## FLORFENICOL- florfenicol injection, solution Sparhawk Laboratories, Inc

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FLORFENICOL Injectable Solution 300 mg/mL

Approved by FDA under ANADA # 200-588

For intramuscular and subcutaneous use in beef and non-lactating dairy cattle only.

Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal.

Not for Use in Humans Keep out of reach of children

**CAUTION** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION** Each milliliter contains 300 mg of florfenicol, 250 mg N-methyl-2-pyrrolidone (NMP), 150 mg propylene glycol, and polyethylene glycol qs.

**INDICATIONS** FLORFENICOL INJECTION is indicated for treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni, and for the treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus. Also, it is indicated for the control of respiratory disease in cattle at high risk of developing BRD associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni.

## DOSAGE AND ADMINISTRATION

For treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon (foot rot): FLORFENICOL INJECTION should be administered by intramuscular injection to cattle at a dose rate of 20 mg/kg body weight (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, FLORFENICOL INJECTION can be administered by a single subcutaneous (SC) injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

NOTE: Intramuscular injection may result in local tissue reaction which persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

For control of respiratory disease in cattle at high-risk of developing BRD: FLORFENICOL INJECTION should be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

FLORFENICOL I			
	Recommended		
ANIMAL	3.0 mL/100 lb	6.0 mL/100 lb	Injection

	Body Weight	Body Weight	WEIGHT
	(mL)	(mL)	(lbs)
	6.0	3.0	100
	12.0	6.0	200
	18.0	9.0	300
	24.0	12.0	400
	30.0	15.0	500
	36.0	18.0	600
D	42.0	21.0	700
m m	48.0	24.0	800
si	54.0	27.0	900
]	60.0	30.0	1000



Do not inject more than 10 mL per injection site.

Clinical improvement should be evident in most treated subjects within 24 hours of initiation of treatment. If a positive response is not noted within 72 hours of initiation of treatment, the diagnosis should be re-evaluated.

**CONTRAINDICATIONS** Do not use in animals that have shown hypersensitivity to florfenicol.

**USER SAFETY WARNINGS: NOT FOR HUMAN USE. KEEP OUT OF REACH OF CHILDREN.** This product contains materials that can be irritating to skin and eyes. Avoid direct contact with skin, eyes, and clothing. In case of accidental eye exposure, flush with water for 15 minutes. In case of accidental skin exposure, wash with soap and water. Remove contaminated clothing. Consult a physician if irritation persists. Accidental injection of this product may cause local irritation. Consult a physician immediately. Reproductive and developmental toxicities have been reported in laboratory animals following high, repeated exposures to N-methyl-2-pyrrolidone (NMP). Pregnant women should wear gloves and exercise caution or avoid handling this product. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

**CONTACT INFORMATION:** To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Sparhawk Laboratories, Inc. at 1-800-255-6368 or www.sparhawklabs.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae

**PRECAUTIONS:** Not for use in animals intended for breeding purposes. The effects of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy. Intramuscular injection may result in local tissue reaction which persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be more severe.

Use within 6 months of first puncture. STORAGE INFORMATION: Store between 2°C and 25°C (36°F - 77°F). Protect from light when not in use.

**RESIDUE WARNINGS:** Animals intended for human consumption must not be

slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal.

**ADVERSE REACTIONS** Inappetence, decreased water consumption, or diarrhea may occur transiently following treatment.

## **CLINICAL PHARMACOLOGY**

**CLINICAL PHARMACOLOGY** The pharmacokinetic disposition of florfenicol was evaluated in feeder calves following single intramuscular (IM) administration at the recommended dose of 20 mg/kg body weight. Florfenicol was also administered intravenously (IV) to the same cattle in order to calculate the volume of distribution, clearance, and percent bioavailability1 (Table 1)

TABLE 1. Pharmacokinetic Parameter Values for Florfenicol Following IM Administration of 20 mg/kg Body Weight to Feeder Calves (n=10).

