avoided by good manufacturing practice:

Volatile matter (at 135 °C), not more than 3 percent.

Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 96 percent ethyl alcohol), not more than 1 percent.

2-Amino anthraquinone, not more than 0.2 percent.

Organically combined chlorine in pure dye, 13.0–14.8 percent.

Lead (as Pb), not more than 20 p.p.m.

Arsenic (as As), not more than 3 p.p.m.

Total color, not less than 97 percent.

(c) Uses and restrictions. D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) Certification. All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§74.1205 D&C Green No. 5.

(a) Identity. (1) The color additive D&C Green No. 5 is principally the disodium salt of 2,2′-[(9,10-dihydro-[9,10]

(b) Specifications. (1) D&C Green No. 5 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.

Water insoluble matter, not more than 0.2 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

2-Amino-5-toluenesulfonic acid, not more than 0.2 percent.

Subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.