

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 10, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.37	90.1	1.43	95.1	2.38	100.1	3.19	105.1	2.11	110.1	1.13
85.2	0.39	90.2	1.45	95.2	2.39	100.2	3.16	105.2	2.09	110.2	1.11
85.3	0.41	90.3	1.47	95.3	2.41	100.3	3.14	105.3	2.07	110.3	1.10
85.4	0.43	90.4	1.49	95.4	2.43	100.4	3.12	105.4	2.05	110.4	1.08
85.5	0.45	90.5	1.51	95.5	2.45	100.5	3.10	105.5	2.03	110.5	1.06
85.6	0.48	90.6	1.53	95.6	2.47	100.6	3.07	105.6	2.01	110.6	1.04
85.7	0.50	90.7	1.55	95.7	2.48	100.7	3.05	105.7	1.99	110.7	1.02
85.8	0.52	90.8	1.57	95.8	2.50	100.8	3.03	105.8	1.97	110.8	1.00
85.9	0.54	90.9	1.59	95.9	2.52	100.9	3.01	105.9	1.95	110.9	0.98
86.0	0.57	91.0	1.61	96.0	2.54	101.0	2.99	106.0	1.93	111.0	0.97
86.1	0.59	91.1	1.63	96.1	2.55	101.1	2.96	106.1	1.91	111.1	0.95
86.2	0.61	91.2	1.65	96.2	2.57	101.2	2.94	106.2	1.89	111.2	0.93
86.3	0.63	91.3	1.66	96.3	2.59	101.3	2.92	106.3	1.87	111.3	0.91
86.4	0.65	91.4	1.68	96.4	2.61	101.4	2.90	106.4	1.85	111.4	0.89
86.5	0.68	91.5	1.70	96.5	2.62	101.5	2.88	106.5	1.83	111.5	0.87
86.6	0.70	91.6	1.72	96.6	2.64	101.6	2.85	106.6	1.81	111.6	0.86
86.7	0.72	91.7	1.74	96.7	2.66	101.7	2.83	106.7	1.79	111.7	0.84
86.8	0.74	91.8	1.76	96.8	2.68	101.8	2.81	106.8	1.77	111.8	0.82
86.9	0.76	91.9	1.78	96.9	2.69	101.9	2.79	106.9	1.75	111.9	0.80
87.0	0.78	92.0	1.80	97.0	2.71	102.0	2.77	107.0	1.73	112.0	0.78
87.1	0.80	92.1	1.82	97.1	2.73	102.1	2.75	107.1	1.71	112.1	0.76
87.2	0.83	92.2	1.84	97.2	2.74	102.2	2.72	107.2	1.69	112.2	0.75
87.3	0.85	92.3	1.86	97.3	2.76	102.3	2.70	107.3	1.67	112.3	0.73
87.4	0.87	92.4	1.88	97.4	2.78	102.4	2.68	107.4	1.65	112.4	0.71
87.5	0.89	92.5	1.90	97.5	2.80	102.5	2.66	107.5	1.63	112.5	0.69
87.6	0.91	92.6	1.92	97.6	2.81	102.6	2.64	107.6	1.61	112.6	0.67
87.7	0.93	92.7	1.93	97.7	2.83	102.7	2.62	107.7	1.59	112.7	0.66
87.8	0.95	92.8	1.95	97.8	2.85	102.8	2.60	107.8	1.57	112.8	0.64
87.9	0.97	92.9	1.97	97.9	2.86	102.9	2.57	107.9	1.55	112.9	0.62
88.0	1.00	93.0	1.99	98.0	2.88	103.0	2.55	108.0	1.53	113.0	0.60
88.1	1.02	93.1	2.01	98.1	2.90	103.1	2.53	108.1	1.51	113.1	0.59
88.2	1.04	93.2	2.03	98.2	2.91	103.2	2.51	108.2	1.50	113.2	0.57
88.3	1.06	93.3	2.05	98.3	2.93	103.3	2.49	108.3	1.48	113.3	0.55
88.4	1.08	93.4	2.07	98.4	2.95	103.4	2.47	108.4	1.46	113.4	0.53
88.5	1.10	93.5	2.08	98.5	2.96	103.5	2.45	108.5	1.44	113.5	0.51
88.6	1.12	93.6	2.10	98.6	2.98	103.6	2.43	108.6	1.42	113.6	0.50
88.7	1.14	93.7	2.12	98.7	3.00	103.7	2.41	108.7	1.40	113.7	0.48
88.8	1.16	93.8	2.14	98.8	3.01	103.8	2.38	108.8	1.38	113.8	0.46
88.9	1.18	93.9	2.16	98.9	3.03	103.9	2.36	108.9	1.36	113.9	0.44
89.0	1.20	94.0	2.18	99.0	3.05	104.0	2.34	109.0	1.34	114.0	0.43
89.1	1.22	94.1	2.20	99.1	3.06	104.1	2.32	109.1	1.32	114.1	0.41
89.2	1.25	94.2	2.21	99.2	3.08	104.2	2.30	109.2	1.30	114.2	0.39
89.3	1.27	94.3	2.23	99.3	3.10	104.3	2.28	109.3	1.28	114.3	0.37
89.4	1.29	94.4	2.25	99.4	3.11	104.4	2.26	109.4	1.27	114.4	0.36
89.5	1.31	94.5	2.27	99.5	3.13	104.5	2.24	109.5	1.25	114.5	0.34
89.6	1.33	94.6	2.29	99.6	3.14	104.6	2.22	109.6	1.23	114.6	0.32
89.7	1.35	94.7	2.31	99.7	3.16	104.7	2.20	109.7	1.21	114.7	0.31