Parameter	Median	Range
C <sub>max</sub> (μg/mL)	3.07*	1.43 - 5.60
t <sub>max</sub> (hr)	3.33	0.75 - 8.00
T ½ (hr)	18.3**	8.30 - 44.0
AUC (μg•min/mL)	4242	3200 - 6250
Bioavailability (%)	78.5	59.3 - 106
Vd <sub>ss</sub> (L/kg)***	0.77	0.68 - 0.85
Clt (mL/min/kg)***	3.75	3.17 - 4.31

<sup>\*\*</sup> mean value

C<sub>max</sub> Maximum serum concentration

 $T_{max}$  Time at which  $C_{max}$  is observed

T ½ Biological half-life

AUC Area under the curve

Vd<sub>ss</sub> Volume of distribution at steady state

Clt Total body clearance

Florfenicol was detectable in the serum of most animals through 60 hours after intramuscular administration with a mean concentration of 0.19  $\mu$ g/mL. The protein binding of florfenicol was 12.7%, 13.2%, and 18.3% at serum concentrations of 0.5, 3.0, and 16.0  $\mu$ g/mL, respectively.

#### MICROBIOLOGY

Florfenicol is a synthetic, broad-spectrum antibiotic active against many Gram-negative

<sup>\*\*\*</sup> following IV administration

and Gram-positive bacteria isolated from domestic animals. It acts by binding to the 50S ribosomal subunit and inhibiting bacterial protein synthesis. Florfenicol is generally considered a bacteriostatic drug, but exhibits bactericidal activity against certain bacterial species. In vitro studies demonstrate that florfenicol is active against the bovine respiratory disease (BRD) pathogens Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni, and that florfenicol exhibits bactericidal activity against strains of M. haemolytica and H. somni. Clinical studies confirm the efficacy of florfenical against BRD as well as against commonly isolated bacterial pathogens in bovine interdigital phlegmon including Fusobacterium necrophorum and Bacteroides melaninogenicus. The minimum inhibitory concentrations (MICs) of florfenicol for BRD organisms were determined using isolates obtained from natural infections from 1990 to 1993. The MICs for interdigital phlegmon organisms were determined using isolates obtained from natural infections from 1973 to 1997 (Table 2).

TABLE 2. Florfenicol Minimum Inhibitory Concentration (MIC) Values\* of Indicated Pathogens Isolated From Natural Infections of Cattle.

Indicated pathogens	Years of isolation	Number of isolates	MIC50** (μg/mL)	MIC90** (μg/mL)
Mannheimia haemolytica	1990 to 1993	398	0.5	1
Pasteurella multocida	1990 to 1993	350	0.5	0.5
Histophilus somni	1990 to 1993	66	0.25	0.5
Fusobacterium necrophorui	m 1973 to 1997	33	0.25	0.25
Bacteroides melaninogenicu	s 1973 to 1997	20	0.25	0.25

<sup>\*</sup> The correlation between the in vitro susceptibility data and clinical effectiveness is unknown.

**ANIMAL SAFETY** A 10X safety study was conducted in feeder calves. Two intramuscular injections of 200 mg/kg were administered at a 48-hour interval. The calves were monitored for 14 days after the second dose. Marked anorexia, decreased water consumption, decreased body weight, and increased serum enzymes were observed following dose administration. These effects resolved by the end of the study.

A  $1\times$ ,  $3\times$ , and  $5\times$  (20, 60, and 100 mg/kg) safety study was conducted in feeder calves for  $3\times$  the duration of treatment (6 injections at 48-hour intervals). Slight decrease in feed and water consumption was observed in the  $1\times$  dose group. Decreased feed and water consumption, body weight, urine pH, and increased serum enzymes, were observed in the  $3\times$  and  $5\times$  dose groups. Depression, soft stool consistency, and dehydration were also observed in some animals (most fre-quently at the  $3\times$  and  $5\times$  dose levels), primarily near the end of dosing.

A 43-day controlled study was conducted in healthy cattle to evaluate effects of

<sup>\*\*</sup> The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

NUFLOR Injectable Solution administered at the recommended dose on feed consumption. Although a tran-sient decrease in feed consumption was observed, NUFLOR Injectable Solution administration had no long-term effect on body weight, rate of gain, or feed consumption.

**STORAGE INFORMATIONStore between 2°C and 25°C (36°F - 77°F).** Protect from light when not in use. Use within 6 months of first puncture. Refrigeration is not required. The solution is light yellow to straw colored. Color does not affect potency.

**HOW SUPPLIED** FLORFENICOL INJECTION is packaged in 100 mL (NDC 58005-742-04), 250 mL (NDC 58005-742-05), and 500 mL (NDC 58005-742-06) glass sterile multiple-dose vials.

