# Appendix A

APPENDIX A

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## Results

### Wet Stool Weights

The Wet Stool Weights ranged from 3.63 to 12.16 g. There were no statistical differences between 5% Fraction BC and 5% Psyllium ST in stool wet weights (11.65 and 12.16 g, respectively), indicating that given at equivalent 5% doses, Fraction BC and Psyllium provide similar fecal bulking properties. The Fraction BC and Psyllium ST treatments produced significantly higher wet stools weights than the Alphacel and No Fiber treatments, demonstrating the fecal bulking properties of the fibers.

As in previous rat laxation studies, Alphacel produced a high fecal bulk effect (8.58 g) and significantly heavier stool weights than the No Fiber treatment, however, the true measure of water-holding capacity is the stool water data, and Alphacel did not deliver any significant water-holding effects (see Stool Water data – grams and percent).

The No Fiber results demonstrated that a diet without fiber has very little fecal bulking effect, as evidenced by low wet stool weights from the No Fiber group (3.63 g).

All wet stool results in this study were lower than those typically seen in this model. The reason for the lower wet stool weights is not known. In three previous studies, Psyllium

ST produced the following wet stool weights: METR# 28 = 17.5 g, METR# 31 = 17.9 g, METR# 32 = 17.99 g. Wet stool weights in the current study were 12.16 g.

Fraction BC wet stool weights results were lower than those seen typically seen in this model, however, this is the first time isopropanol-processed BC has been tested in this model, and the Psyllium ST results were also atypically low. In two previous studies, Fraction BC produced the following wet stool weights: METR# 31 (lyophilized) = 16.3 g, METR# 32 (vacuum tray dried) = 18.8 g. In the current study, Fraction BC processed with isopropanol produced wet stools weighing 11.65 g.

Alphacel wet stool weights were lower than those typically seen in this model. In three previous studies, Alphacel produced the following wet stool weights: METR# 28 = 12.66 g, METR# 30 = 10.30 g, METR# 32 = 11.58 g. In the current study, Alphacel wet stool weights were 8.58 g.

Wet stool weights from the No Fiber group were also lower than those typically seen in this model. In three previous studies, No Fiber produced the following wet stool weights: METR# 28 = 6.87 g, METR# 30 = 4.40g, METR# 32 = 4.32 g. Wet stool weights in the current study were 3.63 g. Note: No Fiber wet weights were slightly higher in METR# 28 due to cholesterol in the diet.

**Stool Water (Grams)**

The Stool Water weights ranged from 1.15 to 5.38 g. There were no statistical differences between 5% Fraction BC and 5% Psyllium ST in stool water (5.38 and 5.03 g, respectively), indicating that given at equivalent 5% doses, Fraction BC and Psyllium fibers provide similar water-holding capacity. The Fraction BC and Psyllium ST treatments produced significantly higher stool water weights than the Alphacel and No Fiber treatments, demonstrating the water-holding properties of the fibers.

Alphacel did not deliver any significant water-holding effects, as evidenced by stool water results that were not significantly different from the No Fiber treatment (1.61 and 1.15 g, respectively).

The No Fiber results demonstrated that a diet without fiber does not contain significant water levels, as evidenced by low stool water results (1.15 g). These results were expected.

The Psyllium ST, BC, and No Fiber stool water weights in this study were lower than those typically seen in this model. The reason for the low stool water results is not known. In three previous studies, Psyllium ST produced the following stool water weights: METR# 28 = 7.96 g, METR# 31 = 8.6 g, METR# 32 = 8.4 g. Stool water weights in the current study were = 5.03 g.

Fraction BC stool water weights were lower than those seen typically seen in this model, however, this is the first time isopropanol-processed BC has been tested in this model, and the Psyllium ST results were also atypically low. In two previous studies, Fraction BC produced the following stool water weights: METR# 31 (lyophilized) = 7.9 g, METR# 32 (vacuum tray dried) = 9.02 g. In the current study, Fraction BC processed with isopropanol produced stool water weights of 5.38 g.

Alphacel stool water weights were similar to those typically seen in this model. In three previous studies, Alphacel produced the following stool water weights: METR# 28 = 2.70 g, METR# 30 = 1.58 g, METR# 32 = 1.84 g. In the current study, Alphacel stool water weights were 1.61 g.

Stool water weights from the No Fiber group were slightly lower than those typically seen in this model. In three previous studies, No Fiber produced the following wet stool weights: METR# 28 = 3.05 g, METR# 30 = 1.12 g, METR# 32 = 1.24 g. Stool water weights in the current study were 1.15 g. Note: No Fiber wet weights were slightly higher in METR# 28 due to cholesterol in the diet.

**Percent Stool Water**

Note that very small differences in percent water content can achieve statistical significance and result in relatively large changes in stool viscosity. The Percent Stool Water levels ranged from 19 – 44%. There were no statistical differences between 5% Psyllium ST and 5% Fraction BC and in percent stool water (41 and 44%, respectively),

indicating that given at equivalent 5% doses, Fraction BC and Psyllium fibers provide similar water-holding capacity. Fraction BC produced directionally more stool water content than Psyllium 44% vs. 41%, indicating that Fraction BC has potential to deliver laxation efficacy via better water-holding capacity than Psyllium ST.

The Fraction BC and Psyllium ST treatments produced significantly higher stool water content than the Alphacel and No Fiber treatments, demonstrating the water-holding properties of the fibers. For comparison, Alphacel treatment produced only 19% stool water, significantly less than the all of the other treatments including No Fiber.

The No Fiber treatment produced 31% stool water. Without fiber in the diet, stools are extremely small, with little or no fecal bulking. While the No Fiber stools appeared to contain a significant amount of water based on Percent Stool Water results (31%), compared with Alphacel (19%), the No Fiber group had extremely low Stool Water levels (1.15 g) similar to Alphacel (1.61 g). These results demonstrate the need to collect both "Stool Water (g)" and "Percent Stool Water" measures in rat laxation studies, and to use both No Fiber and Alphacel treatments as negative controls for the model.

The Psyllium ST Percent Stool Water results were slightly lower than those seen in three previous studies: METR# 28 = 44%, METR# 31 = 47%, METYR# 32 = 46%. Percent Stool Water results from Psyllium ST in the current study were 41%.

Fraction BC Percent Stool Water results were also slightly lower than those seen in two previous studies: METR# 31 (lyophilized) = 47%, METR# 32 (vacuum tray dried) = 48%. Fraction BC Percent Stool Water results from the current study were 44%.

Alphacel Percent Stool Water results were similar to those from three previous studies: METR# 28 = 21%, METR# 30 = 15%, METR# 32 = 16%. Alphacel Percent Stool Water results from the current study were 19%.

No Fiber Percent Stool Water results were similar to those from previous studies: METR# 30 = 25%, METT# 32 = 29 g. No Fiber Percent Stool Water results from the current study were 31%.