

(cont. from page. stud)

Purpose: To study the effect of pH on formation of particles in TRAVATAN BAC Free, 0.004% (FID 102047) at different concentrations of 12-hydroxystearic acid.
Adjud 8-9-06

ADJUNCTIVE DATA #58-22-06

PAGE 4 pages

REF LN11781:81

Experimental:

Equipment:

- Mettler P6503S Balance Asset no. A1726 Lab C124
- Orion 210AT pH Meter Asset no. A1232 Lab C124
- Stir plates
- 100 ml glass bottles

Materials:

- 0.2% 12-hydroxystearic acid in propylene glycol Lot 06-44911-1 exp 2-04-07 (FID 111161)
- Propylene glycol RPA 00196021 expires 10-05-06
- TRAVATAN BAC Free, 0.004% No zinc chloride or propylene glycol (FID 111169) Lot 06-44925-1 exp. 2-7-07
- 1N Sodium Hydroxide Batch 06-43811 exp 4-7-07
- 0.1% Zinc Chloride solution Batch 06-44262 exp 5-18-07

Procedure:

Procedure for each sample:

1. Add the calculated amount of 2000 ppm stock of 12-hydroxystearic acid in propylene glycol.
2. Add the calculated amount of propylene glycol.
3. Add the indicated amount of Travatan-Z 0.004%, no zinc or propylene glycol (FID 111169).
4. Mix and Adjust pH.
5. Add the calculated amount of Zinc Chloride stock solution. Mix. *mix'd for about 18 hours.* #58-11-06

See adjunctive notebook for table with actual amounts measured. Table includes calculated amounts of each item from procedure above.

Visual Observation of Particles: #58-11-06

Observe visually if particles can be seen in each sample.
Samples reobserved on 8-14-06. Samples 17, 24, 26, and 28 now have particles that can be seen visually.
All data can be found with adjunctive data. Samples 35-46 observed on 8-15-06.

N/A #58-01-06

(cont. on page 82)

Verified By: *[Signature]*

Date 8-22-06

Entered By: *[Signature]*

Date 8-22-06

(cont. from page 81)

Turbidity Measurement:

Measure and record the turbidity of each sample.

Samples 1-34 measured on 8-11-06. samples 1-34 were remeasured and recorded on 8-14-06.

Samples were measured by not being shaken and by being shaken.

Samples 35-41 measured and recorded on 8-15-06. samples 35-41 were shaken before measurement.

All data can be found with adjunctive data.

Particulate Matter by Microscope Testing:

Samples 6, 7, 12, 13, 14, 37, and 38 were submitted for particulate matter, microscope as well as pH testing.

LIMS submission ID: 100091567 (samples 6, 7, 12, 13, 14, 37, and 38)

Samples 11 and 36 were submitted for particulate matter, microscope as well as pH testing. LIMS submission ID: 100091621 (samples 11 and 36)

Analytical Chemistry Results: (Particulate matter, microscope and pH)

All Submission Results reports can be found with adjunctive data

Samples 6, 7, 11, 36 did not show any white crystalline particles.

Samples 12, 13, 14, 37, and 38 showed white crystalline particles.

All pH measurements can be found on submission results reports in adjunctive data.

Conclusion:

All data recorded. A summary of data can be found in the table that follows. Note that Batch 06-44925 (CFD 111169) contained an assay value of 12-HSA of 2 ppm (LIMS Submission ID: 100091463). A column in the table that follows shows the total concentration of 12-HSA of each sample.

ADJUNCTIVE DATA ^{AS 8-22-06}

PAGE 21 pages

REF LW11781-82

N/A 8-22-06
AS

(cont. on page 83)

Verified By: //

Date

Entered By: // / /

Date

(cont. from page 82)

Sample ID	12-HSA Concentration added to sample	Total 12-HSA Concentration (amount added plus amount found in formulation)	pH	Turbidity (NTU)	Visual Observation of Particles	Microscopic Observation
1	0	2	5.59	2.6	No	Not Evaluated
2	0	2	6.00	2.3	No	Not Evaluated
3	0	2	6.51	2.8	No	Not Evaluated
4	3	5	5.53	2.5	No	Not Evaluated
5	3	5	5.75	2.8	No	Not Evaluated
6	3	5	5.90	2.7	No	White Crystalline Particles Not Observed
7	3	5	6.00	3.0	No	White Crystalline Particles Not Observed
8	3	5	6.11	9.3	Yes	Not Evaluated
9	3	5	6.25	6.8	No	Not Evaluated
10	3	5	6.50	9.0	Yes	Not Evaluated
35	4.5	6.5	5.50	3.0	No	Not Evaluated
36	4.5	6.5	5.75	2.8	No	White Crystalline Particles Not Observed
37	4.5	6.5	5.90	5.9	No	White Crystalline Particles Observed
38	4.5	6.5	6.00	5.6	No	White Crystalline Particles Observed
39	4.5	6.5	6.10	13	Yes	Not Evaluated
40	4.5	6.5	6.25	17	Yes	Not Evaluated
41	4.5	6.5	6.50	18	Yes	Not Evaluated
11	6	8	5.58	2.6	No	White Crystalline Particles Not Observed
12	6	8	5.75	6.2	No	White Crystalline Particles Observed
13	6	8	5.90	5.1	No	White Crystalline Particles Observed
14	6	8	6.00	9.3	Yes	White Crystalline Particles Observed
15	6	8	6.10	16	Yes	Not Evaluated
16	6	8	6.25	8.3	No	Not Evaluated
17	6	8	6.50	9.2	Yes	Not Evaluated
18	9	11	5.57	25	Yes	Not Evaluated
19	9	11	5.80	15	Yes	Not Evaluated
20	9	11	5.90	21	Yes	Not Evaluated
21	9	11	6.00	20	Yes	Not Evaluated
22	9	11	6.17	18	No	Not Evaluated
23	9	11	6.25	20	Yes	Not Evaluated
24	9	11	6.52	12	Yes	Not Evaluated
25	15	17	5.57	28	Yes	Not Evaluated
26	15	17	5.75	20	Yes	Not Evaluated
27	15	17	5.90	30	Yes	Not Evaluated
28	15	17	6.00	26	Yes	Not Evaluated
29	15	17	6.10	38	Yes	Not Evaluated
30	15	17	6.25	30	No	Not Evaluated
31	15	17	6.50	26	No	Not Evaluated
32	15	17	5.54	3.2	No	Not Evaluated
33	15	17	6.00	3.8	No	Not Evaluated
34	15	17	6.50	3.3	No	Not Evaluated

Handwritten:
 8-22-06

(cont. on page END)

Verified By: _____ Date: _____ Entered By: _____ Date: _____