

§ 74.1307

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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 10 percent.
- Ether-soluble matter, passes test entitled "The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7," which is an Appendix A to part 74.
- 2-Amino-5-methylbenzenesulfonic acid, sodium salt, not more than 0.2 percent.
- 3-Hydroxy-2-naphthalenecarboxylic acid, sodium salt, not more than 0.4 percent.
- 3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, sodium salt, not more than 0.5 percent.
- p*-Toluidine, not more than 15 parts per million.
- 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.* The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(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. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982]

§ 74.1307 D&C Red No. 7.

(a) *Identity.* (1) The color additive D&C Red No. 7 is principally the calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5281-04-9). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid and the resulting dye converted to the calcium salt with calcium chloride.

(2) Color additive mixtures for drug use made with D&C Red No. 7 may con-

tain 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 drugs.

(b) *Specifications.* The color additive D&C Red No. 7 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 10 percent.
- Ether-soluble matter, passes test entitled "The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7," which is an Appendix A to part 74.
- 2-Amino-5-methylbenzenesulfonic acid, calcium salt, not more than 0.2 percent.
- 3-Hydroxy-2-naphthalenecarboxylic acid, calcium salt, not more than 0.4 percent.
- 3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, calcium salt, not more than 0.5 percent.
- p*-Toluidine, not more than 15 parts per million.
- 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.* The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(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. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982]

§ 74.1317 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[[4-(phenylazo)phenyl]azo]-2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 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. 17 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:

Volatile matter (at 135 °C), not more than 5 percent.

Matter insoluble in both toluene and water (color additive mixed in toluene and the resultant residue isolated and mixed with water to obtain the matter insoluble in both toluene and water), not more than 0.5 percent.

Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.

Aniline, not more than 0.2 percent.

4-Aminoazobenzene, not more than 0.1 percent.

2-Naphthol, not more than 0.2 percent.

1-(Phenylazo)-2-naphthol, not more than 3 percent.

1-[[2-(phenylazo) phenyl]azo]-2-naphthalenol, not more than 2 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. 17 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. 17 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 42 FR 27225, May 27, 1977]

#### § 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086-94-9), and may contain smaller amounts of 2',4',5'-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2',4',7'-tribromofluorescein (CAS Reg. No. 25709-84-6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluores-

cein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 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 drugs.

(b) *Specifications.* The color additive D&C Red No. 21 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 halides and sulfates (calculated as sodium salts), not more than 10 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Phthalic acid, not more than 1 percent.

2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.

2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.

Brominated resorcinol, not more than 0.4 percent.

Fluorescein, not more than 0.2 percent.

Sum of mono- and dibromofluoresceins, not more than 2 percent.

Tribromofluoresceins, not more than 11 percent.

2',4',5',7'-Tetrabromofluorescein, not less than 87 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.* The color additive D&C Red No. 21 may be safely used for 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. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]