Table 14.1.01
Summary of Populations
All Subjects

	Placebo (N = xxx)		Low Dose (N = xxx)		High Dose (N = xxx)		Total (N = xxx)	
	n (%)		n (%)		n (%)		n (%)	
Intent-To-Treat (ITT)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Safety	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Efficacy	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Completed Study	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)

Note: N in column headers represents number of subjects entered in study (i.e., signed informed consent). The ITT population includes all subjects randomized. The Safety population includes all randomized subjects known to have taken at least one dose of randomized study drug. The Efficacy population includes all subjects in the safety population who also have at least one post-baseline CATScore assessment.

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Table 14.2.01
Summary of Demographic and Baseline Characteristics
Intent to Treat

		Placebo (N=xxx)		Low Dose (N=xxx)		High Dose (N=xxx)		Total (N = xxx)	
		n (%)		n (%)		n (%)		n (%)	
Age (Years)	n	xxx		xxx		xxx		xxx	
	Mean	xx.x		xx.x		xx.x		xx.x	
	STD	x.xx		x.xx		x.xx		x.xx	
	Median	xx.x		xx.x		xx.x		xx.x	
	Min	xx.x		xx.x		xx.x		xx.x	
	Max	xx.x		xx.x		xx.x		xx.x	
Age	<30 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	30 – 45 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	>45 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Sex	Female	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Male	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Race	Asian	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Black	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Caucasian	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Hispanix	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Other	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)

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Table 14.3.1.1
Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

| System Organ Class/ Preferred Term | Placebo (N=xxx) | | | Study Drug | | | | | | | | |
| | | | | Low Dose (N = xxx) | | | High Dose (N = xxx) | | | Total (N = xxx) | | |
	[AEs]	n (%)		[AEs]	n (%)		[AEs]	n (%)		[AEs]	n (%)	
Any Adverse Events	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)
System Organ Class 1 Preferred Term 11 Preferred Term 12 Preferred Term 13	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)	[xx]	xx	(xx.x)

Note 1: A subject who reported two or more different preferred terms in the same system organ class is counted only once in the system organ class.
Note 2: Subjects with adverse events in different systems organ class are counted only once in the overall total.
Note 3: N is the number of subjects within the treatment group in the population, n is the number of subjects who reported the adverse event and % is calculated by n/N*100. [AEs] is the number of AE reports.

Table 14.3.1.2
Incidence of Treatment-Emergent Adverse Events by Treatment Group
Safety Population

System Organ Class/ Preferred Term	Placebo (N=xxx)			Study Drug							Fisher's Exact p-values	
				Low Dose (N = xxx)			High Dose (N = xxx)			Total (N = xxx)		Placebo vs. Low Dose	Placebo vs. High Dose
	n (%)		[AEs]	n (%)		[AEs]	n (%)		[AEs]	n (%)	[AEs]		
Any Body System	xx	(xx.x)	[xx]	xx	(xx.x)	[xx]	xx (xx.x)		[xx]	xx (xx.x)	[xx]	x.xxx	x.xxx
System Organ Class 1 Preferred Term 11 Preferred Term 12 Preferred Term 13	xx (xx.x)		[xx]	xx	(xx.x)	[xx]	xx (xx.x)		[xx]	xx (xx.x)	[xx]	x.xxx	x.xxx

Note 1: A subject who reported two or more different preferred terms in the same system organ class is counted only once in the system organ class total. Subjects with adverse events in different systems organ class are counted only once in the overall total (subjects with adverse event).
Note 2: N is the number of subjects within the treatment group in the population, n is the number of subjects who reported the adverse event and % is calculated by n/N*100. [AEs] is the number of AE reports.

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Table 14.3.13
CATScore- Categorical Analysis
Efficacy Population

| | | Placebo (N = xxx) n (%) | Study Drug | | p-value |
	Assessment		Low Dose (N = xxx) n (%)	High Dose (N = xxx) n (%)	
Week x	n	xx	xx	xx	x.xxx
	Marked Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Moderate Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Minimal Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	No Change	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Minimal Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Moderate Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Marked Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Week y	n	xx	xx	xx	x.xxx
	Marked Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Moderate Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Minimal Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	No Change	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Minimal Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Moderate Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Marked Worsening	xx (xx.x)	xx (xx.x)	xx (xx.x)	
Week ...n	n	xx	xx	xx	x.xxx
	Marked Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Moderate Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	Minimal Improvement	xx (xx.x)	xx (xx.x)	xx (xx.x)	
	......				