

***Colouring agents exempt from batch certification***

<b>Name of colorants</b>	<b>Color</b>	<b>Uses</b>
Alumina (dried aluminum hydroxide)	Drugs generally include eye area use.	Drugs generally.
Annatto extract	Orange-Red	Ingested drugs generally and external drugs including eye area use.
Calcium carbonate	White	Drugs generally, For surface coloring only.
Canthaxanthin	Reddish-Orange	Ingested drugs generally
Caramel	Dark-Brown	Ingested and topically applied drugs generally
$\beta$ -Carotene	Red-Orange	Ingested drugs generally; Externally applied drugs including eye area
Cochineal extract	Red	Ingested and externally applied drug
Carmine	Deep Red	Ingested and externally applied drugs



Potassium sodium copper chlorophyllin (chlorophyllin-copper complex)	Green to Black	Dentifrices that are drugs (not to exceed 0.1%)
Dihydroxyacetone	Brown	Externally applied drugs
Bismuth oxychloride	White	Externally applied drugs including eye area use.
Synthetic iron oxide	Red, Yellow, and Black	Ingested or topically applied drugs ingested dosage by man not to exceed 5 mg/d (as Fe).
Ferric ammonium ferrocyanide	Blue	Externally applied drugs including eye area use.
Ferric ferrocyanide	Prussian Blue	Externally applied drugs including eye area use.
Chromium hydroxide green	Green	Externally applied drugs including eye area use.
Chromium oxide greens	Greens	Externally applied drugs including eye area use.
Guanine	Green	Externally applied drugs including eye area use.
Mica-based pearlescent pigments	Bluish-Gray or Grayish-White Color of Pearls	Ingested drugs not to exceed 3%. Iron not to exceed 55 wt %.
Pyrophyllite	Brown Green, Brownish Yellow, Greenish, Gray Green, Gray White	Externally applied drugs

Mica

Clear or Yellowish

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Externally applied drugs 

including eye area use.

Dentifrices.

Talc	Light to Dark Green, Brown, White, Grey,	Drugs generally
Titanium dioxide	White	Drugs generally including eye area use.
Aluminum powder	Silver-White	Externally applied drugs including eye area use.
Bronze powder	Yellow	Externally applied drugs including eye area use.
Copper powder	Shiny Orange-Red Metallic	Externally applied drugs including eye area use.
Zinc oxide	Yellow-Gray	Externally applied drugs including eye area use.

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### ***Color additives subject to batch certification***

<b>Name of colorants</b>	<b>Color</b>	<b>Uses and Restrictions</b>
FD&C Blue No. 1	Bright Blue	Ingested drugs generally; Externally applied drugs; Eye area use (includes lake).
FD&C Blue No. 2	Indigo Blue	Ingested drugs.
D&C Blue No. 4	Deep Blue	Externally applied drugs
FD&C Green No. 3	Deep Green	Drugs generally
D&C Green	No. 5	BlackishGreen

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D&C Green No. 6	Bright Green	Externally applied drugs.
D&C Green No. 8	Light Green Liked Fresh Leaf	Externally applied drugs (not to exceed 0.01% (by weight)).
D&C Orange No. 4	Dark Orange	Externally applied drugs
D&C Orange No. 5	Orange	Externally applied drugs (not to exceed 5 mg/daily dose of drug); Mouthwashes and dentifrices.
D&C Orange No. 10	Orange	Externally applied drugs
D&C Orange No. 11	Orange	Externally applied drugs
FD&C Red No. 3	Red	Ingested drugs.
FD&C Red No. 4	Red	Externally applied drugs
D&C Red No. 6	Red	Quaternary ammonium-type germicidal solutions for external application (not to exceed 0.1% (by wt) of finished drug product).
D&C Red No. 7	Red	Drugs such that total with D&C Red No. 6 not to exceed 5 mg/daily dose of drug.
D&C Red No. 17		

Red

Externally applied drugs

D&C Red No. 21	Red	Drugs generally
D&C Red No. 22	Red	Drugs generally
D&C Red No. 27	Red	Drugs generally
D&C Red No. 28	Red	Drugs generally
D&C Red No. 30	Red	Drugs generally
D&C Red No. 31	Red	Externally applied drugs.
D&C Red No. 33	Red	Ingested drugs, other than mouthwashes and dentifrices (not to exceed 0.75 mg/daily dose of drug); externally applied drugs; Mouthwashes and dentifrices.
D&C Red No. 34	Red	Externally applied drugs
D&C Red No. 36	Red	Ingested drugs, other than mouthwashes and dentifrices, not to exceed 1.7 mg/daily dose for drugs taken less than 1 yr; not to exceed 1.0 mg/daily dose for drugs taken more than 1 yr; Externally applied drugs
D&C Red No. 39	Red	Quaternary ammonium type germicidal solutions for external application (not to exceed 0.1% (by wt) of finished drug product).
FD&C Red No. 40		

Red

Drugs generally; Eye area use (includes lake).

D&C Violet No. 2	Violet	Externally applied drugs
FD&C Yellow No. 5	Yellow	Ingested drugs generally; Externally applied drugs; Eye area use (includes lake).
FD&C Yellow No. 6	Yellow	Drugs generally
D&C Yellow No. 7	Yellow	Externally applied drugs
Ext. D&C Yellow No. 7	Yellow	Externally applied drugs
D&C Yellow No. 8	Yellow	Externally applied drugs
D&C Yellow No. 10	Yellow	Drugs generally
D&C Yellow No. 11	Yellow	Externally applied drugs

FD&C = Food, Drug & Cosmetics, D&C = Drug & Cosmetics

Note that, the following colorants are no longer authorized for drugs:

- Bone Black
- Chlorophyll copper complex
- Charcoal NF XI
- Fustic
- Ultramarine blue – use in cosmetics is allowed