

ZAMIVET 80 80g/1kg enramycin

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Overview

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- 2. Chemical Structure
- 3. Mechanism of action
- 4. Activity Spectrum of Anti-Infectives
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Polypeptide Antibiotic



Polypeptide

• a chain of amino acids linked together by peptide bonds



Amino acids



Non-ribosomally synthesized peptides

- Largely produced by bacteria, fungi, and streptomycetes
- Major component of the natural host defense molecules of these species.
- Anti-infective and antitumor antibiotics

Enramycin

ZAMIRA[®] AUSTRALIA

Enramycin is a polypeptide antibiotic produced by *Streptomyces fungicidus*

Chemical Structure





Enramycin

Mechanism of action



- Acts as a MurG inhibitor involved peptidoglycan synthesis in Gram positive bacteria.
- MurG catalyzes the transglycosylation reaction in the last step of peptidoglycan biosynthesis.
- Inhibition of this step greatly compromises cell wall integrity leading to cell lysis.
- Active within the gastrointestinal tract where it modifies the intestinal flora and maintains the integrity of the gut.

Bacterial Cell Wall





Mechanism of action







Compromises cell wall integrity leading to cell lysis

Activity Spectrum of Anti-Infectives



Gram Positive



Staphylococci



Streptococci



Corynebacterium



Clostridium

Enramycin



- Not absorbed from the intestinal tract
- High safety margin
- No cross-resistance between enramycin and other available antibiotics
- No detectable residue in tissues

Overview : Benefits of Enramycin



- 1. Disease Control
- 2. Performance Improvements
- 3. Environmental Benefits
- 4. Other benefits

Disease Control

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Disease Control



- Necrotic enteritis in poultry
- Clostridial enteritis in piglets
- Swine dysentery

Disease Control Poultry

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Necrotic Enteritis

- Necrotic enteritis (NE) is an enteric bacterial disease of poultry caused by *Clostridium perfringens*.
- Necrotic enteritis in poultry is caused by Clostridium perfringens type A & C.
- The disease is characterized by damage to the intestinal mucosa by toxins produced by *Clostridium perfringens*.
- Mild or subclinical form of NE is associated with poor growth and feed utilization.





Clinical Signs & Lesions









Various Predisposing Factors for Necrotic Enteritis



Risk factor	Reference				
Infectious					
Coccidiosis	ong, 1973; Alsheikhly & Alsaieg, 1980; Baba et al., 1992;				
(Eimeria infection)	Baba et al., 1997; Hofacre et al., 1998a				
Immunosuppression	McReynolds et al., 2004b				
Non-infectious					
Fish meal	Wijewant & Senevira, 1971b				
Barley	Riddell & Kong, 1992; Kaldhusdal & Skjerve, 1996; Annet et al., 2002				
Wheat	Branton et al., 1987; Riddell & Kong, 1992; Kaldhusdal & Skjerve, 1996 Annett et al., 2002				
Increased digesta viscosity (NSPs)	Kosher, 2003				
Lipids	Dahiya et al., 2006				
Dietary protein	Truscott & Alsheikhly, 1977; Kaldhusdal & Skjerve, 1996; Drew et al., 2004; Dahiya et al., 2005a; Wilkie et al., 2005;				
Managment					
Litter	Cowen et al., 1987; Droual et al., 1994; Williams, 2005; Hermans & Morgan, 2007; Mikkelsen et al., 2009; Palliyeguru et al., 2010				

Immunological Equilibrium - Clostridial Enteropathies





Necrotic enteritis : Disease Induction & Predisposing Factors





Clostridial Proliferation and Intestinal Instability





Oocysts per gram of litter by flock age





Oocysts per gram of litter by flock age





Age of flock (weeks)

Impact of Clostridial enteritis on the daily gain & performance of broilers





	Mortality	Body weight gain	FCR units
Clinical	Up to 30% of flock		
	3 to 7% of flock		+> 0,7
	+1% versus control	-5%	+0,05 - 0,1
Subclinical	+0,8% versus control	-4%	+0,04 - 0,08

