lowed 1 to 2 days later by 5000 to 10 000 units of chorionic gonadotrophin. Oocyte retrieval is performed 34 to 35 hours later.

Urofollitropin is also used with chorionic gonadotrophin to stimulate spermatogenesis in the treatment of **male infertility**, although a preparation with combined luteinising activity, such as human menopausal gonadotrophins, may be preferred. The usual dose of urofollitropin provides 150 units of FSH three times a week. Treatment with urofollitropin and chorionic gonadotrophin should be continued for at least 4 months. For a brief discussion of hypogonadism see p.2079.

Infertility. For reference to the use of preparations with follicle-stimulating hormone activity in infertility, see p.2080.

References to the use of urofollitropin.

1. McFaul PB, *et al.* Treatment of clomiphene citrate-resistant polycystic ovarian syndrome with pure follicle-stimulating hormone or human menopausal gonadotropin. *Fertil Steril* 1990; **53:** 792–7.
2. European Metrodin HP Study Group. Efficacy and safety of highly purified urinary follicle-stimulating hormone with human chorionic gonadotropin for treating men with isolated hypogonadotropic hypogonadism. *Fertil Steril* 1998; **70:** 256–62.
3. Crain JL, *et al.* Outcome comparison of in vitro fertilization treatment with highly purified subcutaneous follicle-stimulating hormone (Fertinex, a urofollitropin) versus intramuscular menotropins. *Am J Obstet Gynecol* 1998; **179:** 299–307.
4. Lenton E, *et al.* Induction of ovulation in women undergoing assisted reproductive techniques: recombinant human FSH (follitropin alpha) versus highly purified urinary FSH (urofollitropin HP). *Hum Reprod* 2000; **15:** 1021–7.
5. Mohamed MA, *et al.* Urinary follicle-stimulating hormone (FSH) is more effective than recombinant FSH in older women in a controlled randomized study. *Fertil Steril* 2006; **85:** 1398–1403.

Preparations

BP 2008: Urofollitropin Injection.

Proprietary Preparations (details are given in Part 3)
Arg.: Follitrin; Fostimon; ***Austral.:*** Metrodin; ***Braz.:*** Metrodin; ***Canad.:*** Bravelle; Fertinorm†; ***Chile:*** Follitrin; ***Cz.:*** Fostimon; Metrodin†; ***Fr.:*** Fostimon; ***Gr.:*** Bravelle; Metrodin†; ***Hong Kong:*** Follimon†; Fostimon; Metrodin†; ***Hung.:*** Fostimon; Metrodin†; ***India:*** Gonotrop F; Metrodin; Neogentin; ***Irl.:*** Metrodin†; ***Israel:*** Metrodin†; ***Ital.:*** Fostimon; Metrodin†; ***Mex.:*** Fostimon; ***Neth.:*** Bravelle; Metrodin†; ***Port.:*** Bravelle; Fostimon; Metrodin; ***Rus.:*** Metrodin (Метродин); ***S.Afr.:*** Metrodin†; ***Singapore:*** Metrodin†; ***Spain:*** Neo Fertinorm†; ***Switz.:*** Fostimon; Metrodin†; ***Thai.:*** Follimon; ***Turk.:*** Metrodin; ***UK:*** Fostimon; ***USA:*** Bravelle; Fertinex; Metrodin.

Zeranol *(BAN, USAN, rINN)* ⊗

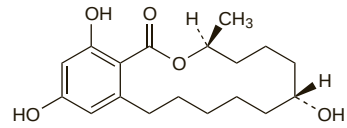
MK-188; P-1496; THFES (HM); Zearalanol; Zéranol; Zeranolum.

(3*S*,7*R*)-3,4,5,6,7,8,9,10,11,12-Decahydro-7,14,16-trihydroxy-3-methyl-1*H*-2-benzoxacyclotetradecin-1-one.

Зеранол

$C_{18}H_{26}O_5$ = 322.4.

CAS — 26538-44-3.



Profile

Zeranol is a nonsteroidal oestrogen that has been used for the management of menopausal and menstrual disorders. It has also been used as a growth promotor in veterinary practice. Its anabolic properties may be subject to abuse in sport.

◊ WHO specifies an acceptable daily intake of zeranol as a residue in foods and recommends maximum residue limits in various animal tissues.[1] However, it should be noted that, in the European Union the use of zeranol in veterinary medicine is prohibited. Certain other steroidal hormones are permitted for restricted use but their use as growth promotors is banned.

