

## § 520.82b

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

(c) *Conditions of use*. (1) The drug is used in dogs and cats for reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.<sup>1</sup>

(2) It is administered at a dosage level of 1 to 2 milligrams per pound of body weight. The dosage can be repeated every 12 hours, as indicated.<sup>1</sup>

(3) Not for use in animals intended for food purposes.

(4) For use only by or on the order of a licensed veterinarian.<sup>1</sup>

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

### § 520.82b Aminopropazine fumarate, neomycin sulfate tablets.

(a) *Specifications*. The drug is in tablet form. Each tablet contains both aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base and neomycin sulfate equivalent to 50 milligrams of neomycin base.

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

(c) *Conditions of use*. (1) The drug is used in dogs to control bacterial diarrhea caused by organisms susceptible to neomycin and to reduce smooth muscle contractions.<sup>1</sup>

(2) It is administered at a dosage level of one to two tablets per 10 pounds of body weight twice daily for 3 days.<sup>1</sup>

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

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

## § 520.88 Amoxicillin oral dosage forms.

### § 520.88a Amoxicillin trihydrate film-coated tablets.

(a) *Specifications*. Each tablet contains amoxicillin trihydrate equivalent to 50, 100, 150, 200, or 400 milligrams of amoxicillin.

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

## 21 CFR Ch. I (4-1-04 Edition)

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 5 milligrams per pound of body weight, twice a day.

(ii) *Indications for use*. Treatment of infections of the respiratory tract (tonsillitis, tracheobronchitis), genitourinary tract (cystitis), gastrointestinal tract (bacterial gastroenteritis), and soft tissues (abscesses, lacerations, wounds), caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, *Proteus mirabilis*, and bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 50 milligrams (5 to 10 milligrams per pound of body weight) once a day.

(ii) *Indications for use*. Treatment of infections caused by susceptible organisms as follows: upper respiratory tract due to *S. aureus*, *Streptococcus* spp., and *E. coli*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract due to *E. coli*; and skin and soft tissue (abscesses, lacerations, and wounds) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations*. Administer for 5 to 7 days or 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

### § 520.88b Amoxicillin trihydrate for oral suspension.

(a) *Specifications*. When reconstituted, each milliliter contains amoxicillin trihydrate equivalent to 50 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(1) *Conditions of use*—(i) *Dogs*—(A) *Amount*. 5 milligrams per pound of body weight twice daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: respiratory tract (tonsillitis, tracheobronchitis) caused by *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary tract (cystitis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal tract (bacterial gastroenteritis) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis caused by *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; and soft tissues (abscesses, lacerations, and wounds) caused by *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Cats*—(A) *Amount*. 50 milligrams (5 to 10 milligrams per pound) once daily.

(B) *Indications for use*. Treatment of infections caused by susceptible strains of organisms as follows: upper respiratory tract due to *Staphylococcus* spp., *Streptococcus* spp., *Hemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary tract (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal tract due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(C) *Limitations*. Use for 5 to 7 days or 48 hours after all symptoms have subsided. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

(c) *Sponsors*. See Nos. 000856 and 051311 in § 510.600(c) of this chapter.

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

(ii) *Indications for use*. Treatment of bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., *Staphylococcus* spp.,

and *E. coli*, and soft tissue infections (abscesses, wounds, lacerations) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis* and *Staphylococcus* spp.

(iii) *Limitations*. Use for 5 to 7 days. Continue for 48 hours after all symptoms have subsided. If no improvement is seen in 5 days, review diagnosis and change therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 37319, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992, as amended at 60 FR 55658, Nov. 2, 1995; 62 FR 13302, Mar. 20, 1997; 67 FR 67521, Nov. 6, 2002; 68 FR 54658, Sept. 18, 2003; 68 FR 55824, Sept. 29, 2003]

#### § 520.88c Amoxicillin trihydrate oral suspension.

(a) *Specifications*. Each 0.8-milliliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*. *Swine*—(1) *Amount*. 40 milligrams orally, twice a day using a dosing pump.

(2) *Indications for use*. Treatment of baby pigs under 10 pounds for porcine colibacillosis caused by *Escherichia coli* susceptible to amoxicillin.

(3) *Limitations*. Treat animals for 48 hours after all symptoms have subsided but not beyond 5 days. Do not slaughter during treatment or for 15 days after latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37319, Aug. 18, 1992, as amended at 60 FR 55658, Nov. 2, 1995]

#### § 520.88d Amoxicillin trihydrate soluble powder.

(a) *Specifications*. Each gram contains amoxicillin trihydrate equivalent to 115.4 milligrams of amoxicillin.

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.38 of this chapter.

(d) *Conditions of use*. *Preruminating calves including veal calves*—(1) *Amount*. 400 milligrams per 100 pounds of body weight twice daily.