Role of coccidiosis in Necrotic Enteritis





Predisposing Factors for Necrotic Enteritis





2015 Top 10 Broiler Health Issues Surveyed



Ranking	Philippines	Thailand	Japan	China	Korea	Vietnam	India	Indonesia	Asia
1	CRD	ND	Colibacillosis	AI(LP,HP)	Chick quality	HPAI	CAstV	ND	CRD
2	Chick quality	IB	RVR	IB	IB	ND	CRD	AI	IB
3	RVR	CRD	BMM	CRD	Lameness (Infectious)	IBD	AI	CRD	AI
4	RSS	MG	Metabolic issues	RVR	Cocci	IB	RSS	Gut health	ND
5	Gut health	MS	Chick quality	MG	DOA	CRD	IB	RVR	Chick quality
6	DOA	IBD	Cocci	MS	Metabolic issues	MG	FAdV	Chick quality	RVR
7	IB	Cocci	NE/GD	FAdV	IBD	MS	IBD	Metabolic issues	Соссі
8	ND	Lameness (Infectious)	HPAI	Cocci	FAdV	Cocci	Mycotoxin	SMS	IBD
9	Lameness (Structural)	FAdV	Lameness (Infectious)	Gut health	NE/GD	Gut health	Cocci	Cocci	MG
10	CAV	RVR	IBD	Chick quality	Salmonellosis	Mycotoxin	NE/GD	IBD	Gut health

CRD is including colibacillosis, RVR: Respiratory Vaccine Reaction, RSS: Runting and Stunting Syndrome, DOA: Dead On Arrival in slaughter house, BMM: Breast Muscle Myopathy, Metabolic issues include Ascites and SDS



Ranking	Philippines	Thailand	Japan	China	Korea	Vietnam	India	Indonesia	Asia
1	FC	ND	RT	AI(LP,HP)	RT	HPAI	MD	Metabolic disorder	IB
2	SMS	IB	NE/GD	IB	EYP	ND	IB	Gut health	AI
3	Cocci	MG	Cocci	Lameness (Infectious)	IB	IB	CAV	EYP	ЕҮР
4	Chick quality	MS	Lameness (Infectious)	EYP	HPAI	MG	NE/GD	Lameness (Infectious)	Cocci
5	ILT	Gut health	Red mite	Cocci	APV	MS	MG	NE/GD	Gut health
6	IC	EYP	EYP	MG/MS	Gut health	FAdV	IBD	Trauma	MG
7	Gut health	Cocci	Chick quality	Gut health	MS	APV	ND	Cocci	NE/GD
8	NE/GD	Chick quality	Metabolic disorder	APV	REO	CAV	FAdV	FC	ND
9	Lameness (Nutrition)	Aspergilllo sis	HPAI	MD	Metabolic disorder	Salpingitis	ILT	Parasite	MS
10	Parasite	FAdV	FAdV	Salmonellosis	Chick quality	Salmonellosis	Metabolic disorder	IBV	Lameness (Infectious)

FC: Fowl Cholera, SMS: Spiking mortality syndrome, IC: Infectious Coryza, NE: Necrotic Enteritis, GD: Gangrenous Dermatitis, EYP: Egg Yolk Peritonitis, FAdV: Fowl Adenovirus, RT: Ruptured Tendon

Disease Control Swine

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Evolution of Piglet Intestinal Flora







Before Birth

Digestive system is sterile

During Lactation

Small Intestine

- Lactobacillus
- Streptococcus

Large Intestine

Anaerobic Gram
positives



After Weaning

Small intestine

Higher proportion
of coliforms

Large Intestine

• Gram negative



Intestinal normal flora takes some time to be 100% balanced and functional



Population of enteric bacterial in the intestine is affected by



- 1. Nutritional factors
 - Feed and litter contaminated with large numbers of pathogenic enteric bacteria have been convincingly implicated as a source of infection
- 2. Environmental factors
- 3. Health status of the gut of the pig

Various Predisposing Factors for Swine Enteric Bacterial Infection



Infectious **Non - Infectious** Viral Agent Feed Rotavirus Structure and pellet quality Coronavirus • Palatability • Circovirus • Formulation and content ٠ **Mycotoxins** • **Bacterial Agent**