**REFERENCE** 1. Lobell RD, Varma KJ, et al. Pharmacokinetics of florfenicol following intravenous and intramuscular doses to cattle. J Vet Pharmacol Therap. 1994;17:253-258.

Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA

Made in USA

F-7475

Rev. 07-23

## **Principal Display Panel**

Injectable Solution **300 mg/m**L Sterile Multiple-Dose Vial

For intramuscular and subcutaneous use in beef and non-lactating dairy cattle only.

Not for use in female dairy cattle 20 months of age or older or in calves to be processed for veal. Not for Use in Humans Keep out of reach of children

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-588

IMPORTANT: See Product Information insert for complete directions and warnings before using.

**DESCRIPTION:** Each millifiter contains 300 mg of florfenicol, 250 mg N-methyl-2-pyrrolidone (NMP), 150 mg propylene glycol, and polyethylene glycol qs.

#### DOSAGE AND ADMINISTRATION

For treatment of bovine respiratory disease (BRD) and bovine interdigital phlegmon (foot rot); FLORENICOL INJECTION should be administered by intranuscular injection to cattle at a dose rate of 20 mg/kg body weight. (3 mL/100 lbs). A second dose should be administered 48 hours later. Alternatively, FLORFENICOL INJECTION can be administered by a single subcutaneous (SC) injection to cattle at a dose rate of 40 mg/kg body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. **The** injection should be given only in the neck.

For control of respiratory disease in cattle at high-risk of developing BRD: FLORFENICOL INJECTION should be administered by a single subcutaneous injection to cattle at a dose rate of 40 mg/gR body weight (6 mL/100 lbs). Do not administer more than 10 mL at each site. The injection should be given only in the neck.

EXP. DATE: 10TN0:

NDC 58005-742-06

## FLORFENICOL INJECTION

### Injectable Solution 300 mg/mL Sterile Multiple-Dose Vial

For intramuscular and subcutaneous use in beef and non-lactating dairy cattle only.

Not for use in female dairy cattle 20 months of age or older or in calves to be processed for yeal. Not for Use in Humans Keep out of reach of children

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NET CONTENTS: 500 mL

LABORATORIES, INC.

RESIDUE WARNINGS: Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. This product is not approved for use in female cattle growth of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for yeal.

PRECAUTIONS: Not for use in animals intended for breeding purposes. The effects of florfenical on bovine reproductive performance, pregnancy, and lactation have not been determined. Intramuscular injection may result in local tissue reaction which persists beyond 28 days. This may result in trim loss of edible tissue at slaughter. Tissue reaction at injection sites other than the neck is likely to be

Use within 6 months of first puncture.

STORAGE INFORMATION: Store between 2°C and 25°C (36°F - 77°F). Protect from light when not in use.

Made in USA

F-7425-06

Rev. 07-23

TABLE 2. Referenced Minimum Inhibitory Concentration (MIC) Values\* of Indicated Pathogens Isolated From Natural Infections of Cattle.

Indicated pathogens	Year of isolation	Number of isolates	MIC50** (µg/ml.)	MIC90** (pg/mL)
Mannhatma Asomolytisa	1990 to 1990	396	0.5	10
Pasterrata matanta	1990 to 1980	350	0.5	0.5
Motophilia: contri	1990 to 1993	66	0.25	0.5
Рипобывенит лектирбитит	1973 to 1997	33	0.25	0.25
Besteroides melaninogenicus	1933 to 1997	20	0.25	0.25

The correlation between the Wiwtosiscept bility data and clinical effectiveness is inknown.
 The lowest MIC to encompass 50% and 90% of the most susceptible isolates, respectively.

ANIMAL SAFETY A 100 safety study was conducted in feeder cakes. Fee intractions of 200 might were administed at 6 46-or integer, the cakes were commissioned for 14 days after the second does. Marked amonts, decreased valuer consumption, decreased below weight, and increased serum entymes were observed following does administration. These effects resolved by the end of the study.

