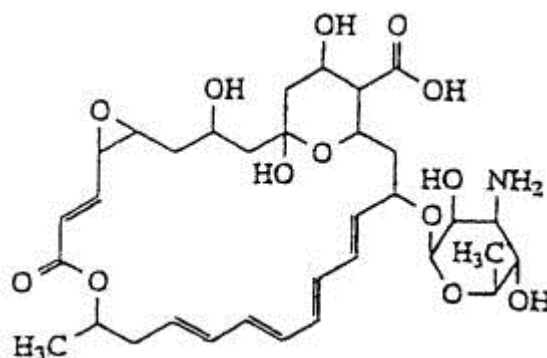


<b>M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)</b>	<b>FINISHED PRODUCT INFORMATIONS</b>
QUALITY CONTROL AND ASSURANCE	PRODUCT : NATAMYCIN
MSDS no. BPPL 121 (Available on Request)	SPECIFICATION NO. FP- 121 (Enclosed)

1. **NOMENCLATURE** : Pimaricin
2. **CAS NO.** : 7681-93-8
3. **MELTING POINT** : 280°C (Decomposed)
4. **HSN CODE** : 29419090
5. **EMPIRICAL FORMULA** :  $C_{33}H_{47}NO_{13}$
6. **MOL. WT.** : 665.73

7. **STRUCTURAL FORMULA**



8. **DESCRIPTION** :
- : White to Yellow Crystalline Powder. (Cream –coloured to slightly Yellow Powder.)
  - : No Taste or Odour.
  - : Not soluble in Water.
  - : Insoluble in Higher Alcohols, Ether and Ester.
  - : Slightly soluble in Methanol .
  - : Completely soluble in Glacial Acetic acid and Di Methyl Sulfoxide. (DMSO) .
9. **APPLICATIONS** :
- : As Food Additive, it used to protect food from Mold and Yeast growth.
  - : Globally used in Cheese, Juice, Wine And Meat Industry.
  - : Surface Treatment for Semi – Dried, Cured Meat products, Yogurts, Man-made butter.

<b>M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)</b>	<b>FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATIONS</b>
QUALITY CONTROL AND ASSURANCE	PRODUCT : NATAMYCIN (Q/LWR01-2007) / E 235 (Food Preservative)
MSDS no. BPPL 121 (Available on Request)	SPECIFICATION NO. FP- 121

1. **DESCRIPTION** : White to Yellow Crystalline Powder.  
(Cream –coloured to slightly Yellow Powder.)  
: No Taste or Odour.
2. **SOLUBILITY** : Not soluble in Water.  
: Insoluble in Higher Alcohols, Ether and Ester.  
: Slightly soluble in Methanol .  
: Completely soluble in Glacial Acetic acid and Di Methyl Sulfoxide. (DMSO) .
3. **MOISTURE CONTENT** : 6.0 % to 9.0 %
4. **pH** : 5.0 to 7.5
5. **NATAMYCIN CONTENT** : More than 50%
6. **ARSENIC (As)** : NMT 1 ppm
7. **HEAVY METALS (Pb)** : NMT 0.002% (20 ppm).
8. **SPECIFIC ROTATION** : + 2760° to + 2800°
9. **ASH** : NMT 0.5%
10. **MERCURY (Hg)** : NMT 0.0001% (1 ppm).

<b>M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)</b>	<b>FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATIONS</b>
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- 11. MICROBIAL LIMIT TEST :**
- Count of Colony : NMT 100 cfu/gm.  
 Pathogen : Absent  
 E. Coli : Negative (in 25 gms.)  
 Salmonella : Negative (in 25 gms.)
- 12. PACKING :**
- 250 gms./ 500 gms. Plastic Bottle /  
 Aluminium Foil Bag.  
 1000 gms. (1.0 Kg) Plastic Bottle /  
 Aluminium Foil Bag.  
 10 Bottles / Case  
 20 Bottle / Case  
 As per customer's requirement.
- 13. STORAGE :**
- Sealed keeping in cool place where  
 there is no direct sunshine exposure  
 and the temp. is 2°C to 15°C.  
 It is sensitive to oxidant and Ultraviolet  
 Radition. (U.V)
- 14. SHELF LIFE :**
- 2 Years.



## STABILITY OF NATAMYCIN

MANY FACTORS CAN INFLUENCE THE STABILITY OF NATAMYCIN, AS UNDER

1. pH VALUE
2. TEMP.
3. LIGHT
4. OXIDANTS
5. HEAVY METALS etc.

### 1. pH VALUE :

Natamycin is Most Stable Under Acidic Conditions, preferably between pH Range of 4.0 To 7.0 The activity is lost in highly Alkaline conditions.

Refer the Table below

MEDIUM	REMARK
pH, Less than 3.0	30% activity is lost .
pH = 3.0 to 5.0	10% activity is lost.
pH = 5.0 to 7.0	No activity is lost .
pH More than 9.0	30% activity is lost.

### 2. TEMPERATURE:

Natamycin is **stable** at Room Temp., **more stable** under dry condition. The desiccated Natamycin could endure 100°C in short-time. But the activity will be decreased when it is kept for more than 24 hours at more than 50 °C temp. .

### 3. LIGHT :

Natamycin in powder or solution is sensitive to UV (Ultra Violet ) or (Gamma Rays )  $\gamma$  Rays, which will cause the lose of activity. So, the direct sunlight exposure should be avoided.

#### 4. OXIDANTS :

Natamycin is sensitive to oxidants, such as Peroxide, Chlorine Dioxide, and Bleaching powder etc, which will decrease the activity of Natamycin.

The use of antioxidants, e.g. Vitamin C, could prevent it.

#### 5. HEAVE METALS :

The Pb (Lead), Hg (Mercury), Fe (Iron) , and Ni (Nickle) etc. could affect the stability of Natamycin. So, Natamycin or its solution should be stored in container made of Glass, Plastic or Stainless Steel.

The EDTA could also be mixed with it to prevent the lose of activity.

### SOLUBILITY OF NATAMYCIN

SOLVENT	SOLUBILITY
Distilled Water . [(pH) = 4.0 to 8.0 ]	Practically Insoluble . Very low soluble. 0.005 gm – 0.01 gm /100 ml. water. (30 mg. to 100 mg. / lit. water at RT).
pH More than 9.0 / Less than 3.0	Solubility increases, but it decreases the Anti fungal activity .
High Alcohols, Ether and Ester	Very low soluble .
Methanol	Very slightly soluble.
Glacial Acetic Acid and DMSO	Completely soluble. 18.50 gm – 100 ml. Glacial Acetic Acid.