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 10, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	1.37	94.8	2.32	99.8	3.18	104.8	2.18	109.8	1.19	114.8	0.29
89.9	1.39	94.9	2.34	99.9	3.19	104.9	2.15	109.9	1.17	114.9	0.27
90.0	1.41	95.0	2.36	100.0	3.21	105.0	2.13	110.0	1.15		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 30, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.51	90.1	2.00	95.1	3.32	100.1	4.45	105.1	2.96	110.1	1.58
85.2	0.54	90.2	2.03	95.2	3.35	100.2	4.42	105.2	2.93	110.2	1.56
85.3	0.57	90.3	2.05	95.3	3.38	100.3	4.39	105.3	2.90	110.3	1.53
85.4	0.61	90.4	2.08	95.4	3.40	100.4	4.36	105.4	2.87	110.4	1.51
85.5	0.64	90.5	2.11	95.5	3.43	100.5	4.33	105.5	2.84	110.5	1.48
85.6	0.67	90.6	2.14	95.6	3.45	100.6	4.30	105.6	2.81	110.6	1.45
85.7	0.70	90.7	2.17	95.7	3.47	100.7	4.27	105.7	2.79	110.7	1.43
85.8	0.73	90.8	2.19	95.8	3.50	100.8	4.23	105.8	2.76	110.8	1.40
85.9	0.76	90.9	2.22	95.9	3.52	100.9	4.20	105.9	2.73	110.9	1.38
86.0	0.79	91.0	2.25	96.0	3.55	101.0	4.17	106.0	2.70	111.0	1.35
86.1	0.82	91.1	2.28	96.1	3.57	101.1	4.14	106.1	2.67	111.1	1.33
86.2	0.85	91.2	2.30	96.2	3.60	101.2	4.11	106.2	2.65	111.2	1.30
86.3	0.88	91.3	2.33	96.3	3.62	101.3	4.08	106.3	2.62	111.3	1.27
86.4	0.92	91.4	2.36	96.4	3.65	101.4	4.05	106.4	2.59	111.4	1.25
86.5	0.95	91.5	2.38	96.5	3.67	101.5	4.02	106.5	2.56	111.5	1.22
86.6	0.98	91.6	2.41	96.6	3.69	101.6	3.99	106.6	2.53	111.6	1.20
86.7	1.01	91.7	2.44	96.7	3.72	101.7	3.96	106.7	2.51	111.7	1.17
86.8	1.04	91.8	2.47	96.8	3.74	101.8	3.93	106.8	2.48	111.8	1.15
86.9	1.07	91.9	2.49	96.9	3.77	101.9	3.90	106.9	2.45	111.9	1.12
87.0	1.10	92.0	2.52	97.0	3.79	102.0	3.87	107.0	2.42	112.0	1.10
87.1	1.13	92.1	2.55	97.1	3.81	102.1	3.84	107.1	2.39	112.1	1.07
87.2	1.16	92.2	2.57	97.2	3.84	102.2	3.81	107.2	2.37	112.2	1.05
87.3	1.19	92.3	2.60	97.3	3.86	102.3	3.78	107.3	2.34	112.3	1.02
87.4	1.22	92.4	2.63	97.4	3.89	102.4	3.75	107.4	2.31	112.4	0.99
87.5	1.25	92.5	2.65	97.5	3.91	102.5	3.72	107.5	2.28	112.5	0.97
87.6	1.28	92.6	2.68	97.6	3.93	102.6	3.69	107.6	2.26	112.6	0.94
87.7	1.31	92.7	2.71	97.7	3.96	102.7	3.66	107.7	2.23	112.7	0.92
87.8	1.34	92.8	2.73	97.8	3.98	102.8	3.63	107.8	2.20	112.8	0.89
87.9	1.37	92.9	2.76	97.9	4.00	102.9	3.60	107.9	2.17	112.9	0.87
88.0	1.39	93.0	2.79	98.0	4.03	103.0	3.57	108.0	2.15	113.0	0.84
88.1	1.42	93.1	2.81	98.1	4.05	103.1	3.54	108.1	2.12	113.1	0.82
88.2	1.45	93.2	2.84	98.2	4.07	103.2	3.51	108.2	2.09	113.2	0.80
88.3	1.48	93.3	2.86	98.3	4.10	103.3	3.48	108.3	2.07	113.3	0.77
88.4	1.51	93.4	2.89	98.4	4.12	103.4	3.45	108.4	2.04	113.4	0.75
88.5	1.54	93.5	2.92	98.5	4.14	103.5	3.42	108.5	2.01	113.5	0.72
88.6	1.57	93.6	2.94	98.6	4.17	103.6	3.39	108.6	1.98	113.6	0.70
88.7	1.60	93.7	2.97	98.7	4.19	103.7	3.36	108.7	1.96	113.7	0.67
88.8	1.63	93.8	2.99	98.8	4.21	103.8	3.33	108.8	1.93	113.8	0.65
88.9	1.66	93.9	3.02	98.9	4.23	103.9	3.31	108.9	1.90	113.9	0.62
89.0	1.69	94.0	3.05	99.0	4.26	104.0	3.28	109.0	1.88	114.0	0.60
89.1	1.71	94.1	3.07	99.1	4.28	104.1	3.25	109.1	1.85	114.1	0.57
89.2	1.74	94.2	3.10	99.2	4.30	104.2	3.22	109.2	1.82	114.2	0.55
89.3	1.77	94.3	3.12	99.3	4.33	104.3	3.19	109.3	1.80	114.3	0.52
89.4	1.80	94.4	3.15	99.4	4.35	104.4	3.16	109.4	1.77	114.4	0.50
89.5	1.83	94.5	3.17	99.5	4.37	104.5	3.13	109.5	1.74	114.5	0.48
89.6	1.86	94.6	3.20	99.6	4.39	104.6	3.10	109.6	1.72	114.6	0.45
89.7	1.89	94.7	3.22	99.7	4.41	104.7	3.07	109.7	1.69	114.7	0.43