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A IX, 3X, and 5X [20, 80] and 100 mg/kg] safety study was conducted in feeder calves for 3X, the duration of treatment for injections at 48-box intervals. Slight decrease in feed and water consumption was observed in the 1X does group. Decreased level and water consumption, body weelght, unine pH, and in reased serror marrynes, were observed in the 2X and 5X does groups. Depression, soft stool consistency, and deflydration were also observed in the 3X and 5X does groups. See the same stool of the same shall be sufficiently as the same shall be sufficiently as the same shall be same s

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STORAGE INFORMATION Store between 2°C and 25°C SIUSHASE INFURMATION Store between 7°C and 2°C.

JOSEP — 77% - Protect from light when not in use. Use within 6 months of from the protect from light when not have closed Color does not after potents. Refrigeration is not required. The solution is light yellow to straw colored Color does not after potenty.

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Manufactured by Made in USA
Sparhawk Laborationes, Inc.
Lenexs, KS 66215, USA
Rev. 07-23

RESIDUE WARNINGS: Animals intended for human consumption must not be claughtered within 28 days of the last intransaccular treatment. Animals intended for human occumption must not be shapeltered within 38 days of subcataneous treatment. This product is not approved for sea in formale dairy cattle 20 months of age or older, including dyf adiny cows. Uso in those cattle may cause drug residees in milk and/or in calves from to those courts. A withfrawal poriod has not been established in pre-maintaing calves. Do not use in calves to be processed for eval.

PRECAUTIONS: Not for use in arimals intended for breeding purposes. The effects of Biorleinci on bouline reproductive performance, pregnancy, and lactation have not been followinger, distribution have not been following register may result in local bissule reaction which persists beyond 26 days. This may result in time loss of solide bissule at staughter. Tissue reaction at effection sites other than the neck is likely to be more severe. PRECAUTIONS: Not for use in animals intended for breeding purposes. The effects of florienical on

Use within 6 months of first puncture.

STORAGE INFORMATION: Store between 2°C and 25°C (36°F – 77°F). Protect from light when not in use. Made in USA

F-7425-06 Rev. 07-23

PRODUCT ed by FDA under ANADA # 200-586

FLORFENICOL INJECTION Injectable Solution

For intramuscular and subcutaneous use in beef and non-lactating dairy cattle only.

Not for use in female dairy cattle 20 months of age or older or in calves to be processed for yeal.

Not for Use in Humans Keep out of reach of children

CAUTION Federal law restricts this drug to use by or on the order of a licensed veterinanan.

Control reservation to technical situation is a season of DESCRIPTION RESERVATION. THE PROTECTION is a season of DESCRIPTION RESERVATION RESERVATION. THE PROTECTION CONTROL Each millister of seate Child Fall Coll May 1,000 and 1,000 and

with Fiscolacionium pecuniforum and Biocheologies melastragamentas. Also, it is indicated for the control of ERO amonatory and a superior and

NOTE: Intramuscular injection may result in local bissue reaction which persists beyond 28 days. This may result in imm loss of editie issue at alsughter. Tissue reaction at imjection sites other than the neck is likely to be more severe.

severe.
For control of respiratory disease in cattle at high-risk of developing BRD: FLORFENIDOL INJECTION should be administered by a single solucianeous injection cattle at a dose rate of Hunging body weight is mUPO bel. Up not administer more should be given only in 10 mL at each size. The injection should be given only in the next.

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FLORFENICOL INJECTION DOSAGE GUIDE

	DOSAGE	SC DOSAGE
ANIMAL WEIGHT	3.0 mL/100 lb Body Weight	6.0 mL/100 lb Body Weight
(lbs)	(mL)	(mL)
100	3.0	6.0
200	6.0	12.0
300	9.0	18.0
400	12.0	24.0
500	15.0	30.0
600	18.0	36.0
700	21.0	42.0
800	24.0	48.0
900	27.0	54.0
1000	30.0	60.0
	WEIGHT (Ibs) 100 200 300 400 500 800 300 900	DOSAGE   ANIMAL   30 mL/100 b   100 mL/100 b   100 mL/100 b   100 mL/100 mL/1

mended Injection Location



Do not inject more than 10 mL per injection site.

Clinical improvement should be evident in most treated subjects within 24 hours of initiation of treatment. If a positive exponse is not noved within 27 hours of initiation of treatment, the diagnosis should be re-evaluated.

CONTRAINDICATIONS Do not use in animals that have shown hype reensitivity to florenicol.