<u>Management</u>

- Available feed space
- Available water space
- Distribution of waterers
- Water quality
- Air quality
- Temperature
- Stocking density

- Clostridium
- Brachyspira •
- E.coli •

Parasites

- Cryptosporidium sp
- Isospora suis
- Trichuris suis

Non-infectious Diarrhea



- Inflammation without pathogen detection
- Disruption in the intestinal
 - o Diet change
 - o Diets ingredient change
 - Water quality
 - Mineral levels or mycotoxins

Epidemiology of Enteric Bacterial Infection





Transmission of infection between pigs and the environment



Transmission of enteric bacteria from sows to their progeny



External vectors in transmission of enteric bacteria
Pathogenesis of Disease: Interactions Between Pathogens, Host, and Environment







	Early Pe	Early Period Days		Late Period Days		
	0-3	3-7	7-14	15-21	Level	
Agalactia	•	•	•	•	Moderate	
Clostridia	•	<u> </u>	•		High	
Coccidiosis		•	•	•	Low	
Colibacillosis	•	•	•		Moderate	
PED	•	•	•	•	Low	
PRRS	•	•	•	•	Variable	
Rotavirus			•	•	Low	
TGE	•	•	•	•	High	

Muirhead et al (1997)

Age Distribution of Diarrheal Diseases in Pigs Enteric Bacterial Disease



		Age Group	
	Nursing	Weaning	Growing Finishing Breeding
Clostridium difficile enteritis	<u>ት</u> ት ር ር ር	仓	仓
Clostridium perfringens type A enteritis	仓仓	仓	-
Clostridium perfringens type C enteritis	仓仓	-	-
Enteric colibacillosis	<u>ት</u> ት ት	<u> </u>	-
Intestinal spirochetosis	-	仓仓	<u> </u>
Porcine proliferative enteritis	-	仓仓	<u> </u>
Salmonella enteritis	٢	仓仓	仓仓仓
Swine dysentery	<u></u>	企 企	<u> </u>
D.L.H. Harris (2013)			

[-] Rare or does not occur

[①] Uncommon

[û û] Common

[ûûû] Very common

Impact on Animal Performance





Clinical Findings





Clinical Findings





Porcine proliferative enteritis

Catarrhal Colitis

Swine Dysentery



Clostridium perfringens type C enteritis



Clostridium perfringens type A enteritis



Porcine proliferative enteritis

Important Pig Diseases in SEA



Table 6. Important pig diseases currently endemic in Southeast Asia.

Diseases and pathogen	Transmissible	Diseases and pathogen	Transmissible
Enzootic Pneumonia Pasteurellosis Porcine Pleuropneumonia Bordetella Atrophic Rhinitis Porcine Respiratory Coronavirus	Zoonose	Epidemic Diarrhea Transmissible gastroenteritis Round Worm Oesophagostomiasis Leptospirosis Brucellosis	Zoonose Zoonose
Swine influenza Glassers Disease	Zoonose	Parvovirus Porcine Reproductive and Respiratory Syndrome	
Streptococcus meningitis Lungworm	Zoonose	Erysipelas Tuberculosis	Zoonose
Colibacillosis Oedema Disease	Zoonose	Exudative Epidermitis Mange	
Salmonellosis Rotavirus Coccidiosis	Zoonose	Encephalomyocarditis Nipah Encephalitis Foot and Mouth Disease	Zoonose Zoonose
Swine Dysentery Spirochaetal diarrhoea Proliferative Enteropathy	Zoonose	Swine Versicular Disease Pseudorabies Classical Swine Fever	Zoonose

Performance Improvements

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Performance Improvements



Poultry

- Prevents necrotic enteritis in poultry.
- Has been shown to treat necrotic enteritis in broilers.
- Significantly reduces environmental loading of excreta and nitrogen.
- Increased rate of bodyweight gain.
- Lower feed requirements for each unit of gain.

Environmental Benefits

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Reduced nitrogen excretion (all species)

Increase the efficiency of nutrient utilisation, improving retention of N and P and decreasing excretion when nutrient intake matches requirements.