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 30, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	1.91	94.8	3.25	99.8	4.43	104.8	3.04	109.8	1.66	114.8	0.40
89.9	1.94	94.9	3.28	99.9	4.45	104.9	3.01	109.9	1.64	114.9	0.38
90.0	1.97	95.0	3.30	100.0	4.47	105.0	2.99	110.0	1.61		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 45, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.55	90.1	2.15	95.1	3.58	100.1	4.77	105.1	3.18	110.1	1.71
85.2	0.59	90.2	2.18	95.2	3.61	100.2	4.74	105.2	3.15	110.2	1.68
85.3	0.62	90.3	2.21	95.3	3.63	100.3	4.71	105.3	3.12	110.3	1.65
85.4	0.65	90.4	2.24	95.4	3.66	100.4	4.68	105.4	3.09	110.4	1.62
85.5	0.69	90.5	2.27	95.5	3.69	100.5	4.65	105.5	3.06	110.5	1.59
85.6	0.72	90.6	2.30	95.6	3.72	100.6	4.62	105.6	3.03	110.6	1.57
85.7	0.75	90.7	2.33	95.7	3.74	100.7	4.59	105.7	3.00	110.7	1.54
85.8	0.79	90.8	2.36	95.8	3.77	100.8	4.56	105.8	2.97	110.8	1.51
85.9	0.82	90.9	2.39	95.9	3.79	100.9	4.52	105.9	2.94	110.9	1.48
86.0	0.85	91.0	2.42	96.0	3.82	101.0	4.49	106.0	2.91	111.0	1.45
86.1	0.89	91.1	2.45	96.1	3.85	101.1	4.46	106.1	2.88	111.1	1.43
86.2	0.92	91.2	2.48	96.2	3.87	101.2	4.43	106.2	2.85	111.2	1.40
86.3	0.95	91.3	2.51	96.3	3.90	101.3	4.39	106.3	2.82	111.3	1.37
86.4	0.98	91.4	2.54	96.4	3.93	101.4	4.36	106.4	2.79	111.4	1.34
86.5	1.02	91.5	2.57	96.5	3.95	101.5	4.33	106.5	2.76	111.5	1.32
86.6	1.05	91.6	2.60	96.6	3.98	101.6	4.30	106.6	2.73	111.6	1.29
86.7	1.08	91.7	2.63	96.7	4.00	101.7	4.26	106.7	2.70	111.7	1.26
86.8	1.12	91.8	2.66	96.8	4.03	101.8	4.23	106.8	2.67	111.8	1.23
86.9	1.15	91.9	2.68	96.9	4.06	101.9	4.20	106.9	2.64	111.9	1.21
87.0	1.18	92.0	2.71	97.0	4.08	102.0	4.17	107.0	2.61	112.0	1.18
87.1	1.21	92.1	2.74	97.1	4.11	102.1	4.13	107.1	2.58	112.1	1.15
87.2	1.25	92.2	2.77	97.2	4.13	102.2	4.10	107.2	2.55	112.2	1.13
87.3	1.28	92.3	2.80	97.3	4.16	102.3	4.07	107.3	2.52	112.3	1.10
87.4	1.31	92.4	2.83	97.4	4.18	102.4	4.04	107.4	2.49	112.4	1.07
87.5	1.34	92.5	2.86	97.5	4.21	102.5	4.00	107.5	2.46	112.5	1.04
87.6	1.37	92.6	2.89	97.6	4.24	102.6	3.97	107.6	2.43	112.6	1.02
87.7	1.41	92.7	2.91	97.7	4.26	102.7	3.94	107.7	2.40	112.7	0.99
87.8	1.44	92.8	2.94	97.8	4.29	102.8	3.91	107.8	2.37	112.8	0.96
87.9	1.47	92.9	2.97	97.9	4.31	102.9	3.88	107.9	2.34	112.9	0.94
88.0	1.50	93.0	3.00	98.0	4.34	103.0	3.84	108.0	2.31	113.0	0.91
88.1	1.53	93.1	3.03	98.1	4.36	103.1	3.81	108.1	2.28	113.1	0.88
88.2	1.56	93.2	3.06	98.2	4.39	103.2	3.78	108.2	2.25	113.2	0.86
88.3	1.60	93.3	3.08	98.3	4.41	103.3	3.75	108.3	2.22	113.3	0.83
88.4	1.63	93.4	3.11	98.4	4.44	103.4	3.72	108.4	2.19	113.4	0.80
88.5	1.66	93.5	3.14	98.5	4.46	103.5	3.69	108.5	2.17	113.5	0.78
88.6	1.69	93.6	3.17	98.6	4.49	103.6	3.65	108.6	2.14	113.6	0.75
88.7	1.72	93.7	3.20	98.7	4.51	103.7	3.62	108.7	2.11	113.7	0.72
88.8	1.75	93.8	3.22	98.8	4.53	103.8	3.59	108.8	2.08	113.8	0.70
88.9	1.78	93.9	3.25	98.9	4.56	103.9	3.56	108.9	2.05	113.9	0.67
89.0	1.81	94.0	3.28	99.0	4.58	104.0	3.53	109.0	2.02	114.0	0.64
89.1	1.85	94.1	3.31	99.1	4.61	104.1	3.50	109.1	1.99	114.1	0.62
89.2	1.88	94.2	3.34	99.2	4.63	104.2	3.46	109.2	1.96	114.2	0.59
89.3	1.91	94.3	3.36	99.3	4.65	104.3	3.43	109.3	1.94	114.3	0.57
89.4	1.94	94.4	3.39	99.4	4.68	104.4	3.40	109.4	1.91	114.4	0.54
89.5	1.97	94.5	3.42	99.5	4.70	104.5	3.37	109.5	1.88	114.5	0.51
89.6	2.00	94.6	3.45	99.6	4.72	104.6	3.34	109.6	1.85	114.6	0.49
89.7	2.03	94.7	3.47	99.7	4.74	104.7	3.31	109.7	1.82	114.7	0.46

