§ 74.1330  
(e) Certification. All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1330  D&C Red No. 30.  
(a) Identity. (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzol[b]thien-2(3H)-ylidene)-4-methyl-benzol[b]thiophen-3(2H)-one (CAS Reg. No. 2379–74–0).

(b) Specifications. D&C Red No. 30 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:

Volatile matter (at 135 °C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) Uses and restrictions. D&C Red No. 30 may be safely used in coloring drugs generally in amounts consistent with current good manufacturing practice.

(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 D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1331  D&C Red No. 31.  
(a) Identity. (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenesulfonic acid.

(b) Specifications. D&C Red No. 31 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 good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
Aniline, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) Uses and restrictions. D&C Red No. 31 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(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 D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1333  D&C Red No. 33.  
(a) Identity. (1) The color additive D&C Red No. 33 is principally the disodium salt of 5-amino-4-hydroxy-3-(phenylazo)-2,7-naphthalenesulfonic acid (CAS Reg. No. 3367–66–6). To manufacture the additive, the product obtained from the nitrous acid diazotization of aniline is coupled with 4-hydroxy-5-amino-2,7-naphthalenesulfonic acid in an alkaline aqueous medium. The color additive is isolated as the sodium salt.

(b) Specifications. D&C Red No. 33 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:

Volatile matter (at 135 °C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 percent.

(c) Uses and restrictions. D&C Red No. 33 may be safely used in externally applied drugs in amounts consistent with current good manufacturing practice.
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§ 74.1334 D&C Red No. 34.

(a) Identity. (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-(1-sulfo-2-naphthalenylazo)-2-naphthalene-carboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) Specifications. D&C Red No. 34 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 practices:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.

Water-insoluble matter, not more than 0.3 percent.

4-Amino-5-hydroxy-2,7-naphthalenedisulfonic acid, disodium salt, not more than 0.3 percent.

4,5-Dihydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt, not more than 3.0 percent.

Aniline, not more than 23 parts per million.

4-Aminozobenzene, not more than 180 parts per billion.

1,3-Diphenyltriazene, not more than 125 parts per billion.

4-Aminophenyl, not more than 275 parts per billion.

Azobenzene, not more than 1 part per million.

Benzidine, not more than 20 parts per billion.

Lead (as Pb), not more than 20 parts per million.

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

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) Uses and restrictions. The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs, in amounts consistent with good manufacturing practice.

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

(e) Certification. All batches of D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1336 D&C Red No. 36.

(a) Identity. (1) The color additive D&C Red No. 36 is 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol (CAS Reg. No. 2814–77–9). The color additive is manufactured by diazotization of 2-chloro-4-nitrobenzenamine in acid medium and coupling with 2-naphthalenol in acid medium.