- 1. Decrease microbial degradation of essential amino acid
- 2. Improve absorption, enabling amino acid utilisation
- 3. Reductions in nitrogen excretion.
- 4. Ammonia gas emission from the manure was markedly decreased by feeding these lower-protein diets

Other Benefits

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- Protein sparing
- Energy sparing
- Improved mineral absorption
- Improved immune status
- Drier litter and reduced foot problems

Production and Economic Impacts

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The Real Silent Performance Killer





Impact on Poultry Performance



- High mortality rate : up to 30% of the flock.
- <u>Subclinical level:</u>
 - FCR to increase with 6-9 points & final bodyweight to reduce between 3-5%
- Annual losses to producers due to subclinical NE:
 - Est. US\$0.015 cent to US\$0.05 cent per birds (2000)

Economical Importance in Poultry Industry



- NE occurs worldwide and causes considerable financial losses to poultry producers due to mortality and treatment cost.
- Producer often adopt the figure of USD 0.05 per chick derived from a USD 2 billion loss on a worldwide scale estimated in 2000.
- Since then, parameter have changed, as have the true costs of NE, would come closed to <u>US\$6 billion</u> in 2015.
- A later study found that the cost was closer to US\$0.625 per bird.

<u>Due to:</u>

- 1. Increased mortality.
- 2. Increased feed conversion ratio.
- 3. Decreased weight gain.

Production and Economic Impacts of Swine Enteric Bacterial Infection



Subclinical infections

- Diarrhoea is rarely observed in pigs sub-clinically affected with bacterial infections
- Decreased feed intake
- Reduce pig weights or weight gains
- Variation in pig weights (increased in infected pigs relative to non-infected pigs)
- Reductions in ADG and increased FCR
- The economic impact of sub-clinical infection is difficult to estimate because many producers are unaware that sub-clinical infection is present in their herd.

Production and Economic Impacts of Swine Enteric Bacterial Infection



Enteric bacterial infections occur worldwide and causes considerable financial losses to swine producers due to morbidity, mortality and treatment cost.

Due to:

- 1. Increased mortality.
- 2. Increased feed conversion ratio.
- 3. Decreased weight gain.

	Sour infooted	Nursing/Gro	ower/Finisher	
	Sow mected	Morbidity	Mortality	
Swine dysentery	Up to 25%	75 - 90%	25 - 30%	
Clostridium difficile enteritis		7 - 10%	Up to 50%	
Clostridium perfringens type A enteritis		> 90%	< 1%	
Porcine proliferative enteritis		10 - 15%	50%	
Intestinal Spirochetosis		5 - 15%	1 - 2%	

Summary



Benefits in poultry

- Improves liveweight gain and feed conversion efficiency of broilers.
- Prevents necrotic enteritis in broilers and caged birds.
- Has been shown to treat necrotic enteritis in broilers.
- Significantly reduces environmental loading of excreta and nitrogen.

Summary



Benefits in pigs

- Improves the growth rate and feed conversion efficiency of treated pigs.
- Treatment of pregnant sows decreased the incidence and severity of clostridial enteritis in their piglets.
- Treated sows lose less weight and wean greater numbers of heavier piglets.
- Controls swine dysentery (SD) in growing-finishing pigs.

What is a veterinary feed directive (VFD)?

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What is a veterinary feed directive?

In United States agricultural policy, a Veterinary Feed Directive (VFD) is

- a written statement that authorizes the owner or caretaker of animals to obtain and use animal feed containing VFD drugs to treat their animals
- in accordance with the FDA-approved directions for use.

FDA – Veterinary Feed Directive (VFD)



What is a VFD drug?

A VFD drug is

- intended for use in animal feeds
- VFD drug is permitted only under the professional supervision of a licensed veterinarian.



