

Appendix 2. Excipients used in the Softgel and Table formulations. The AREDS1 excipients are those used in the dosage forms investigated in this study; the AREDS2 excipients are those used in the dosage forms in that Trial, here for reference.

AREDS2 Softgels	Excipients AREDS1 Tablets	AREDS1 Softgels
Gelatin	Microcrystalline cellulose	Gelatin
Vegetable oil	Dicalcium phosphate	Glycerin
Glycerin	Gelatin	Soybean oil
Hydrogenated Vegetable Oil	Hydroxypropyl methylcellulose	Coconut oil
Lecithin	Silicon dioxide	Corn oil
Beeswax	Magnesium stearate	Lecithin
Caramel color	Polyethylene glycol	Vegetable glycerides
Tocopherols	Sucrose	Beeswax
	Dextrin	Polyunsaturated oils
	Titanium dioxide	Caramel
	Corn starch	Titanium dioxide
	FD&C Red #40 Lake	FD&C Red #40 Lake
	Dextrose monohydrate	Oxalic acid
	Lecithin	Metal salts
	Ascorbyl palmitate	dl-alpha-tocopherol
	FD&C Yellow #6 Lake	FD&C Yellow #6 Lake
	dl-alpha-Tocopherol	Cuprous oxide
	Sodium ascorbate	
	Sorbic acid	
	Sodium benzoate	
	Polysorbate 80	

For tablets, oil-based nutrients were provided as gelatin-coated beadlets dispersible in a mixture of solid actives, flow controlling powders such as microcrystalline cellulose and dicalcium phosphate, lubricants like magnesium stearate that contribute to proper flow rheology during blending and compression, and antioxidants or stabilizers to assure stability of actives during manufacture and storage. A number of minor ingredients that originate in preparations of the raw material actives often are reported as excipients. Polymers and colorants provide an exterior region that contributes to the esthetics of the tablet presentation.

For softgel capsules, similarly there are two separate regions, a liquid, or at least flowable, core and an enclosing capsule. The core is composed of actives, oils, viscoelastic and suspending agents sufficient to assure uniformity in composition during manufacture, minor ingredients accompanying the actives, and like the tablets antioxidants and stabilizers to assure stability. The polymer capsule is routinely comprised primarily of a biopolymer, which in these formulations is gelatin to which plasticizers and other minor ingredients are added to assure compatibility with the core, proper flow, and adherence during fusion of the capsule halves at the time of manufacture. The levels of excipients are proprietary.