



I N F O R M A T I O N

S H E E T

Approved Drug Colorants for Internal Use in Japan-1^{*a}

Name	CAS Number	Color Index Number	Precedent Limit	Compendia
Black Iron Oxide	12227-89-3	77499	1.539 mg	JPE
Caramel			1500 mg	JPE
Carbon Black	1333-86-4	77268:1	0.096 mg	JPE
Carmine	1390-65-4	75470	1.8 mg	JPE
β-Carotene	7235-40-7	40800	0.1%	JPE
Copper Chlorophyll			1.8 mg	Japan Pharmaceutical Codex
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	83-88-5		0.8 mg	JP
Riboflavin Butyrate			0.4 mg	JP
Riboflavin Sodium Phosphate			2 mg	JP
Rose Oil	8007-01-0		0.1 mg	NF
Rye Green Leaf Extract			2 mg	JPE
Sodium Copper Chlorophyllin			75 mg	Japan Pharmaceutical Codex
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

*a These colorants appear in the application column in the Japanese Pharmaceutical Excipients Directory 2007 (Japanese Version) as coloring agents. Precedent limits are quoted from the Japanese Pharmaceutical Excipients Directory 2007 (Japanese Version). Each limit represents the maximum daily intake that a patient should consume from the use of a particular dosage form.



Approved Drug Colorants for Internal Use in Japan-2 ^{*b}

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

***b** Based on colors approved by the MHW's "Ministerial Ordinance to establish Tar colors which can be used in Pharmaceuticals"; No. 30; August 31, 1966. Aluminum lakes of these colors are also authorized.

***c** 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.

***d** These colorants make the list of the application column in the Japanese Pharmaceutical Excipients Directory 2007 (Japanese Version) as coloring agents.

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World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Website: www.colorcon.com/pharma

e-mail: info@colorcon.com

Locations

United States

Santa Ana, California
Indianapolis, Indiana
Humacao, Puerto Rico
Stoughton, Wisconsin

Telephone

714-549-0631
317-545-6211
787-852-3815
608-887-8970

Facsimile

714-549-4921
317-545-6218
787-852-0030
608-887-8984

Locations

Asia/Pacific

Singapore
Fuji-gun, Shizuoka, Japan
Shanghai, China
Goa, India
Gyeonggi-do, Korea

Telephone

65-6438-0318
81-5-4465-2711
86-21-5442-2222
91-832-288-3434
82-31-296--2173

Facsimile

65-6438-0178
81-5-4465-2730
86-21-5442-2229
91-832-288-3440
82-31-296-2178

Canada

St. Laurent, QC, Canada

514-337-8341

514-337-9159

Europe

Dartford, Kent, England
Massey, France
Idstein, Germany
Gallarate, Italy
Budapest, Hungary
Istanbul, Turkey
Barcelona, Spain

44-1322-293000
33-1-6447-9750
49-6126-9961-0
39-0331-776932
36-1-200-8000
90-216-465-0360
34-9-3589-3756

44-1322-627200
33-1-6932-5983
49-6126-9961-11
39-0331-776831
36-1-200-8010
90-216-465-0361
34-9-3589-3792

Latin America

Buenos Aires, Argentina
Cotia, Brasil
Bogota, Colombia
Caracas, Venezuela
Santa Fe, México

54-11-4552-1565
55-11-4612-4262
571-418-1202
58-212-237-9842
52-55-3000-5700

54-11-4552-3997
55-11-4612-3307
571-418-1257
58-212-238-2259
52-55-3000-5701 /02

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