

COMMISSION

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Guidelines for Use of California Table Grape Powder in Health Research Studies

Background on the Freeze-Dried Whole Table Grape Powder

The grape powder provided by the California Table Grape Commission (commission) is made from whole California grapes; it is not an extract.

Any results observed in clinical studies using grape powder should be directly attributed to grape consumption. In the powder, the grapes are provided in freeze-dried, powdered form. The powder is not made available for commercial use or sale. It was created solely for the purpose of providing researchers with access to California grapes year-round to ensure solid, reproducible data.

A 3/4 cup serving of fresh grapes (126 g) is equivalent to 23 g of the commission freeze-dried whole table grape powder.

Table Grape Powder Use in Human Clinical Studies

In human studies, the grape powder should be mixed with water, and then consumed all at once as a drink. The following protocol (Appendix A) suggests 6 oz. of water to 46 g of powder, but the amount of water may be adapted to subject's tolerance level, as long as the full dose of grape powder is consumed within 30 minutes. Please note that the powder does not dissolve completely as it is made from whole grapes, including the skin. When mixed with water it creates a suspension, not a solution.

The table grape powder will be packaged in vacuum-sealed pouches according to the dose approved for the study. The table grape powder is very hygroscopic, so must be protected from moisture and water until reconstituted. Subjects should keep their powder pouches stored in the freezer at all times.

A table grape powder placebo is available for use in control diets.

Recommended dosage range for human studies: between 46 g - 69 g per day (to provide between 1.5 to 2.25 cups of grapes per day).

Table Grape Extract Available for Use in Cell Studies

The commission will provide the grape powder extract needed for funded proposals that are also conducting supplemental *in vitro* work.

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Appendix A Suggested Dosing Protocol for Grape Powder – 46 g Dose*

Important Information

- Material should be stored in moisture impermeable packaging at -70 C until weighing.
- Hygroscopic material: protect from water until reconstituted.
- Dose subject within 30 minutes of reconstitution.
- Re-shake material just prior to dosing. The mixture creates a suspension, not a solution.

Purpose

To disperse 46 g of grape powder in 180 mL (6 fl. oz.) of water. *A larger dose may require more water.

Equipment

- Ziploc Snap 'N Seal XS container (1 cup) or equivalent. For subjects consuming at home, a glass may be used.
- Volumetric measuring device.
- Water (for reconstitution and rinse).

Procedure

Step	Instructions	Signature/Date
1.	Pour approximately 180 mL (6 fl. oz.) of water into	
	container/glass.	
2.	Open powder pouch and pour into water. Record	
	weight of powder and time of reconstitution.	
	Weight of Powderg	
	Time of Reconstitution	
3.	If using a jar, close lid tightly and shake for a	
	minimum of 30 seconds. If using a glass, stir for a	
	minimum of 30 seconds.	
4.	Visually confirm that no un-wetted powder	
	remains. Continue shaking or stirring if needed.	
5.	Just prior to subject consuming it, shake/stir	
	material for a minimum of 30 seconds.	
6.	Subject consumes reconstituted table grape	
	powder. Note: must be dosed within 30 minutes	
	of reconstitution.	
	Time of Dosing	
7.	Rinse container with at least 30 mL (1 fl. oz.) of	
	water.	
8.	Subject consumes rinse water.	