1. FAO/WHO. Evaluation of certain veterinary drug residues in food: thirty-second report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser 763* 1988. Also available at: http://libdoc.who.int/trs/WHO_TRS_763.pdf (accessed 30/06/08)

Soaps and Other Anionic Surfactants

Soaps and other anionic surfactants dissociate in aqueous solution to form an anion, which is responsible for the surface activity, and a cation which is devoid of surface-active properties. They are widely used for their emulsifying and cleansing properties. The term **detergent** is used to describe a surface-active agent with such properties that concentrates at oil-water interfaces. Anionic surfactants used in pharmaceutical preparations include:

- **Alkali-metal** and **ammonium soaps** (monovalent alkyl carboxylates) which are the sodium, potassium, and ammonium salts of the higher fatty acids
- **Metallic soaps** (polyvalent alkyl carboxylates), the calcium, zinc, magnesium, and aluminium salts of the higher fatty acids; they produce water-in-oil emulsions and are often formed by chemical reaction during the preparation of the emulsion
- **Amine soaps**, which are salts of amines with fatty acids
- **Alkyl sulfates** or **sulfated fatty alcohols**, salts of the sulfuric acid esters of the higher fatty alcohols
- **Alkyl ether sulfates** or **ethoxylated alkyl sulfates**, formed by sulfating ethoxylated alcohols.
- **Sulfated oils**, which are prepared by treating fixed oils with sulfuric acid and neutralising with sodium hydroxide solution.

Many **sulfonated compounds** have been produced that possess surface-active properties and are used as detergents; they include alkyl sulfonates, alkyl aryl sulfonates, and amide sulfonates. Docusate sodium (p.1725), a sulfonated dibasic acid ester, has medicinal and pharmaceutical uses.

Ampholytic (or amphoteric) surfactants possess at least one anionic group and at least one cationic group in the molecule and can therefore have anionic, nonionic, or cationic properties depending on the pH. When the strength of the cationic portion of the molecule is equivalent to that of the anionic portion the isoelectric point occurs at pH 7 and the molecule is said to be balanced. Ampholytic surfactants have the detergent properties of anionic surfactants and the disinfectant properties of cationic surfactants. Their activity depends on the pH of the media in which they are used. Compounds used include aminocarboxylic acids, aminopropionic acid derivatives, imidazoline derivatives, and dodicin. Long-chain betaines are sometimes classed as ampholytic surfactants.

Balanced ampholytic surfactants are reputed to be non-irritant to the eyes and skin and have therefore been used in baby shampoos.

Aluminium Monostearate

Aluminii monostearas; Aluminium, monostéarate de; Aluminum Monostearate; Glinu monostearynian; Monoestearato de aluminio; Monostearato de aluminio. Dihydroxy(octadecanoato-*O*-)aluminium; Dihydroxy(stearato)aluminium.

Алюминия Моностеарат

CAS — 7047-84-9.

Pharmacopoeias. In *Jpn* and *Pol.* Also in *USNF.*

USNF 26 (Aluminum Monostearate). A compound of aluminium with a mixture of solid organic acids obtained from fats and consisting mainly of variable proportions of aluminium monostearate and aluminium monopalmitate. A fine, white to yellowish-white, bulky powder with a faint characteristic odour. Insoluble in water, in alcohol, and in ether.

Profile

Aluminium monostearate is used as a gelling agent in oil-based cosmetic and pharmaceutical formulations. It may also be used as a stabiliser in cosmetic emulsions.

Calcium Stearate

Calcii stearas; Calcium, stéarate de; Estearato de calcio; Kalcio stearatas; Kalciumstearat; Kalcium-sztearát; Kalsiumsteraraatti; Stearan vápenatý. Calcium octadecanoate.

Кальция Стеарат

CAS — 542-42-7 (calcium palmitate); 1592-23-0 (calcium stearate).

Pharmacopoeias. In *Eur.* (see p.vii), *Int.*, and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Calcium Stearate). A mixture of calcium salts of different fatty acids consisting mainly of stearic acid ($C_{36}H_{70}CaO_4$ = 607.0) and palmitic acid ($C_{32}H_{62}CaO_4$ = 550.9) with minor proportions of other fatty acids. The fatty acid fraction contains not less than 40.0% of stearic acid and the sum of stearic acid and palmitic acids is not less than 90.0%. A fine, white or almost white, crystalline powder. Practically insoluble in water and in alcohol.

