

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<sub>f</sub>* 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  $\mu$ 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<sub>f</sub>* 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