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 45, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.06	94.8	3.50	99.8	4.76	104.8	3.28	109.8	1.79	114.8	0.43
89.9	2.09	94.9	3.53	99.9	4.78	104.9	3.25	109.9	1.76	114.9	0.41
90.0	2.12	95.0	3.55	100.0	4.80	105.0	3.22	110.0	1.74		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 60, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.58	90.1	2.25	95.1	3.74	100.1	4.97	105.1	3.32	110.1	1.78
85.2	0.61	90.2	2.28	95.2	3.77	100.2	4.94	105.2	3.29	110.2	1.75
85.3	0.65	90.3	2.31	95.3	3.79	100.3	4.91	105.3	3.26	110.3	1.72
85.4	0.68	90.4	2.34	95.4	3.82	100.4	4.88	105.4	3.23	110.4	1.69
85.5	0.72	90.5	2.37	95.5	3.85	100.5	4.85	105.5	3.20	110.5	1.67
85.6	0.75	90.6	2.40	95.6	3.88	100.6	4.82	105.6	3.16	110.6	1.64
85.7	0.79	90.7	2.43	95.7	3.90	100.7	4.78	105.7	3.13	110.7	1.61
85.8	0.82	90.8	2.46	95.8	3.93	100.8	4.75	105.8	3.10	110.8	1.58
85.9	0.86	90.9	2.50	95.9	3.96	100.9	4.72	105.9	3.07	110.9	1.55
86.0	0.89	91.0	2.53	96.0	3.99	101.0	4.69	106.0	3.04	111.0	1.52
86.1	0.93	91.1	2.56	96.1	4.02	101.1	4.65	106.1	3.00	111.1	1.49
86.2	0.96	91.2	2.59	96.2	4.04	101.2	4.62	106.2	2.97	111.2	1.46
86.3	0.99	91.3	2.62	96.3	4.07	101.3	4.58	106.3	2.94	111.3	1.43
86.4	1.03	91.4	2.65	96.4	4.10	101.4	4.55	106.4	2.91	111.4	1.40
86.5	1.06	91.5	2.68	96.5	4.13	101.5	4.52	106.5	2.88	111.5	1.37
86.6	1.10	91.6	2.71	96.6	4.15	101.6	4.48	106.6	2.85	111.6	1.35
86.7	1.13	91.7	2.74	96.7	4.18	101.7	4.45	106.7	2.82	111.7	1.32
86.8	1.16	91.8	2.77	96.8	4.21	101.8	4.42	106.8	2.78	111.8	1.29
86.9	1.20	91.9	2.80	96.9	4.23	101.9	4.38	106.9	2.75	111.9	1.26
87.0	1.23	92.0	2.83	97.0	4.26	102.0	4.35	107.0	2.72	112.0	1.23
87.1	1.27	92.1	2.86	97.1	4.29	102.1	4.31	107.1	2.69	112.1	1.20
87.2	1.30	92.2	2.89	97.2	4.31	102.2	4.28	107.2	2.66	112.2	1.17
87.3	1.33	92.3	2.92	97.3	4.34	102.3	4.25	107.3	2.63	112.3	1.15
87.4	1.37	92.4	2.95	97.4	4.37	102.4	4.21	107.4	2.60	112.4	1.12
87.5	1.40	92.5	2.98	97.5	4.39	102.5	4.18	107.5	2.57	112.5	1.09
87.6	1.43	92.6	3.01	97.6	4.42	102.6	4.15	107.6	2.54	112.6	1.06
87.7	1.47	92.7	3.04	97.7	4.45	102.7	4.11	107.7	2.51	112.7	1.03
87.8	1.50	92.8	3.07	97.8	4.47	102.8	4.08	107.8	2.47	112.8	1.01
87.9	1.53	92.9	3.10	97.9	4.50	102.9	4.05	107.9	2.44	112.9	0.98
88.0	1.57	93.0	3.13	98.0	4.53	103.0	4.01	108.0	2.41	113.0	0.95
88.1	1.60	93.1	3.16	98.1	4.55	103.1	3.98	108.1	2.38	113.1	0.92
88.2	1.63	93.2	3.19	98.2	4.58	103.2	3.95	108.2	2.35	113.2	0.89
88.3	1.67	93.3	3.22	98.3	4.60	103.3	3.91	108.3	2.32	113.3	0.87
88.4	1.70	93.4	3.25	98.4	4.63	103.4	3.88	108.4	2.29	113.4	0.84
88.5	1.73	93.5	3.28	98.5	4.65	103.5	3.85	108.5	2.26	113.5	0.81
88.6	1.77	93.6	3.31	98.6	4.68	103.6	3.81	108.6	2.23	113.6	0.78
88.7	1.80	93.7	3.34	98.7	4.71	103.7	3.78	108.7	2.20	113.7	0.75
88.8	1.83	93.8	3.37	98.8	4.73	103.8	3.75	108.8	2.17	113.8	0.73
88.9	1.86	93.9	3.40	98.9	4.76	103.9	3.71	108.9	2.14	113.9	0.70
89.0	1.89	94.0	3.42	99.0	4.78	104.0	3.68	109.0	2.11	114.0	0.67
89.1	1.93	94.1	3.45	99.1	4.81	104.1	3.65	109.1	2.08	114.1	0.64
89.2	1.96	94.2	3.48	99.2	4.83	104.2	3.62	109.2	2.05	114.2	0.62
89.3	1.99	94.3	3.51	99.3	4.85	104.3	3.58	109.3	2.02	114.3	0.59
89.4	2.02	94.4	3.54	99.4	4.88	104.4	3.55	109.4	1.99	114.4	0.56
89.5	2.06	94.5	3.57	99.5	4.90	104.5	3.52	109.5	1.96	114.5	0.54
89.6	2.09	94.6	3.60	99.6	4.92	104.6	3.49	109.6	1.93	114.6	0.51
89.7	2.12	94.7	3.63	99.7	4.94	104.7	3.45	109.7	1.90	114.7	0.48

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 60, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.15	94.8	3.65	99.8	4.96	104.8	3.42	109.8	1.87	114.8	0.45
89.9	2.18	94.9	3.68	99.9	4.98	104.9	3.39	109.9	1.84	114.9	0.43
90.0	2.21	95.0	3.71	100.0	5.00	105.0	3.36	110.0	1.81		



ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 75, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.59	90.1	2.31	95.1	3.85	100.1	5.10	105.1	3.42	110.1	1.83
85.2	0.63	90.2	2.34	95.2	3.87	100.2	5.07	105.2	3.39	110.2	1.80
85.3	0.66	90.3	2.38	95.3	3.90	100.3	5.04	105.3	3.36	110.3	1.77
85.4	0.70	90.4	2.41	95.4	3.93	100.4	5.01	105.4	3.32	110.4	1.74
85.5	0.74	90.5	2.44	95.5	3.96	100.5	4.98	105.5	3.29	110.5	1.71
85.6	0.77	90.6	2.47	95.6	3.99	100.6	4.95	105.6	3.26	110.6	1.68
85.7	0.81	90.7	2.50	95.7	4.02	100.7	4.92	105.7	3.22	110.7	1.65
85.8	0.84	90.8	2.54	95.8	4.05	100.8	4.89	105.8	3.19	110.8	1.62
85.9	0.88	90.9	2.57	95.9	4.08	100.9	4.85	105.9	3.16	110.9	1.59
86.0	0.92	91.0	2.60	96.0	4.10	101.0	4.82	106.0	3.12	111.0	1.56
86.1	0.95	91.1	2.63	96.1	4.13	101.1	4.79	106.1	3.09	111.1	1.53
86.2	0.99	91.2	2.66	96.2	4.16	101.2	4.75	106.2	3.06	111.2	1.50
86.3	1.02	91.3	2.70	96.3	4.19	101.3	4.72	106.3	3.03	111.3	1.47
86.4	1.06	91.4	2.73	96.4	4.22	101.4	4.68	106.4	3.00	111.4	1.44
86.5	1.09	91.5	2.76	96.5	4.24	101.5	4.65	106.5	2.96	111.5	1.42
86.6	1.13	91.6	2.79	96.6	4.27	101.6	4.61	106.6	2.93	111.6	1.39
86.7	1.16	91.7	2.82	96.7	4.30	101.7	4.58	106.7	2.90	111.7	1.36
86.8	1.20	91.8	2.85	96.8	4.33	101.8	4.54	106.8	2.87	111.8	1.33
86.9	1.23	91.9	2.88	96.9	4.36	101.9	4.51	106.9	2.83	111.9	1.30
87.0	1.27	92.0	2.92	97.0	4.38	102.0	4.47	107.0	2.80	112.0	1.27
87.1	1.30	92.1	2.95	97.1	4.41	102.1	4.44	107.1	2.77	112.1	1.24
87.2	1.34	92.2	2.98	97.2	4.44	102.2	4.40	107.2	2.74	112.2	1.21
87.3	1.37	92.3	3.01	97.3	4.47	102.3	4.37	107.3	2.71	112.3	1.18
87.4	1.41	92.4	3.04	97.4	4.49	102.4	4.33	107.4	2.67	112.4	1.15
87.5	1.44	92.5	3.07	97.5	4.52	102.5	4.30	107.5	2.64	112.5	1.12
87.6	1.48	92.6	3.10	97.6	4.55	102.6	4.27	107.6	2.61	112.6	1.09
87.7	1.51	92.7	3.13	97.7	4.58	102.7	4.23	107.7	2.58	112.7	1.06
87.8	1.55	92.8	3.16	97.8	4.60	102.8	4.20	107.8	2.55	112.8	1.03
87.9	1.58	92.9	3.19	97.9	4.63	102.9	4.16	107.9	2.52	112.9	1.01
88.0	1.61	93.0	3.22	98.0	4.66	103.0	4.13	108.0	2.48	113.0	0.98
88.1	1.65	93.1	3.25	98.1	4.68	103.1	4.09	108.1	2.45	113.1	0.95
88.2	1.68	93.2	3.28	98.2	4.71	103.2	4.06	108.2	2.42	113.2	0.92
88.3	1.72	93.3	3.31	98.3	4.74	103.3	4.03	108.3	2.39	113.3	0.89
88.4	1.75	93.4	3.34	98.4	4.76	103.4	3.99	108.4	2.36	113.4	0.86
88.5	1.78	93.5	3.37	98.5	4.79	103.5	3.96	108.5	2.33	113.5	0.83
88.6	1.82	93.6	3.40	98.6	4.82	103.6	3.92	108.6	2.30	113.6	0.81
88.7	1.85	93.7	3.43	98.7	4.84	103.7	3.89	108.7	2.26	113.7	0.78
88.8	1.88	93.8	3.46	98.8	4.87	103.8	3.86	108.8	2.23	113.8	0.75
88.9	1.92	93.9	3.49	98.9	4.89	103.9	3.82	108.9	2.20	113.9	0.72
89.0	1.95	94.0	3.52	99.0	4.92	104.0	3.79	109.0	2.17	114.0	0.69
89.1	1.98	94.1	3.55	99.1	4.94	104.1	3.76	109.1	2.14	114.1	0.66
89.2	2.02	94.2	3.58	99.2	4.97	104.2	3.72	109.2	2.11	114.2	0.63
89.3	2.05	94.3	3.61	99.3	4.99	104.3	3.69	109.3	2.08	114.3	0.61
89.4	2.08	94.4	3.64	99.4	5.01	104.4	3.65	109.4	2.05	114.4	0.58
89.5	2.12	94.5	3.67	99.5	5.03	104.5	3.62	109.5	2.02	114.5	0.55
89.6	2.15	94.6	3.70	99.6	5.05	104.6	3.59	109.6	1.99	114.6	0.52
89.7	2.18	94.7	3.73	99.7	5.07	104.7	3.55	109.7	1.96	114.7	0.49