CONTRAINDICATIONS to not use in animals that nave about hype from both policy and format with a superior and the superior and

contains more treated excupations as sery immersal and. CONTRACT INFORMATION: To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contract Sparthawk, Laborationes, Inc. at 1-800-55-5688 or www.sparthawklacc.com. For additional information about advisere drug expendence reporting for animal drugs, contact TDA at 1-808-FDA-VETS or www.fbs.gov/iepor/amimalae

PRECAUTIONS: Not for use in animals in ended for breeding purposes. The effects of Ronfenical on bowne reproductive

performance, pregnancy, and lactation have not been determined. Identity studies in dogs, rats, and male have associated the use of finderincial with testicular dependence and attoply, lintransocular nection may result in local studies necesion within persists beyond 25 days. This may result in tim loss of edithe issue at staughter. Issue reaction at repetion size of the finant here is taken between the result of the persist studies.

cation are other than the neck of likely to be more sever RESIDUE WARNINOS. Annuals intended for human consumption must not be staughtered within 28 days of the last intransacrular treatment. Annuals intended for human occountrion must not be staughtered within 38 days of subcutaneous treatment. This product is not approved for user freinable dayr calls 20 days of subcutaneous treatment. This product cover, July in these copies may cause drug cover. July in these copies may cause drug cover. A withdrawal proof has not been stablished in pre-rumnating capters. Do not use in calves to be processed for weak.

COMINCAL PHARMACOLOGY The pharmacolinetic disposition of flarfenrod was evaluated in feeder calves following single infrarequestian? (MM) administration at the recommended dose of 20 mg/kg body weight Florfenrod was also administration in order to calculate the volume of disministration and cardier in order to calculate the volume of disministration contains an order to calculate the volume of disministration cannot be a calculated by flories of disministration.

TABLE 1. Pharmacokinetic Parameter Values for Horfenicol Following IM Administration of 20 mg/kg Body Weight to Feeder Calves (n=10).

Parameter	Median	Range
C <sub>ree</sub> (µg/m L)	3.07*	1.43 - 5.80
T <sub>erec</sub> (hr)	3.33	0.75 - 8.00
T ½ (hr)	18.3**	8.30 - 44.0
AUC (µg • min/mL)	4242	3200 - 6250
Bioavalability (%)	78.5	59.3 - 106
Vd <sub>ss</sub> (L/kg)***	0.77	0.68 - 0.85
Cl, Im L/min/kg)***	3.75	3.17 - 4.31

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hough 600-nos are instanceusian administration with a
mean concentration of 0.13 grifu. The protein briding of

florenicid was 127%, 137%, and 138% at serims

concentrations of 0.5, 3.0, and 10.0 gph1, respectively.

MICROBIOLOGY Horfenicol is a syntheti, it had-spectrum antibotic active against many Grain-negative and financial state of the synthetic active against many Grain-negative and financial state that state the industrial state of the synthetic and synthetic and synthetic and special protein synthetics. Professiol is generally considered a bacteriostatic drug, but exhibits bacteriodal activity against certain berefinal species. If with student activity against certain between species, the with students of the students of the

and assertations inhibitory concentrations (MICs) of forfenced for 880 organisms were determined using isolates obtained from natural infections from 1990 to 1993. The MICs for interdigital phlegmon organisms were determined using isolates obtained from natural infections from 1973 to 1970 (Table 2).

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## **FLORFENICOL**

florfenicol injection, solution

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<b>Product</b>	Inform	ation

PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:58005-742 **Product Type** 

**Route of Administration** INTRAMUSCULAR, SUBCUTANEOUS

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength FLORFENICOL (UNII: 9J97307Y1H) (FLORFENICOL - UNII:9J97307Y1H) FLORFENICOL 300 mg in 1 mL

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
1	NDC:58005-742-04	100 mL in 1 VIAL, MULTI-DOSE				
2	NDC:58005-742-05	250 mL in 1 VIAL, MULTI-DOSE				
3	NDC:58005-742-06	500 mL in 1 VIAL, MULTI-DOSE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200588	10/11/2023		

## **Labeler -** Sparhawk Laboratories, Inc (147979082)

Establishment					
Name	Address	ID/FEI	Business Operations		
Sparhawk Laboratories, Inc		147979082	manufacture, ANALYSIS		

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Zhejiang Hisoar Pharmaceutical Co. Ltd.		421271589	API MANUFACTURE	

Revised: 11/2023 Sparhawk Laboratories, Inc