§ 73.1075 Canthaxanthin.

(a) Identity and specifications. (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of § 73.75(a)(1) and (b).

(2) Color additive mixtures for drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) Uses and restrictions. Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.


§ 73.1070 Calcium carbonate.

(a) Identity. (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate (CaCO3).

(2) Color additive mixtures for drug use made with calcium carbonate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) Specifications. Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the United States Pharmacopeia XX (1980).

(c) Uses and restrictions. Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.