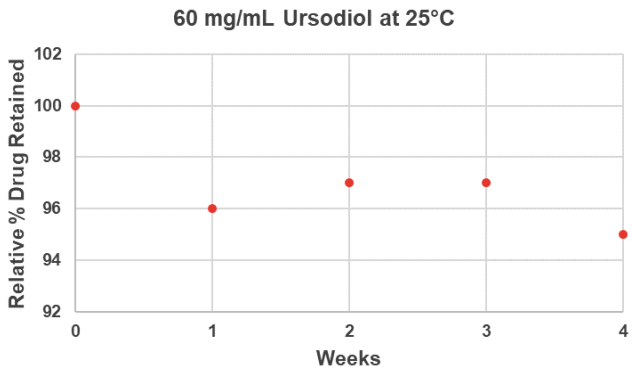
Compounded Formulas - 15 and 60 mg/mL

mg/mL	Yield (mL)	Strength	Number	Q.S with Water to (grams)	Bottle Size (mL)
15	33.3	250 mg tablets	2	31	70
60	35	300 mg capsules	7	36.6	70
15	66.6	250 mg tablets	4	62	70
60	70	300 mg capsules	14	73.2	70
15	100	250 mg tablets	6	93	120
60	105	300 mg capsules	21	109.8	120

Formulas were compounded using 250 mg immediate-release tablets containing microcrystalline cellulose, povidone K29/32, polyethylene glycol 3350, magnesium stearate, hypromellose, ethylcellulose, dibutyl sebacate, polyethylene glycol 8000, carnauba wax, and sodium starch glycolate type a potato.
Formulas were also compounded using 300 mg capsules containing silicon dioxide, ferric oxide red, gelatine, magnesium stearate, corn starch, and ferrosoferric oxide.

Representative Stability Graphs





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