

§ 520.1044c

21 CFR Ch. I (4-1-02 Edition)

§ 520.1044c Gentamicin sulfate soluble powder.

(a) *Specifications.* Each gram of gentamicin sulfate soluble powder contains gentamicin sulfate equivalent to 16.7, 66.7, or 333.3 milligrams of gentamicin.

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Amount.* Colibacillosis: gentamicin sulfate equivalent to 25 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 0.5 milligram per pound of body weight per day; swine dysentery: gentamicin sulfate equivalent to 50 milligrams of gentamicin per gallon of drinking water for 3 consecutive days, to provide 1 milligram per pound of body weight per day.

(2) *Indications for use.* In weanling swine for control and treatment of colibacillosis caused by strains of *E. coli* sensitive to gentamicin, and in swine for control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

(3) *Limitations.* For use in swine drinking water only. Do not store or offer medicated drinking water in rusty containers since the drug is quickly destroyed in such containers. Medicated drinking water should be prepared daily and be the sole source of drinking water for 3 consecutive days. Treatment may be repeated if dysentery recurs. Do not slaughter treated swine for food for at least 10 days following treatment.

[49 FR 29778, July 24, 1984, as amended at 52 FR 7832, Mar. 13, 1987; 52 FR 48675, Dec. 24, 1987; 62 FR 29013, May 29, 1997]

§ 520.1100 Griseofulvin.

(a) *Chemical name.* 7-Chloro-2',4,6-trimethoxy-6'-methylspiro [benzofuran-2(3H), 1'-[2]-cyclohexene]-3,4'-dione.

(b) *Specifications.* Complies with U.S.P. for griseofulvin microsize.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) As a soluble powder for horses, it is administered as a drench or as a top dressing on feed. It is used for equine ringworm infection caused by *Trichophyton equinum* or

Microsporium gypseum. Administer for not less than 10 days a daily dose as follows: Adults, 2.5 grams; yearlings, 1.25 to 2.5 grams; and foals, 1.25 grams. Not for use in horses intended for food. For use only by or on the order of a licensed veterinarian.

(2)(i) Boluses containing 2.5 grams of griseofulvin are used in horses for treating ringworm infection caused by *Trichophyton equinum*. It is administered to adult horses at a level of one bolus per day, to yearlings at one-half to one bolus per day, and to foals at one-half bolus per day. All three dosage levels should be administered for a period of not less than 10 days. In responsive cases, treatment should be continued until all infected areas are proven negative by appropriate culture. Not for use in horses intended for food.

(ii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) Dogs and cats: (i) *Amount.* 125- and 500-milligram tablets administered orally as follows:

(a) Daily (single or divided) dose:

Body weight (pounds)	Dosage (milligrams)
Up to 6	62.5
6 to 18	125
18 to 36	250
36 to 48	375
48 to 75	500

(b) Weekly (single) dose: If experience indicates that treatment is more effective for the drug given in large doses, administer at intervals of 7 to 10 days, a dose equal to 10 milligrams/pound of body weight x body weight x number of days between treatments. Dosage should be adjusted according to response. Administer additional dose after the animal is free of infection.

(ii) *Indications for use.* For treatment of fungal infections of the skin, hair, and claws caused by *Trichophyton mentagrophytes*, *T. rubrum*, *T. schoenleini*, *T. sulphurem*, *T. verrucosum*, *T. interdigitale*, *Epidermophyton floccosum*, *Microsporium gypseum*, *M. canis*, *M. audouini*.

(iii) *Limitations.* For satisfactory diagnosis, a microscopic tissue examination or culture is recommended prior to treatment. Treatment should be continued for 3 to 4 weeks in skin and

hair infections, and up to 4 months for infections involving nails or claws. Clipping of hair, nails, and claws to help remove any remaining viable fungi is indicated. Safety for use of griseofulvin for pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 42948, Sept. 29, 1976; 43 FR 28458, June 30, 1978; 52 FR 7832, Mar. 13, 1987; 54 FR 30205, July 19, 1989]

§ 520.1120 Haloxon oral dosage forms.

§ 520.1120a Haloxon drench.

(a) *Chemical name.* 3-Choloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications.* Haloxon assay of not less than 96 percent by infrared spectrum at 8.62 microns.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Special considerations.* Do not use any drug, insecticide, pesticide, or other chemical having cholinesterase-inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(e) *Related tolerances.* See § 556.310 of this chapter.

(f) *Conditions of use.* It is used as a drench as follows:

(1) *Cattle*—(i) *Amount.* 141.5 grams per packet.

(ii) *Indications for use.* Control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus*, and *Cooperia*.

(iii) *Limitations.* (a) Dissolve each packet in 32 fluid ounces of water and administer as follows:

Weight of animal (pounds)	Dose (fluid ounces)
Up to 100	1/2
100 to 150	3/4
150 to 200	1
200 to 300	1 1/2
300 to 450	2
450 to 700	3
700 to 1,000	4
1,000 to 1,200	5
Over 1,200	6

(b) Do not treat within 1 week of slaughter; do not treat dairy animals

of breeding age; animals should be re-treated in 3 to 4 weeks.

[40 FR 13838, Mar. 27, 1975, as amended at 45 FR 10333, Feb. 15, 1980; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.1120b Haloxon boluses.

(a) *Chemical name.* 3-Chloro-7-hydroxy-4-methylcoumarin bis (2-chloroethyl) phosphate.

(b) *Specifications.* Each bolus contains 10.1 grams of haloxon.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Related tolerances.* See § 556.310 of this chapter.

(e) *Conditions of use.* (1) Haloxon bolus is an anthelmintic used in cattle for the control of gastrointestinal roundworms of the genera *Haemonchus*, *Ostertagia*, *Trichostrongylus* and *Cooperia*.

(2) It is administered by giving one bolus per approximately 500 pounds body weight (35 to 50 milligrams per kilogram of body weight).

(3) For most effective results, re-treat animals in 3 to 4 weeks. If reinfection is likely to occur, additional re-treatments may be necessary.

(4) Do not use any drug, pesticide or other chemical having cholinesterase inhibiting activity either simultaneously or within a few days before or after treatment with haloxon.

(5) Do not treat animals within one week of slaughter.

(6) Do not treat dairy animals of breeding age or older.

[40 FR 13838, Mar. 27, 1975, as amended at 44 FR 61591, Oct. 29, 1979; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.1130 Hetacillin oral dosage forms.

§ 520.1130a Hetacillin potassium capsules.

(a) *Specifications.* Each capsule contains hetacillin potassium equivalent to 50, 100, or 200 milligrams of ampicillin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) *Dogs*—(i) *Amount.* 5 milligrams per pound of body