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 75, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.21	94.8	3.76	99.8	5.09	104.8	3.52	109.8	1.93	114.8	0.47
89.9	2.25	94.9	3.79	99.9	5.11	104.9	3.49	109.9	1.90	114.9	0.44
90.0	2.28	95.0	3.82	100.0	5.13	105.0	3.45	110.0	1.86		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 90, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.61	90.1	2.36	95.1	3.93	100.1	5.20	105.1	3.49	110.1	1.87
85.2	0.64	90.2	2.39	95.2	3.96	100.2	5.17	105.2	3.46	110.2	1.84
85.3	0.68	90.3	2.43	95.3	3.99	100.3	5.14	105.3	3.43	110.3	1.81
85.4	0.72	90.4	2.46	95.4	4.02	100.4	5.11	105.4	3.39	110.4	1.78
85.5	0.75	90.5	2.49	95.5	4.05	100.5	5.08	105.5	3.36	110.5	1.75
85.6	0.79	90.6	2.53	95.6	4.08	100.6	5.05	105.6	3.32	110.6	1.72
85.7	0.83	90.7	2.56	95.7	4.10	100.7	5.02	105.7	3.29	110.7	1.69
85.8	0.86	90.8	2.59	95.8	4.13	100.8	4.99	105.8	3.26	110.8	1.66
85.9	0.90	90.9	2.62	95.9	4.16	100.9	4.95	105.9	3.22	110.9	1.63
86.0	0.94	91.0	2.66	96.0	4.19	101.0	4.92	106.0	3.19	111.0	1.60
86.1	0.97	91.1	2.69	96.1	4.22	101.1	4.89	106.1	3.16	111.1	1.57
86.2	1.01	91.2	2.72	96.2	4.25	101.2	4.85	106.2	3.12	111.2	1.54
86.3	1.05	91.3	2.75	96.3	4.28	101.3	4.82	106.3	3.09	111.3	1.51
86.4	1.08	91.4	2.79	96.4	4.31	101.4	4.78	106.4	3.06	111.4	1.47
86.5	1.12	91.5	2.82	96.5	4.33	101.5	4.74	106.5	3.03	111.5	1.44
86.6	1.15	91.6	2.85	96.6	4.36	101.6	4.71	106.6	2.99	111.6	1.41
86.7	1.19	91.7	2.88	96.7	4.39	101.7	4.67	106.7	2.96	111.7	1.38
86.8	1.22	91.8	2.91	96.8	4.42	101.8	4.64	106.8	2.93	111.8	1.35
86.9	1.26	91.9	2.95	96.9	4.45	101.9	4.60	106.9	2.89	111.9	1.32
87.0	1.30	92.0	2.98	97.0	4.48	102.0	4.57	107.0	2.86	112.0	1.29
87.1	1.33	92.1	3.01	97.1	4.50	102.1	4.53	107.1	2.83	112.1	1.26
87.2	1.37	92.2	3.04	97.2	4.53	102.2	4.50	107.2	2.80	112.2	1.23
87.3	1.40	92.3	3.07	97.3	4.56	102.3	4.46	107.3	2.76	112.3	1.20
87.4	1.44	92.4	3.10	97.4	4.59	102.4	4.43	107.4	2.73	112.4	1.18
87.5	1.47	92.5	3.14	97.5	4.62	102.5	4.39	107.5	2.70	112.5	1.15
87.6	1.51	92.6	3.17	97.6	4.64	102.6	4.36	107.6	2.67	112.6	1.12
87.7	1.54	92.7	3.20	97.7	4.67	102.7	4.32	107.7	2.63	112.7	1.09
87.8	1.58	92.8	3.23	97.8	4.70	102.8	4.29	107.8	2.60	112.8	1.06
87.9	1.61	92.9	3.26	97.9	4.73	102.9	4.25	107.9	2.57	112.9	1.03
88.0	1.65	93.0	3.29	98.0	4.75	103.0	4.22	108.0	2.54	113.0	1.00
88.1	1.68	93.1	3.32	98.1	4.78	103.1	4.18	108.1	2.50	113.1	0.97
88.2	1.72	93.2	3.35	98.2	4.81	103.2	4.15	108.2	2.47	113.2	0.94
88.3	1.75	93.3	3.38	98.3	4.84	103.3	4.11	108.3	2.44	113.3	0.91
88.4	1.79	93.4	3.42	98.4	4.86	103.4	4.08	108.4	2.41	113.4	0.88
88.5	1.82	93.5	3.45	98.5	4.89	103.5	4.04	108.5	2.38	113.5	0.85
88.6	1.85	93.6	3.48	98.6	4.92	103.6	4.01	108.6	2.34	113.6	0.82
88.7	1.89	93.7	3.51	98.7	4.94	103.7	3.97	108.7	2.31	113.7	0.79
88.8	1.92	93.8	3.54	98.8	4.97	103.8	3.94	108.8	2.28	113.8	0.76
88.9	1.96	93.9	3.57	98.9	4.99	103.9	3.90	108.9	2.25	113.9	0.73
89.0	1.99	94.0	3.60	99.0	5.02	104.0	3.87	109.0	2.22	114.0	0.71
89.1	2.03	94.1	3.63	99.1	5.04	104.1	3.83	109.1	2.19	114.1	0.68
89.2	2.06	94.2	3.66	99.2	5.07	104.2	3.80	109.2	2.15	114.2	0.65
89.3	2.09	94.3	3.69	99.3	5.09	104.3	3.77	109.3	2.12	114.3	0.62
89.4	2.13	94.4	3.72	99.4	5.11	104.4	3.73	109.4	2.09	114.4	0.59
89.5	2.16	94.5	3.75	99.5	5.13	104.5	3.70	109.5	2.06	114.5	0.56
89.6	2.19	94.6	3.78	99.6	5.15	104.6	3.66	109.6	2.03	114.6	0.53
89.7	2.23	94.7	3.81	99.7	5.17	104.7	3.63	109.7	2.00	114.7	0.50

