

Stearate (MYRJ 52). Various samples of the composition were stored for 1 week, 2 weeks, 1 month, 2 months, and 3 months, respectively, at 25° C., 40° C. and 50° C., respectively at ambient humidity. All were resuspendable upon light shaking at all times for about 30 seconds or less.

EXAMPLE 14

A more detailed stability analysis was undertaken of the formulation using docusate sodium at 0.04% from Table 5 in Example 6. The results are shown in TABLE 7 below:

TABLE 7

Analysis	Specifications	Initial	1 month (40° C./75% RH)	2 month (40° C./75% RH)	3 month (40° C./75% RH)	3 month (25° C./60% RH)	6 month (25° C./60% RH)	9 month (25° C./60% RH)
Megestrol Acetate	40 mg/mL	98.9%	99.7%	99.6%	98.8%	99.2%	97.5% (U) 98.3% (I)	98.4% (U) 98.0% (I)
Particle Size	TBD	90% < 13 um 50% < 7 um 10% < 1 um	90% < 14 um 50% < 6 um 10% < 1 um	90% < 14 um 50% < 6 um 10% < 1 um	90% < 16 um 50% < 8 um 10% < 1 um	90% < 16 um 50% < 8 um 10% < 1 um	U: 90% < 9 I: 90% < 12 U: 50% < 4 I: 50% < 6 U/I: 10% < 1 (U/I):4.1	U: 90% < 15 I: 90% < 16 U: 50% < 8 I: 50% < 9 U/I: 10% < 1 (u/I):4.0
pH	3.5-5.5	4.1	4.0	4.0	3.9	4.1	(U/I) White suspension	(U/I) White suspension
Appearance	White to off-white suspension	White suspension	White suspension	White suspension	White suspension	White suspension	(U/I) White suspension	(U/I) White suspension
Viscosity (cps)	75-300	175	157	152	147	161	(U) 178.5 (I) 177.0	(U) 152 (I) 156

(U) = bottle upright
(I) = bottle inverted

EXAMPLE 15

Another detailed stability analysis was undertaken of the formulation using docusate sodium at 0.01% prepared according to a "two pot" manufacturing process. The results are shown in TABLE 8 below:

TABLE 8

Analysis	Specifications	Initial	1 month (40° C./75% RH)	2 month (40° C./75% RH)	3 month (40° C./75% RH)	3 month (25° C./60% RH)
Megestrol Acetate	40 mg/mL	Beg- 97.2% Mid-101.6% End-99.3%	100.7% (U) 101.0% (I)	95.8% (U) 100.0% (I)	97.7% (U) 96.5% (I)	98.5% (U) 98.0% (I)
Particle Size (U/I) (microns)	TBD	90% < 15 um 50% < 8 um 10% < 1 um	90% < 12 um 50% < 6 um 10% < 1 um	90% < 16 um 50% < 9 um 10% < 1 um	90% < 18 um 50% < 10 um 10% < 2 um	90% < 17 um 50% < 10 um 10% < 1 um
PH (U/I)	3.5-5.5	4.1	4.1	4.0	4.0	4.1
Appearance	White to off-white suspension	White suspension	White suspension	White suspension	White suspension	White suspension
Viscosity (U/I)(cps)	75-300	207	187	156	156	194

(U) = bottle upright
(I) = bottle inverted
(U/I) = average of bottle upright and bottle inverted values

The foregoing description is illustrative of exemplary embodiments which achieve the objects, features and advantages of the present invention. It should be apparent that many changes, modifications, and substitutions may be made to the described embodiments without departing from the spirit or scope of the invention. The invention is not to be considered as limited by the foregoing description or embodiments, but is only limited by the construed scope of the appended claims.

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. A method for forming an aqueous flocculated suspension containing 40 mg/ml micronized megestrol acetate together with a wetting agent to form a stable, resuspendable flocculated suspension of megestrol acetate, comprising mixing the wetting agent with micronized megestrol acetate in an amount such that about 90% of the floccules of megestrol acetate in the suspension have a diameter of less than 12 to 50 microns, and wherein the flocculated suspen-

sion does not simultaneously contain polysorbate and polyethylene glycol.

2. The method of claim 1, wherein about 90% of the floccules have a diameter of less than 21 to 50 microns.

3. The method of claim 1, wherein about 90% of the floccules have a diameter of less than 23 to 50 microns.

4. The method of claim 1, wherein about 90% of the floccules have a diameter of less than 26 to 50 microns.

5. The method of claim 1, wherein about 90% of the floccules have a diameter of less than 28 to 50 microns.

6. The method of claim 1, wherein about 90% of the floccules have a diameter of less than 12 to 28 microns.

7. The method of claim 1, wherein about 50% of the floccules have a diameter of less than 17 microns.

8. The method of claim 1, wherein about 10% of the floccules have a diameter of less than 7 microns.