

FORMULA NUMBER: 1990

FORMULA NAME: Chlortetracycline Bisulfate 1% Ointment, Veterinary

DOSAGE FORM: Ointment

FORMULA (Rx):

Ingredients	For: 100 grams	Lot#	RPh Initials
Chlortetracycline Bisulfate (Veterinary)	1 g		
Benzalkonium Chloride	10 mg		
Tetrasodium Pyrophosphate	50 mg		
Edetate Disodium Dihydrate	300 mg		
Lanolin (Anhydrous)	15 g		
Mineral Oil	15 g		
Paraffin	70 g		

SYNONYMS:

Aureomycin

USE/TYPE: CATEGORY:

Human Use AntiBacterial Tetracycline

Veterinary Use AntiMycobacterial
Non-Sterile Preparation AntiProtozoal
AntiRickettsial

NOTES:

Chlortetracycline hydrochloride may be substituted for the bisulfate salt. This same formula, utilizing the hydrchloride salt, is used for veterinary ophthalmic preparations.

SPECIALIZED EQUIPMENT:

METHOD OF PREPARATION:

- 1. Calculate the required quantity of each ingredient for the total amount to be prepared.
- 2. Accurately weigh and/or measure each ingredient.
- 3. Warm the paraffin and mineral oil over a water bath to about 50°C and maintain melted.
- 4. Add the anhydrous lanolin to the paraffin and mineral oil melt and mix well.
- 5. Triturate the chlortetracycline bisulfate, benzalkonium chloride, tetrasodium pyrophosphate and edetate disodium to fine powders.
- 6. Gradually incorporate the fine powders into the warmed mixture mixing well after each addition.

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- 7. Allow to cool but still fluid and pour into containers.
- 8. Package and label.

LABELING:

Apply Very Sparingly to Affected Area For External Use Only
For Veterinary Use Keep Out of Reach of Children

Pregnant Women Must Not Handle this Medicine

PRESERVATION, PACKAGING AND STORAGE:

Tight, Light Resistant Container	Keep Out of Direct Sunlight
Do Not Use After	

STABILITY:

A beyond-use date of 6 months can be used for this preparation.

ENDOTOXIN ASSESSMENT:

USE:

For topical administration to farm animals for superficial infections of amoeba and other organisms sensitive to tetracyclines including the treatment of Psittacosis and salmonella. Demethylchlortetracycline is used in a similar manner. Chlortetracycline hydrochloride was available as a 3% Ointment and an ear solution.

STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL:

Assessments may include theoretical weight compared to actual weight, pH, specific gravity, active drug assay and color. Other observations: texture-surface, texture-spatula spread, appearance, feel, rheological properties and physical macroscopic observations should be noted.

REGULATORY CONTROL:

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More information about this formula and its components available at the formula section of https://CompoundingToday.com

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