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 90, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.26	94.8	3.84	99.8	5.19	104.8	3.60	109.8	1.97	114.8	0.48
89.9	2.29	94.9	3.87	99.9	5.21	104.9	3.56	109.9	1.94	114.9	0.45
90.0	2.33	95.0	3.90	100.0	5.22	105.0	3.53	110.0	1.90		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 120, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.62	90.1	2.43	95.1	4.04	100.1	5.33	105.1	3.60	110.1	1.93
85.2	0.66	90.2	2.46	95.2	4.07	100.2	5.30	105.2	3.56	110.2	1.90
85.3	0.70	90.3	2.50	95.3	4.10	100.3	5.28	105.3	3.53	110.3	1.86
85.4	0.74	90.4	2.53	95.4	4.14	100.4	5.25	105.4	3.49	110.4	1.83
85.5	0.78	90.5	2.57	95.5	4.16	100.5	5.22	105.5	3.46	110.5	1.80
85.6	0.81	90.6	2.60	95.6	4.19	100.6	5.19	105.6	3.42	110.6	1.77
85.7	0.85	90.7	2.63	95.7	4.22	100.7	5.16	105.7	3.39	110.7	1.74
85.8	0.89	90.8	2.67	95.8	4.25	100.8	5.13	105.8	3.35	110.8	1.71
85.9	0.93	90.9	2.70	95.9	4.28	100.9	5.09	105.9	3.32	110.9	1.68
86.0	0.96	91.0	2.73	96.0	4.31	101.0	5.06	106.0	3.29	111.0	1.64
86.1	1.00	91.1	2.77	96.1	4.34	101.1	5.03	106.1	3.25	111.1	1.61
86.2	1.04	91.2	2.80	96.2	4.37	101.2	4.99	106.2	3.22	111.2	1.58
86.3	1.08	91.3	2.83	96.3	4.40	101.3	4.95	106.3	3.18	111.3	1.55
86.4	1.11	91.4	2.87	96.4	4.43	101.4	4.92	106.4	3.15	111.4	1.52
86.5	1.15	91.5	2.90	96.5	4.46	101.5	4.88	106.5	3.11	111.5	1.49
86.6	1.19	91.6	2.93	96.6	4.49	101.6	4.85	106.6	3.08	111.6	1.46
86.7	1.22	91.7	2.97	96.7	4.52	101.7	4.81	106.7	3.05	111.7	1.43
86.8	1.26	91.8	3.00	96.8	4.55	101.8	4.78	106.8	3.01	111.8	1.39
86.9	1.30	91.9	3.03	96.9	4.58	101.9	4.74	106.9	2.98	111.9	1.36
87.0	1.33	92.0	3.07	97.0	4.61	102.0	4.70	107.0	2.95	112.0	1.33
87.1	1.37	92.1	3.10	97.1	4.64	102.1	4.67	107.1	2.91	112.1	1.30
87.2	1.41	92.2	3.13	97.2	4.67	102.2	4.63	107.2	2.88	112.2	1.27
87.3	1.44	92.3	3.16	97.3	4.69	102.3	4.59	107.3	2.84	112.3	1.24
87.4	1.48	92.4	3.20	97.4	4.72	102.4	4.56	107.4	2.81	112.4	1.21
87.5	1.52	92.5	3.23	97.5	4.75	102.5	4.52	107.5	2.78	112.5	1.18
87.6	1.55	92.6	3.26	97.6	4.78	102.6	4.48	107.6	2.74	112.6	1.15
87.7	1.59	92.7	3.29	97.7	4.81	102.7	4.45	107.7	2.71	112.7	1.12
87.8	1.62	92.8	3.32	97.8	4.84	102.8	4.41	107.8	2.68	112.8	1.09
87.9	1.66	92.9	3.36	97.9	4.87	102.9	4.38	107.9	2.64	112.9	1.06
88.0	1.70	93.0	3.39	98.0	4.89	103.0	4.34	108.0	2.61	113.0	1.03
88.1	1.73	93.1	3.42	98.1	4.92	103.1	4.30	108.1	2.58	113.1	1.00
88.2	1.77	93.2	3.45	98.2	4.95	103.2	4.27	108.2	2.55	113.2	0.97
88.3	1.80	93.3	3.48	98.3	4.98	103.3	4.23	108.3	2.51	113.3	0.94
88.4	1.84	93.4	3.52	98.4	5.01	103.4	4.20	108.4	2.48	113.4	0.91
88.5	1.87	93.5	3.55	98.5	5.03	103.5	4.16	108.5	2.45	113.5	0.88
88.6	1.91	93.6	3.58	98.6	5.06	103.6	4.12	108.6	2.41	113.6	0.85
88.7	1.94	93.7	3.61	98.7	5.09	103.7	4.09	108.7	2.38	113.7	0.82
88.8	1.98	93.8	3.64	98.8	5.11	103.8	4.05	108.8	2.35	113.8	0.79
88.9	2.02	93.9	3.67	98.9	5.14	103.9	4.02	108.9	2.32	113.9	0.76
89.0	2.05	94.0	3.71	99.0	5.16	104.0	3.98	109.0	2.28	114.0	0.73
89.1	2.09	94.1	3.74	99.1	5.19	104.1	3.95	109.1	2.25	114.1	0.70
89.2	2.12	94.2	3.77	99.2	5.21	104.2	3.91	109.2	2.22	114.2	0.67
89.3	2.15	94.3	3.80	99.3	5.23	104.3	3.88	109.3	2.19	114.3	0.64
89.4	2.19	94.4	3.83	99.4	5.25	104.4	3.84	109.4	2.15	114.4	0.61
89.5	2.22	94.5	3.86	99.5	5.27	104.5	3.81	109.5	2.12	114.5	0.58
89.6	2.26	94.6	3.89	99.6	5.29	104.6	3.77	109.6	2.09	114.6	0.55
89.7	2.29	94.7	3.92	99.7	5.31	104.7	3.74	109.7	2.06	114.7	0.52

