Effects of Simethicone and Multilac Baby in Infantile Colic
Statistical Analysis Plan
Document Date: March 02, 2020

Cover page

Effects of Simethicone and Multilac Baby in Infantile Colic
Statistical Analysis Plan
Document Date: March 02, 2020

The statistical analyses will be conducted with GraphPad Prism software version 8.2 (GraphPad Software, Dan Diego, California, USA) or MedCalc Statistical Software version 19.2.1 (MedCalc Software Ltd., Ostend, Belgium). The Student t-test will be used to compare mean values of continuous variables approximating a normal distribution. For non-normally distributed variables, the Mann-Whitney U test will be used. The X2 test or Fisher exact test will be used, as appropriate, to compare percentages. The MedCalc Statistical Software version 19.2.1 will be used to calculate the relative risk (RR) and number needed to treat (NNT), all with a 95% confidence interval (CI). The difference between the treatment groups will be considered significant when the p-value will be less than 0.05, when the 95% CI for RR will not include 1.0, or when the 95% CI for mean difference will not include 1.0, or when the 95% CI for mean difference will not include 0. One-way ANOVA followed by Dunnett's multiple comparisons test as well as Cochran-Armitage Chi-squared test for trend will be performed using GraphPad Prism software. All statistical tests will be two-tailed and will be performed at the 5% level of significance. All analyses will be conducted on an intention-to-treat basis, including all patients in the groups to which they will be allocated.