1. **Purpose:** To document the rationale of daily sampling at Giles Manufacturing.

2. **Scope:** The calculation of the upper bound of defects if testing were performed daily and if zero defects were detected.

3. **Calculation:** For zero defect sampling, the upper bound for a 95% confidence interval is defined as:

$$p = 3/n$$

where p is the risk factor and n is the sample size. Giles' process is a continuous process and the batch changes yearly. If a sample is taken daily to affirm the USP results, then n= 365 for an entire year. In than case p would be (3/365 =) 0.00822, or 0.822%. In other words with 95% confidence it can be stated that the USP failure rate is 0.822% or less with daily testing. This is considered acceptable risk considering that Giles has never failed a USP test in its existence as a manufacturer.

There is a base assumption that the testing is correct and that there aren't any special causes of variation.

1. The results data in Table I include testing variability, and the variability is sufficient.
2. Assuming that all raw materials fed into the system meet specification the quality critical special causes are minimal.

4. **Conclusion:** The calculated risk for zero defects at a 95% confidence interval was considered sufficient to do the testing Daily.

5. **Review/Approvals**

Printed Name and Title	*Signature*	*Date*
Patrick Owen - Process Engineer		6/24/2013
C. Matt Haynes - D.R. OPER		6/24/13
Paul Tolles - MAN. CNCL		6/29/13
Deborah Durbin - Dir Quality		6/24/13

6. **Attachments:**
   a. Table I – USP data for 1/25/2008 – 6/21/2013

Table I – USP Data

Date	Lot	Assay (%) 99.00% - 100.50%	Chloride (ppm) <0.014% (140 ppm)	Iron(ppm) <20.00 ppm	LOI(%) 40.00% - 52.00%	pH 5.00 - 9.20
1/25/2008	0208	99.66	<10.00	0.20	51.25	6.80
2/22/2008	0308	99.65	<10.00	0.26	51.60	6.90
3/25/2008	0408	99.66	<10.00	0.29	51.20	6.48
4/25/2008	0508	99.65	<10.00	0.74	50.58	6.64
5/22/2008	0608	99.75	<10.00	0.35	49.41	7.06
6/25/2008	0708	99.67	<10.00	0.27	51.22	6.40
7/28/2008	0808	99.76	<10.00	0.27	51.16	7.11
8/27/2008	0908	99.63	<10.00	0.20	49.08	6.80
9/25/2008	1008	99.65	<10.00	0.18	50.10	7.02
10/30/2008	1108	99.61	<10.00	0.20	51.05	6.85
11/20/2008	1208	99.64	<10.00	0.18	51.26	6.88
12/11/2008	1308	99.62	<10.00	0.22	51.33	6.77
1/7/2009	0109	99.61	<10.00	0.07	48.28	6.73
1/27/2009	0209	99.71	<10.00	0.01	51.38	6.44
2/12/2009	0309	99.75	<10.00	0.01	51.49	6.94
3/5/2009	0409	99.68	<10.00	0.01	51.14	6.29
3/27/2009	0509	99.66	<10.00	0.01	51.26	6.13
4/21/2009	0609	99.83	<10.00	0.14	51.46	6.17
5/7/2009	0709	99.62	<10.00	0.16	51.16	6.20
6/4/2009	0809	99.63	<10.00	0.08	51.29	6.12
6/25/2009	0909	99.74	11.00	0.09	51.24	6.62
7/23/2009	1009	99.69	<10.00	0.09	48.79	6.70
8/20/2009	1109	99.64	<10.00	<0.05	51.03	6.45
9/14/2009	1209	99.84	20.00	<0.07	51.17	6.50
10/21/2009	1309	99.64	30.00	<0.05	51.13	5.59
11/13/2009	1409	99.50	10.00	<0.05	51.13	6.57
12/7/2009	1509	99.47	20.00	<0.05	51.24	6.23
1/11/2010	0110	99.71	<10.00	0.11	51.10	7.40
2/8/2010	0210	99.77	<10.00	0.09	51.18	6.60
3/15/2010	0310	99.67	<10.00	0.09	51.20	6.34
4/21/2010	0410	99.68	<10.00	0.21	51.07	6.86
5/19/2010	0510	99.75	20.00	0.52	51.31	6.50
6/21/2010	0610	99.73	<10.00	0.18	51.10	6.29
7/14/2010	0710	99.85	<10.00	0.14	51.20	6.47