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 120, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.33	94.8	3.95	99.8	5.33	104.8	3.70	109.8	2.02	114.8	0.49
89.9	2.36	94.9	3.98	99.9	5.34	104.9	3.67	109.9	1.99	114.9	0.46
90.0	2.40	95.0	4.01	100.0	5.35	105.0	3.63	110.0	1.96		

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 150, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.64	90.1	2.48	95.1	4.12	100.1	5.42	105.1	3.67	110.1	1.97
85.2	0.67	90.2	2.51	95.2	4.16	100.2	5.40	105.2	3.63	110.2	1.93
85.3	0.71	90.3	2.55	95.3	4.19	100.3	5.37	105.3	3.60	110.3	1.90
85.4	0.75	90.4	2.58	95.4	4.22	100.4	5.34	105.4	3.56	110.4	1.87
85.5	0.79	90.5	2.62	95.5	4.25	100.5	5.31	105.5	3.53	110.5	1.84
85.6	0.83	90.6	2.65	95.6	4.28	100.6	5.29	105.6	3.49	110.6	1.80
85.7	0.87	90.7	2.69	95.7	4.31	100.7	5.25	105.7	3.46	110.7	1.77
85.8	0.91	90.8	2.72	95.8	4.34	100.8	5.22	105.8	3.42	110.8	1.74
85.9	0.95	90.9	2.75	95.9	4.37	100.9	5.19	105.9	3.39	110.9	1.71
86.0	0.98	91.0	2.79	96.0	4.40	101.0	5.16	106.0	3.35	111.0	1.68
86.1	1.02	91.1	2.82	96.1	4.43	101.1	5.12	106.1	3.32	111.1	1.64
86.2	1.06	91.2	2.86	96.2	4.46	101.2	5.09	106.2	3.28	111.2	1.61
86.3	1.10	91.3	2.89	96.3	4.49	101.3	5.05	106.3	3.25	111.3	1.58
86.4	1.14	91.4	2.92	96.4	4.52	101.4	5.01	106.4	3.21	111.4	1.55
86.5	1.17	91.5	2.96	96.5	4.55	101.5	4.98	106.5	3.18	111.5	1.52
86.6	1.21	91.6	2.99	96.6	4.58	101.6	4.94	106.6	3.14	111.6	1.49
86.7	1.25	91.7	3.03	96.7	4.61	101.7	4.91	106.7	3.11	111.7	1.45
86.8	1.29	91.8	3.06	96.8	4.64	101.8	4.87	106.8	3.07	111.8	1.42
86.9	1.32	91.9	3.09	96.9	4.67	101.9	4.83	106.9	3.04	111.9	1.39
87.0	1.36	92.0	3.13	97.0	4.70	102.0	4.80	107.0	3.00	112.0	1.36
87.1	1.40	92.1	3.16	97.1	4.73	102.1	4.76	107.1	2.97	112.1	1.33
87.2	1.44	92.2	3.19	97.2	4.76	102.2	4.72	107.2	2.94	112.2	1.30
87.3	1.47	92.3	3.23	97.3	4.79	102.3	4.68	107.3	2.90	112.3	1.27
87.4	1.51	92.4	3.26	97.4	4.82	102.4	4.65	107.4	2.87	112.4	1.23
87.5	1.55	92.5	3.29	97.5	4.85	102.5	4.61	107.5	2.83	112.5	1.20
87.6	1.58	92.6	3.33	97.6	4.87	102.6	4.57	107.6	2.80	112.6	1.17
87.7	1.62	92.7	3.36	97.7	4.90	102.7	4.54	107.7	2.77	112.7	1.14
87.8	1.66	92.8	3.39	97.8	4.93	102.8	4.50	107.8	2.73	112.8	1.11
87.9	1.69	92.9	3.42	97.9	4.96	102.9	4.46	107.9	2.70	112.9	1.08
88.0	1.73	93.0	3.46	98.0	4.99	103.0	4.43	108.0	2.66	113.0	1.05
88.1	1.77	93.1	3.49	98.1	5.02	103.1	4.39	108.1	2.63	113.1	1.02
88.2	1.80	93.2	3.52	98.2	5.05	103.2	4.35	108.2	2.60	113.2	0.99
88.3	1.84	93.3	3.55	98.3	5.08	103.3	4.32	108.3	2.56	113.3	0.95
88.4	1.88	93.4	3.59	98.4	5.10	103.4	4.28	108.4	2.53	113.4	0.93
88.5	1.91	93.5	3.62	98.5	5.13	103.5	4.24	108.5	2.49	113.5	0.89
88.6	1.95	93.6	3.65	98.6	5.16	103.6	4.21	108.6	2.46	113.6	0.86
88.7	1.98	93.7	3.68	98.7	5.18	103.7	4.17	108.7	2.43	113.7	0.83
88.8	2.02	93.8	3.71	98.8	5.21	103.8	4.13	108.8	2.40	113.8	0.80
88.9	2.06	93.9	3.75	98.9	5.24	103.9	4.10	108.9	2.36	113.9	0.77
89.0	2.09	94.0	3.78	99.0	5.26	104.0	4.06	109.0	2.33	114.0	0.74
89.1	2.13	94.1	3.81	99.1	5.28	104.1	4.02	109.1	2.30	114.1	0.71
89.2	2.16	94.2	3.84	99.2	5.31	104.2	3.99	109.2	2.26	114.2	0.68
89.3	2.20	94.3	3.87	99.3	5.33	104.3	3.95	109.3	2.23	114.3	0.65
89.4	2.23	94.4	3.90	99.4	5.35	104.4	3.92	109.4	2.20	114.4	0.62
89.5	2.27	94.5	3.94	99.5	5.37	104.5	3.88	109.5	2.16	114.5	0.59
89.6	2.30	94.6	3.97	99.6	5.39	104.6	3.85	109.6	2.13	114.6	0.56
89.7	2.34	94.7	4.00	99.7	5.40	104.7	3.81	109.7	2.10	114.7	0.53