Over-the-counter medicine

- Is also known as OTC or non-prescription medicine
- Refer to medicine that you can buy without a prescription
- They are safe and effective when you follow the directions on the label and as directed by your health care professional

FDA – Veterinary Feed Directive (VFD)





National Grain and Feed Association

FDA's Antimicrobial Resistance Policies and the Veterinary Feed Directive

Impacts on Medicated Feed

July 2016

FDA – Veterinary Feed Directive (VFD)



Unaffected by FDA proposals Animal use only Drugs used exclusively in animals: lonophores Polypeptides Carbadox Bambermycin Pleuromutilin Human use only Drugs used exclusively in humans:

- Daptomycin
- Glycylcyclines
- Mupirocin
- Mycobacterium anti-infectives

Affected by FDA proposals

Shared use

Drugs deemed "important for human medicine" and used by both animals and humans, such as:

- Penicillins
- Cephalosporins
- Quinolones
- Fluoroquinolones
 - Tetracyclines

Therapeutic uses

(still allowed under veterinary supervision) Treat animals diagnosed with an illness **Control** the spread of illness in a herd **Prevent** illness in healthy animals when exposure is likely

Production uses

(No longer allowed) **Enhance** growth or improve feed efficiency

- Macrolides
 - Sulfas
 - Glycopeptides
 - Others

OIE List of Antimicrobial Agents of Veterinary Importance



ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
POLYPEPTIDES					
Enramycin	Avian, Swine, Bovine, Rabbit, Ovine	Bacitracin is used in the treatment of necrotic enteritis in poultry. This class is used in the treatment of septicaemias, colibacillosis, salmonellosis, and urinary infections.		X	

VCIA: Veterinary Critically Important Antimicrobial Agents VHIA: Veterinary Highly Important Antimicrobial Agents VIA: Veterinary Important Antimicrobial Agents

Maximum Residue Limits (MRLs) and Risk Management



Recommendations (RMRs) for Residues of Veterinary Drugs in Foods

CODEX	ΑL	II	Μ	E	Ν	ΤA	AR	IU	JS
INTERNATIONAL FOOD STAND	ARDS	F		Food an	nd Agric	ulture	(A) V	Vorld H	lealth

Organization

E-mail: codex@fao.org - www.codexalimentarius.org

Maximum Residue Limits (MRL)

Abamectin		Gentamicin		
Albendazole		Imidocarb		
Amoxicillin		Isometamidium		
Ampicillin		Ivermectin		
Avylamycin		Lasalocid sodium		
Azaperone		Levamisole		
Benzylpenicillin/Procaine ber	nzylpenicillin	Lincomycin		
Carazolol		Lufenuron		
Ceftiofur		Melengestrol acetate		
Chlortetracycline/Oxytetracyc	cline/Tetracycline	Monensin		
Clenbuterol		Monepantel		
Closantel		Moxidectin		
Colistin		Narasin		
Cyfluthrin		Neomycin		
Cyhalothrin		Nicarbazin		
Cypermethrin and alpha-cyp	ermethrin	Phoxim		
Danofloxacin		Pirlimycin		
Deltamethrin		Porcine somatotropin		
Derquantel		Progesterone		
Dexamethasone		Ractopamine		
Diclazuril		Sarafloxacin		
Dicyclanil		Spectinomycin		
Dihydrostreptomycin/Strepto	mycin	Spiramycin		
Diminazene		Sulfadimidine		
Doramectin		Teflubenzuron		
Emamectin benzoate		Testosterone		
Eprinomectin		Thiabendazole		
Erythromycin		Tilmicosin		
Estradiol-17beta		Trenbolone acetate		
Febantel/Fenbendazole/Oxfe	endazole	Trichlorfon (Metrifonate		
Fluazuron		Triclabendazole		
Flubendazole		Tylosin		
Flumequine		Zeranol		

F —

Enramycin Residue Studies



Animal	Poultry			Swine		
ppm	0	20	100	0	20	100
Withdrawal period	0	0	0	0	0	0
Tissues	-	-	-	-	-	-
Blood	-	-	-	-	-	-
Muscle	-	-	-	-	-	-
Liver	-	-	-	-	-	-
Kidney	-	-	-	-	-	-
Spleen	-	-	-	-	-	-
Fat	-	-	-	-	-	-

ZAMIVET 80 80g/1kg enramycin

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Is highly effective in controlling Necrotic Enteritis caused by *Clostridium perfringens*.