USNF 26 (Calcium Stearate). A compound of calcium with a mixture of solid organic acids obtained from fats, consisting mainly of variable proportions of calcium stearate ($C_{36}H_{70}CaO_4$ = 607.0) and calcium palmitate ($C_{32}H_{62}CaO_4$ = 550.9). A fine, white to yellowish-white bulky, unctuous powder, free from gritiness with a slight characteristic odour. Insoluble in water, in alcohol, and in ether.

Profile

Calcium stearate is added to granules as a lubricant in the manufacture of tablets and capsules.

Adverse effects. Acute eosinophilic pneumonia in 1 patient has been attributed to the presence of calcium stearate used as an additive in an antihistamine tablet formulation.[1]

1. Kurai J, *et al.* Acute eosinophilic pneumonia caused by calcium stearate, an additive agent for an oral antihistaminic medication. *Intern Med* 2006; **45:** 1011–16.

Calcium Stearoyl-lactylate

Calcium Stearoyl-2-lactylate; E482. Calcium 2-(1-Carboxyethoxy)-1-methyl-2-oxoethyloctodecanoate.

Стеароиллактилат Кальция

CAS — 5793-94-2.

Sodium Stearoyl-lactylate

E481; Sodium Stearoyl-2-lactylate. Sodium 2-(1-Carboxyethoxy)-1-methyl-2-oxoethyloctadecanoate sodium salt.

Стеароиллактилат Натрия

CAS — 25383-99-7.

Profile

Sodium stearoyl-lactylate has anionic surfactant properties and is used as an emulsifier and stabilising and suspending agent in the food industry, including in foods for special diets. The calcium salt is used similarly.

Magnesium Stearate

572; Estearato de magnesio; Magnesii stearas; Magnésium, stéarate de; Magnesiumsteraraatti; Magnesiumstearat; Magnézium-sztearát; Magnezu stearynian; Magnio stearatas; Stearan hořečnatý.

Стеарат Магния

CAS — 1555-53-9 (magnesium oleate); 2601-98-1 (magnesium palmitate); 557-04-0 (magnesium stearate).

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), *Int.*, *Jpn*, and *Viet.* Also in *USNF.*

Ph. Eur. 6.2 (Magnesium Stearate). A mixture of the magnesium salts of different fatty acids consisting mainly of stearic acid ($C_{36}H_{70}MgO_4$ = 591.2) and palmitic acid ($C_{32}H_{62}MgO_4$ = 535.1) and in minor proportions other fatty acids. The fatty acid fraction contains not less than 40.0% of stearic acid and the sum of stearic acid and palmitic acid is not less than 90.0%. A white or almost white, very fine, light powder, greasy to the touch. Practically insoluble in water and in dehydrated alcohol.

USNF 26 (Magnesium Stearate). A compound of magnesium with a mixture of solid organic acids, and consisting mainly of variable proportions of magnesium stearate ($C_{36}H_{70}MgO_4$ = 591.2) and magnesium palmitate ($C_{32}H_{62}MgO_4$ = 535.1). It is a very fine, light, white powder, slippery to touch. Insoluble in water, in alcohol, and in ether.

Profile

Magnesium stearate is added to granules as a lubricant in the manufacture of tablets and capsules. It has also been used as a dusting powder and in barrier creams.

Preparations

Proprietary Preparations (details are given in Part 3)

Multi-ingredient: ***Philipp.:*** Johnson's Baby Double Protection Powder.

Sodium Cetostearyl Sulfate

Cetoestearilsulfato de sodio; Cétostéaryle (sulfate de) sodique; Cetylstearylschwefelsaures Natrium; Natrii cetylo- et stearylosulfas; Natrio cetostearilo sulfatas; Natrium Cetylosulphuricum; Natrium Cetylstearylosulphuricum; Nátrium-cetil-sztearil-szulfát; Natriumcetostearylsulfat; Natrium-cetylstearyl-sulfát; Natriumsetostearyylisulfaatti; Sodium Cetostearyl Sulphate; Sodu cetostearylosiarczan.

Натрия Цетостеарилсульфат

CAS — 1120-01-0 (sodium cetyl sulfate); 1120-04-3 (sodium stearyl sulfate).