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N= 150, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.37	94.8	4.03	99.8	5.42	104.8	3.77	109.8	2.06	114.8	0.50
89.9	2.41	94.9	4.06	99.9	5.43	104.9	3.74	109.9	2.03	114.9	0.47
90.0	2.44	95.0	4.09	100.0	5.44	105.0	3.70	110.0	2.00		



ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N=1000, TARGET = 100.0)

## SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
85.1	0.70	90.1	2.74	95.1	4.56	100.1	5.85	105.1	4.05	110.1	2.17
85.2	0.75	90.2	2.78	95.2	4.59	100.2	5.84	105.2	4.01	110.2	2.14
85.3	0.79	90.3	2.82	95.3	4.62	100.3	5.82	105.3	3.97	110.3	2.10
85.4	0.83	90.4	2.85	95.4	4.66	100.4	5.80	105.4	3.93	110.4	2.07
85.5	0.87	90.5	2.89	95.5	4.69	100.5	5.78	105.5	3.90	110.5	2.03
85.6	0.92	90.6	2.93	95.6	4.73	100.6	5.76	105.6	3.86	110.6	1.99
85.7	0.96	90.7	2.97	95.7	4.76	100.7	5.73	105.7	3.82	110.7	1.96
85.8	1.00	90.8	3.01	95.8	4.79	100.8	5.71	105.8	3.78	110.8	1.92
85.9	1.04	90.9	3.04	95.9	4.83	100.9	5.68	105.9	3.74	110.9	1.89
86.0	1.09	91.0	3.08	96.0	4.86	101.0	5.65	106.0	3.70	111.0	1.85
86.1	1.13	91.1	3.12	96.1	4.89	101.1	5.62	106.1	3.66	111.1	1.82
86.2	1.17	91.2	3.16	96.2	4.93	101.2	5.59	106.2	3.63	111.2	1.78
86.3	1.21	91.3	3.19	96.3	4.96	101.3	5.55	106.3	3.59	111.3	1.75
86.4	1.25	91.4	3.23	96.4	4.99	101.4	5.52	106.4	3.55	111.4	1.71
86.5	1.30	91.5	3.27	96.5	5.03	101.5	5.48	106.5	3.51	111.5	1.68
86.6	1.34	91.6	3.31	96.6	5.06	101.6	5.44	106.6	3.47	111.6	1.64
86.7	1.38	91.7	3.34	96.7	5.09	101.7	5.41	106.7	3.43	111.7	1.61
86.8	1.42	91.8	3.38	96.8	5.13	101.8	5.37	106.8	3.40	111.8	1.57
86.9	1.46	91.9	3.42	96.9	5.16	101.9	5.33	106.9	3.36	111.9	1.54
87.0	1.50	92.0	3.45	97.0	5.19	102.0	5.29	107.0	3.32	112.0	1.50
87.1	1.55	92.1	3.49	97.1	5.22	102.1	5.25	107.1	3.28	112.1	1.47
87.2	1.59	92.2	3.53	97.2	5.26	102.2	5.21	107.2	3.24	112.2	1.43
87.3	1.63	92.3	3.56	97.3	5.29	102.3	5.17	107.3	3.21	112.3	1.40
87.4	1.67	92.4	3.60	97.4	5.32	102.4	5.13	107.4	3.17	112.4	1.36
87.5	1.71	92.5	3.64	97.5	5.35	102.5	5.09	107.5	3.13	112.5	1.33
87.6	1.75	92.6	3.67	97.6	5.38	102.6	5.05	107.6	3.09	112.6	1.29
87.7	1.79	92.7	3.71	97.7	5.41	102.7	5.01	107.7	3.05	112.7	1.26
87.8	1.83	92.8	3.75	97.8	5.45	102.8	4.97	107.8	3.02	112.8	1.23
87.9	1.87	92.9	3.78	97.9	5.48	102.9	4.93	107.9	2.98	112.9	1.19
88.0	1.91	93.0	3.82	98.0	5.51	103.0	4.89	108.0	2.94	113.0	1.16
88.1	1.95	93.1	3.85	98.1	5.54	103.1	4.85	108.1	2.91	113.1	1.12
88.2	1.99	93.2	3.89	98.2	5.57	103.2	4.81	108.2	2.87	113.2	1.09
88.3	2.03	93.3	3.93	98.3	5.59	103.3	4.77	108.3	2.83	113.3	1.06
88.4	2.07	93.4	3.96	98.4	5.62	103.4	4.73	108.4	2.79	113.4	1.02
88.5	2.11	93.5	4.00	98.5	5.65	103.5	4.69	108.5	2.76	113.5	0.99
88.6	2.15	93.6	4.03	98.6	5.67	103.6	4.65	108.6	2.72	113.6	0.95
88.7	2.19	93.7	4.07	98.7	5.70	103.7	4.61	108.7	2.68	113.7	0.92
88.8	2.23	93.8	4.10	98.8	5.72	103.8	4.57	108.8	2.65	113.8	0.89
88.9	2.27	93.9	4.14	98.9	5.74	103.9	4.53	108.9	2.61	113.9	0.85
89.0	2.31	94.0	4.17	99.0	5.76	104.0	4.49	109.0	2.57	114.0	0.82
89.1	2.35	94.1	4.21	99.1	5.78	104.1	4.45	109.1	2.54	114.1	0.79
89.2	2.39	94.2	4.25	99.2	5.80	104.2	4.41	109.2	2.50	114.2	0.75
89.3	2.43	94.3	4.28	99.3	5.81	104.3	4.37	109.3	2.46	114.3	0.72
89.4	2.47	94.4	4.31	99.4	5.83	104.4	4.33	109.4	2.43	114.4	0.69
89.5	2.51	94.5	4.35	99.5	5.84	104.5	4.29	109.5	2.39	114.5	0.65
89.6	2.55	94.6	4.38	99.6	5.85	104.6	4.25	109.6	2.35	114.6	0.62
89.7	2.58	94.7	4.42	99.7	5.85	104.7	4.21	109.7	2.32	114.7	0.59

ACCEPTANCE LIMITS FOR CONTENT UNIFORMITY(N=1000, TARGET = 100.0)

SAMPLING PLAN 1

(MEETING LIMITS GUARANTEES, WITH 90.0% ASSURANCE, THAT AT LEAST  
95.0% OF SAMPLES TESTED FOR CONTENT UNIFORMITY WILL PASS THE USP TEST)

MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)	MEAN (% CLAIM)	CV (%)
89.8	2.62	94.8	4.45	99.8	5.86	104.8	4.17	109.8	2.28	114.8	0.55
89.9	2.66	94.9	4.49	99.9	5.86	104.9	4.13	109.9	2.25	114.9	0.52
90.0	2.70	95.0	4.52	100.0	5.87	105.0	4.09	110.0	2.21		