

<i>n</i>	<i>t</i> ² = <i>F</i> ₁	<i>n</i>	<i>t</i> ² = <i>F</i> ₁	<i>n</i>	<i>t</i> ² = <i>F</i> ₁
1	161.45	13	4.667	25	4.242
2	18.51	14	4.600	26	4.225
3	10.129	15	4.543	27	4.210
4	7.709	16	4.494	28	4.196
5	6.608	17	4.451	29	4.183
6	5.987	18	4.414	30	4.171
7	5.591	19	4.381	40	4.085
8	5.318	20	4.351	60	4.001
9	5.117	21	4.325	120	3.920
10	4.965	22	4.301	∞	3.841
11	4.844	23	4.279		
12	4.747	24	4.260		

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Dioscorea Rhizome

Dioscoreae Rhizoma

サンヤク

Dioscorea Rhizome is the rhizome (rhizophore) of *Dioscorea japonica* Thunberg or *Dioscorea batatas* Decaisne (*Dioscoreaceae*), from which the periderm has been removed.

Description Cylindrical or irregular cylindrical rhizome, 5 – 15 cm in length, 1 – 4 cm in diameter, occasionally longitudinally split or transversely cut; externally whitish to yellowish white; fractured surface, whitish, smooth and powdery; hard in texture but breakable. Practically odorless and tasteless.

Identification (1) To the cut surface of Dioscorea Rhizome add dilute iodine TS dropwise: a dark blue color develops.

(2) To 0.2 g of pulverized Dioscorea Rhizome add 2 mL of acetic anhydride, warm on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add 0.5 mL of sulfuric acid carefully to make two layers: a red-brown to purple-brown color appears at the zone of contact.

Loss on drying Not more than 14.0% (6 hours).

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 0.5%.

Powdered Dioscorea Rhizome

Dioscoreae Rhizoma Pulveratum

サンヤク末

Powdered Dioscorea Rhizome is the powder of Dioscorea Rhizome.

Description Powdered Dioscorea Rhizome occurs as nearly yellowish white to white; odorless and tasteless.

Under a microscope, Dioscorea rhizome powder reveals starch grains; fragments of parenchyma cells containing starch grains; raphides of calcium oxalate, 100 to 200 μm in length and its containing mucilage cells; ring and scalariform vessels, 15 to 35 μm in diameter; starch grain isosceles deltoïd or oblong, solitary, 18 to 35 μm, hilum and striation being distinct.

Identification To 0.2 g of Powdered Dioscorea Rhizome add 2 mL of acetic anhydride, warm on a water bath for 2 to 3 minutes, and filter. To the filtrate add 0.5 mL of acetic anhydride, shake, and add carefully 0.5 mL of sulfuric acid to make two layers: a red-brown to purple-brown color develops at the zone of contact.

Loss on drying Not more than 14.0% (6 hours).

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 0.5%.

Containers and storage Containers—Tight containers.

Diphenhydramine and Bromovalerylurea Powder

ジフェンヒドラミン・ワレリル尿素散

Method of preparation

Diphenhydramine Tannate	90 g
Bromovalerylurea	500 g
Starch, Lactose, or their mixture	a sufficient quantity
To make 1000 g	

Prepare as directed under Powders, with the above ingredients.

Description Diphenhydramine and Bromovalerylurea Powder occurs as a slightly grayish white powder.

Identification (1) To 0.1 g of Diphenhydramine and Bromovalerylurea Powder add 5 mL of dilute hydrochloric acid, 1 mL of ethanol (95) and 10 mL of water, shake, and filter. To the filtrate add 10 mL of sodium hydroxide TS, and extract with 10 mL of chloroform. Separate the chloroform layer, add 1 mL of bromophenol blue TS, and shake: a yellow color develops in the chloroform layer (diphenhydramine tannate).

(2) Shake 0.02 g of Diphenhydramine and Bromovalerylurea Powder with 10 mL of diethyl ether, filter, and evaporate the filtrate on a water bath. Dissolve the residue in 2 mL of sodium hydroxide TS, and add 5 mL of dimethylglyoxime-thiosemicarbazide TS, and heat on a water bath for 30 minutes: a red color develops (bromovalerylurea).