Pharmacopoeias. In *Eur.* (see p.vii). Also in *USNF.*

Ph. Eur. 6.2 (Sodium Cetostearyl Sulphate). A mixture of sodium cetyl sulfate ($C_{16}H_{33}NaO_4S$ = 344.5) and sodium stearyl sulfate ($C_{18}H_{37}NaO_4S$ = 372.5). A white or pale yellow, amorphous or crystalline powder. Soluble in hot water giving an opalescent solution; practically insoluble in cold water; partly soluble in alcohol.

USNF 26 (Sodium Cetostearyl Sulfate). A mixture of sodium cetyl sulfate ($C_{16}H_{33}NaSO_4$ = 344.5) and sodium stearyl sulfate ($C_{18}H_{37}NaSO_4$ = 372.5). It contains not less than 40% of sodium cetyl sulfate and the sum of the sodium cetyl sulfate content and sodium stearyl sulfate content is not less than 90%, both contents calculated on the anhydrous basis. A white or pale yellow, amorphous or crystalline powder. Soluble in hot water giving an opalescent solution; practically insoluble in cold water; partly soluble in alcohol.

Profile

Sodium cetostearyl sulfate is an anionic emulsifying agent. It is used as a detergent and wetting agent.

Sodium Cocoyl Isetionate

Sodium Cocoyl Isethionate.

Кокоил Изетионат Натрия

CAS — 61789-32-0.

Profile

Sodium cocoyl isetionate is the sodium salt of a sulfonated ester of coconut oil fatty acids. It is an anionic surfactant used as a soap substitute. Sodium cocoyl sarcosinate has been used similarly.

Preparations

Proprietary Preparations (details are given in Part 3)

Fr.: Physiogel; ***Hong Kong:*** Physiogel; ***Indon.:*** Physiogel; ***Ital.:*** Physiogel; ***Malaysia:*** Physiogel; ***Singapore:*** Physiogel; ***Thai.:*** Physiogel.

Multi-ingredient: ***Fr.:*** Oilatum AD†; ***Mex.:*** Bonaven; ***Philipp.:*** Physiogel.

Sodium Laurilsulfate *(pINNM)*

Laurilsulfate de Sodium; Laurilsulfato de sodio; Natrii laurilsulfas; Natrio laurilsulfatas; Natrium Lauryl Sulphuricum; Natriumlaurilsulfat; Nátrium-lauril-szulfát; Natrium-lauryl-sulfát; Natriumlauryylisulfaatti; Sodium Dodecyl Sulphate; Sodium, laurilsulfate de; Sodium Lauryl Sulfate; Sodium Lauryl Sulphate; Sodu dodecylosiarczan patrz: Sodu laurylosiarczan; Sodu laurylosiarczan.

Натрий Лаурилсульфат

CAS — 151-21-3.

Pharmacopoeias. In *Chin.*, *Eur.* (see p.vii), and *Jpn.* Also in *USNF.*

Ph. Eur. 6.2 (Sodium Laurilsulfate; Sodium Lauryl Sulphate BP 2008). A mixture of sodium alkyl sulfates, consisting mainly of sodium dodecyl sulfate ($C_{12}H_{25}NaO_4S$ = 288.4). It contains not less than 85% of sodium alkyl sulfates and not more than a total of 8% of sodium chloride and sodium sulfate. A white or pale yellow powder or crystals. Freely soluble in water giving an opalescent solution; partly soluble in alcohol.

USNF 26 (Sodium Lauryl Sulfate). A mixture of sodium alkyl sulfates, consisting mainly of sodium laurilsulfate ($C_{12}H_{25}NaO_4S$ = 288.4). The combined content of sodium chloride and sodium sulfate is not more than 8%. Small, white or light yellow crystals with a slight, characteristic odour. Soluble 1 in 10 of water giving an opalescent solution.

Incompatibility. Sodium laurilsulfate interacts with cationic surfactants such as cetrimide, resulting in a loss of activity. It is also incompatible with salts of polyvalent metal ions (e.g. aluminium, lead, tin, or zinc) and with acids of pH below 2.5. It is not affected by hard water because of the solubility of the corresponding calcium and magnesium salts.

Profile

Sodium laurilsulfate is an anionic emulsifying agent. It is a detergent and wetting agent, effective in both acid and alkaline solution and in hard water. It is used in medicated shampoos and as a skin cleanser and in toothpastes. It is used in the preparation of Emulsifying Wax (p.2029). Prolonged exposure to sodium laurilsulfate may irritate the skin or mucous membranes.