8/12/2010	0810	99.65	<10.00	0.06	51.38	6.32
9/3/2010	0910	99.67	<20.00	0.10	51.32	6.39
10/13/2010	1010	99.54	<20.00	0.08	51.73	6.65
11/3/2010	1110	99.49	20.00	0.11	51.26	6.05
12/8/2010	1210	99.56	20.00	0.16	51.58	6.65
1/13/2011	0111	99.46	20.00	<0.05	51.94	6.67
2/8/2011	0211	99.37	10.00	0.11	51.25	6.20
3/3/2011	0311	99.40	20.00	0.12	51.40	7.17
3/23/2011	0411	99.53	20.00	0.13	51.41	6.71
4/19/2011	0511	99.26	20.00	0.15	51.48	6.24
5/18/2011	0611	99.29	16.00	0.32	51.87	6.52
6/29/2011	0711	99.46	17.00	0.09	51.02	6.80
8/8/2011	0811	99.39	6.00	0.08	51.06	6.36
9/14/2011	0911	99.34	14.00	0.17	50.95	7.82
10/14/2011	1011	99.36	8.00	0.07	50.95	6.38
11/21/2011	1111	99.21	8.00	<0.05	50.70	6.52
1/5/2012	0112	99.42	6.00	0.08	50.80	6.20
3/16/2012	0212	99.49	8.00	0.10	50.83	6.88
5/4/2012	0312	99.61	8.00	0.11	50.82	6.58
4/16/2012	0412	100.40	Pass	Pass	51.12	6.67
4/27/2012	0512	99.49	Pass	Pass	50.66	7.29
5/14/2012	0612	99.90	Pass	Pass	50.63	7.51
5/25/2012	0712	99.87	Pass	Pass	50.36	6.37
6/11/2012	0812	99.42	Pass	Pass	50.46	6.71
6/25/2012	0912	99.42	Pass	Pass	50.59	7.90
7/9/2012	1012	99.06	Pass	Pass	49.37	8.05
7/23/2012	1112	100.36	Pass	Pass	50.57	8.20
8/7/2012	1212	99.01	Pass	Pass	50.76	8.21
8/20/2012	1312	99.51	Pass	Pass	50.82	8.41
9/3/2012	1412	99.42	Pass	Pass	51.04	7.71
9/17/2012	1512	99.78	Pass	Pass	51.00	7.82
10/3/2012	1612	99.18	Pass	Pass	49.14	7.09
10/15/2012	1712	100.21	Pass	Pass	50.35	6.74
10/29/2012	1812	100.14	Pass	Pass	51.08	6.83
11/12/2012	1912	99.42	Pass	Pass	51.36	7.40
11/26/2012	2012	99.13	Pass	Pass	50.78	6.38
12/10/2012	2112	99.54	Pass	Pass	51.67	6.61
12/21/2012	2212	99.54	Pass	Pass	44.58	5.83
1/7/2013	0113	100.04	Pass	Pass	50.81	7.34
1/22/2013	0213	99.18	Pass	Pass	51.00	7.12

2/5/2013	0313	99.80	Pass	Pass	50.57	7.23
2/20/2013	0413	99.30	Pass	Pass	50.13	6.69
3/8/2013	0513	99.42	Pass	Pass	50.73	7.46
3/21/2013	0613	99.59	Pass	Pass	51.28	6.85
4/3/2013	0713	99.80	Pass	Pass	50.75	6.70
4/18/2013	0813	99.10	Pass	Pass	50.70	6.81
5/1/2013	0913	100.38	Pass	Pass	51.04	6.20
5/16/2013	1013	99.18	Pass	Pass	50.91	6.71
5/30/2013	1113	99.08	Pass	Pass	50.85	6.61
6/13/2013	1213	100.50	Pass	Pass	51.10	7.82
6/21/2013	1313	100.14	Pass	Pass	50.90	7.57

AVG	99.61	15.09	0.16	50.84	6.80
LOW	99.01	6.00	0.01	44.58	5.59
HIGH	100.50	30.00	0.74	51.94	8.41