ZAMIVET 80 consistently and reliably increases rate of weight gain and improves the efficiency of feed utilization.

Active Constituent : 80g/1kg enramycin

Why Use ZAMIVET80?



- Highly effective for use in pigs and poultry as prevention and control of a range of enteric diseases
- Acts in very low inclusion level
- Not absorbed in the gut
- Promotes a healthy gastrointestinal tract, resulting in improved performance
- Reducing ammonia levels in the intestinal contents and blood
- No history of resistance
- High safety margin
- No antibiotic residue issues in meat
- Synergist effects when used with other antimicrobials & anticoccidials
- Stable during the pelleting process and in feeds
- Not used in human therapy

Increase profits with ZAMIVET80



<u>Swine</u>

- Increase piglet weaning weight
- Increase piglets weaned per sow
- Reduce sow weight loss during lactation
- Increase growth in grower/finisher pigs
- Improve feed conversion efficiency

Poultry

- Increase egg production from layers
- Increase growth from broilers
- Reduced mortality
- Improve feed conversion efficiency

Indications - Poultry





For prevention and control of Necrotic Enteritis in poultry caused by *C. perfringens* (Types A and C).

Indications - Swine








Prevention: <u>Prestarter/Starter:</u> **125g/tonne** of finished feed (10 ppm) for 3-5 days.

Grower/Finisher/Prelayer/Layer: 62.5g/tonne of finished feed (5 ppm) for 3-5 days.

Treatment: 250 g/tonne of finished feed (20 ppm) for 5 – 7 days

Usage – Poultry Program



	Phase	Inclusion rate (ppm)
	Starter	6 – 8
Broiler	Grower	4 – 6
	Finisher	3 – 4
	DOC to 4 weeks	10
Breeders	5 to 18 weeks	8
	19 to 24 weeks	6
	Production	4
Layer	Laying	5

Broilers Performance





King Saud University (2012)





Prevention: <u>Prestarter/Starter:</u> **125 g/tonne** of finished feed (10 ppm) for 3-5 days.

<u>Grower/Finisher:</u> 62.5 g/tonne of finished feed (5 ppm) for 3-5 days.

Treatment: 250 g/tonne of finished feed (20 ppm) for 5 – 7 days

Historical Weather - Manila





Historical Weather - Davao





Temperature & Humidity Index - Poultry





Applications - Swine



	Age Group		
	Nursing	Weaning	Growing Finishing Breeding
<i>Clostridium difficile</i> enteritis	仓仓仓	仓	仓
<i>Clostridium perfringens</i> type A enteritis	仓仓	兌	-
<i>Clostridium perfringens</i> type C enteritis	仓仓	-	-
Intestinal spirochetosis	-	<u> </u>	
Porcine proliferative enteritis	-	<u> </u>	仓仓仓
Swine dysentery	仓	<u> </u>	
Feeding Phase	Lactation	Pre-starter / Starter	Grower, Finisher, Breeder
		ZAMIVE	T40

[-] Rare or does not occur [①] Uncommon [①①] Common [①①①] Very common

Withdrawal Period



Swine & Poultry

Seven (7) days



Quality Indicators

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Manufacturing Process Flow





MIC of fecal Clostridium perfringens



	MIC ₅₀	MIC ₉₀
Enramycin	0.2	0.4
Avilamycin	0.25	0.5
Virginiamycin	0.8	2
Oxytetracycline	4	16
Lincomycin	64	8
Colistin	≥100	≥100

Minimum inhibitory concentrations (MICs) are defined as the lowest concentration of an antimicrobial that will inhibit the visible growth of a microorganism

Quality Indicators

- Zamira certifies every batch of ZAMIVET80
- All **ZAMIVET80** batches are tested for potency
- Guaranteed level of bacterial killing potency
- Giving end-users confidence in the product every time



Product – Physical Appearance





Grey to grey-brown powder

Product Stability – Assay



Enramycin Content



Specification: 90 – 110%

Packaging

25kg bags.

Multilayered polyethylene bag to ensure product stability in humid climates.

Shelf Life of 24 months.