(3) Shake 0.3 g of Diphenhydramine and Bromovalerylurea with 5 mL of methanol, filter, and use the filtrate as the sample solution. Dissolve 0.15 of bromovalerylurea and 0.03 g of diphenhydramine tannate in 5 mL each of methanol, and use the solutions as standard solution (1) and standard solution (2). Perform the test as directed under the Thin-layer Chromatography with these solutions. Spot 5 μL each of the sample solution and the stan-

dard solutions (1) and (2) on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate in a mixture of ethyl acetate, ethanol (99.5) and ammonia solution (28) (50:5:1) to a distance of about 10 cm. Air-dry the plate, and examine under ultraviolet light (main wavelength: 254 nm): 3 spots from the sample solution and the corresponding spot from standard solutions (1) and (2) show the same *R_f* value. Spray Dragendorff's TS for spraying evenly on the plate: the spot from the standard solution (2) and the corresponding spot from the sample solution reveal an orange color.

Containers and storage Containers—Well-closed containers.

Diphenhydramine, Phenol and Zinc Oxide Liniment

ジフェンヒドรามミン・フェノール・亜鉛華リニメント

Method of preparation

Diphenhydramine	20 g
Phenol and Zinc Oxide Liniment	980 g
To make 1000 g	

Dissolve and mix the above ingredients.

Description Diphenhydramine, Phenol and Zinc Oxide Liniment is a white to whitish, pasty mass. It has a slight odor of phenol.

Identification (1) To 3 g of Diphenhydramine, Phenol and Zinc Oxide Liniment add 20 mL of hexane, shake well, and separate the hexane layer. Shake thoroughly the hexane solution with 10 mL of 0.2 mol/L hydrochloric acid. Separate the aqueous layer, and adjust with sodium hydroxide TS to a pH of 4.6. Add 1 mL of bromophenol blue-potassium biphthalate TS and 10 mL of chloroform, and shake: a yellow color develops in the chloroform layer (diphenhydramine).

(2) Place 1 g of Diphenhydramine, Phenol and Zinc Oxide Liniment in a porcelain crucible, gradually raise the temperature by heating until the mass is charred, and ignite strongly: a yellow color is produced, and disappears on cooling. To the residue add 10 mL of water and 5 mL of dilute hydrochloric acid, shake well, and filter. Add 2 to 3 drops of potassium hexacyanoferrate (II) TS to the filtrate: a white precipitate is produced (zinc oxide).

(3) Shake 0.5 g of Diphenhydramine, Phenol and Zinc Oxide Liniment with 1 mL of water and 5 mL of chloroform, filter, and use the filtrate as the sample solution. Dissolve 0.01 g each of diphenhydramine and phenol in 5 mL each of chloroform, and use these solutions as standard solution (1) and standard solution (2). Perform the test as directed under the Thin-layer Chromatography with the sample solution and the standard solutions. Spot 5 μ L each of the sample solution and standard solutions (1) and (2) on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5) and ammonia solution (28) (50:5:1) to a distance of about 10 cm, and air-dry the plate. Allow the plate to stand in iodine vapor: two spots

from the sample solution and each spot from standard solution (1) and standard solution (2) show the same *R_f* value. Sublime iodine, and spray Dragendorff's TS evenly upon the plate: the spot from standard solution (1) and the corresponding spot from the sample solution reveal an orange color.

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Freeze-dried Diphtheria Antitoxin, Equine

乾燥ジフテリアウマ抗毒素

Freeze-dried Diphtheria Antitoxin, Equine, is a preparation for injection which is dissolved before use. It contains diphtheria antitoxin in immunoglobulin of horse origin.

It conforms to the requirements of Freeze-dried Diphtheria Antitoxin, Equine, in the Minimum Requirements for Biological Products.

Description Freeze-dried Diphtheria Antitoxin, Equine, becomes a colorless or light yellow-brown, clear liquid or a slightly whitish turbid liquid on addition of solvent.

Diphtheria Toxoid

ジフテリアトキシイド

Diphtheria Toxoid is a liquid for injection containing diphtheria toxoid prepared by treating diphtheria toxin with formaldehyde by a method involving no appreciable loss of the immunogenicity.

It conforms to the requirements of Diphtheria Toxoid in the Minimum Requirements for Biological Products.

Description Diphtheria Toxoid is a clear, colorless to light yellow-brown liquid.

Adsorbed Diphtheria Toxoid for Adult Use

成人用沈降ジフテリアトキシイド

Adsorbed Diphtheria Toxoid for Adult Use is a liquid for injection containing diphtheria toxoid prepared by treating diphtheria toxin with formaldehyde by a method involving no appreciable loss of the immunogenicity and very few antigenic substances other than toxoid, and rendered insoluble with aluminum salt.

It conforms to the requirements of Adsorbed