

## Approved Colorants for Japanese Pharmaceutical Drugs-1 <sup>\*a</sup>

Name	CAS Number	Color Index Number	Precedent Limit	Compendia
Black Iron Oxide	12227-89-3	77499	1.539 mg	JPE
d-Borneol	464-43-7		300 mg	JPE
Caramel			1500 mg	JPE
Carbon Black	1333-86-4	77268:1	0.096 mg	JPE
Carmines	1390-65-4	75470	1.8 mg	JPE
β-Carotene	7235-40-7	40800	0.1%	JPE
Copper Chlorophyll			1.8 mg	JSSFA
Glycyrrhiza Extract			300 mg	JP
Gold Leaf	7440-57-5		14 mg	JPE
Light Anhydrous Silicic Acid	7631-86-9		2.6 g	JP
Medicinal Carbon	16291-96-6		150 mg	JP
2-Octyldodecyl Myristate	22766-83-2		100 mg	JPE
Orange Essence			15 mg	JPE
Powdered Green Tea			100 mg	JPE
Red Ferric Oxide	1309-37-1	77491	95.4 mg	JPE
Riboflavin (Vitamin B2)	83-88-5		0.8 mg	JP
Riboflavin Butyrate	83-88-5		0.4 mg	JP
Riboflavin Sodium Phosphate	130-40-5		2 mg	JP
Rose Oil	8007-01-0		0.1 mg	NF
Rye Green Leaf Extract			2 mg/g	JPE
Sodium Copper Chlorophyllin			75 mg	Japan Pharmaceutical Codex , JSSFA
Sodium Hydroxide	1310-73-2		224 mg	JP
Talc	14807-96-6		3384 mg	JP
Titanium Oxide	13463-67-7	77891	384 mg	JP
Yellow Ferric Oxide	1310-14-1	77492	5.67 mg	JPE

<sup>\*a</sup> These colorants are cited from the list of coloring matters in Japanese Pharmaceutical Excipients Directory 2016 (Japanese Version). Precedent limits are quoted from the Directory. Each limit represents the maximum daily intake that a patient should consume from the use of a particular dosage form.

## Approved Colorants for Japanese Pharmaceutical Drugs-2 <sup>\*b</sup>

Japanese Name	Alternate Name	FDA Name	Color Index Number	CAS Number
Red #2	Amaranth, Acid Red 27		16185	915-67-3
Red #3	Erythrosine, Acid Red 51	FD&C Red #3	45430	16423-68-0
Red #102	New Coccine (Ponceau4R), Acid Red 18		16255	2611-82-7
Red #104(1)	Phloxine B, Acid Red 92	D&C Red #28	45410	18472-87-2
Red #105(1)	Rose Bengal, Acid Red 94		45440	632-69-9
Red #106	Acid Red, Acid Red 52		45100	3520-42-1
Yellow #4	Tartrazine, Acid Yellow 23	FD&C Yellow #5	19140	1934-21-0
Yellow #5	Sunset Yellow FCF, Food Yellow 3	FD&C Yellow #6	15985	2783-94-0
Green #3	Fast Green FCF, Food Green 3	FD&C Green #3	42053	2353-45-9
Blue #1	Brilliant Blue FCF, Food Blue 2	FD&C Blue #1	42090	3844-45-9
Blue #2	Indigo Carmine, Acid Blue 74	FD&C Blue #2	73015	860-22-0

**\*b** Based on these colorants approved by the MHLW's "Ministerial Ordinance to establish tar colors which can be used in Pharmaceuticals"; No. 126; July 29, 2003.

Aluminium lakes of these dyes are also authorized.

Not more than 0.1% by weight of color (lake or dye) can be used in a dosage form. If one colorant was combined with other colorants, total weight of these colorants must be less than 0.1% of the final product.

The colorants used in Japan must meet the specification of the Ministerial Ordinance.

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