

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	RAW MATERIALS INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : SODIUM ALENDRONATE TRIHYDRATE.
MSDS no. BPPL 034	SPECIFICATION NO. FP-034

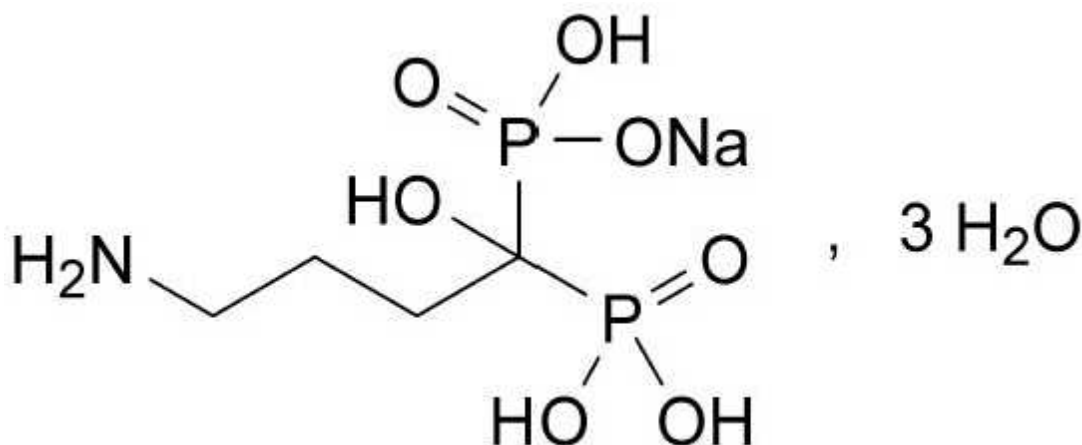
1. NOMENCLATURE : Alendronate Sodium Trihydrate.
: Sodium Alendronate hydrate.
: (4-Amino-1-hydroxybutylidene)
Bisphosphonic acid Monosodium salt
Trihydrate.
: 4-Amino-1-hydroxy-1-phosphonobutyl
Phosphonic Acid, Monosodium, trihydrate.
: Alendronic acid monosodium salt
trihydrate.

2. CAS NO. : 121268-17-5

3. EMPIRICAL FORMULA : $C_4H_{12}NNaO_7P_2, 3H_2O$.

4. MOL. WT. : 325.1

5. STRUCTURAL FORMULA :



6. DESCRIPTION : A white or almost white, crystalline powder, soluble in water, very slightly soluble in Methanol, practically insoluble in Methylene Chloride.

7. APPLICATIONS : Inhibition of bone resorption.
: For treatment of postmenopausal osteoporosis.

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1. DESCRIPTION : A white or almost white, crystalline powder,
2. SOLUBILITY : Soluble in water:
Very slightly soluble in Methanol,
Practically insoluble in Methylene Chloride.
3. CLARITY & COLOR OF SOLUTION : 1% w/v solution is Clear and colourless
4. pH (1% w/v Soln.) : Between 4.0 and 5.0
5. MELTING POINT : 273°C to 277°C
6. 4-AMINO BUTANOIC ACID : NMT 0.5%
(By TLC)
7. PHOSPHATE : NMT 0.5%
PHOSPHITE : NMT 0.5%
(By HPLC)
8. HEAVY METAL : NMT 20 PPM
9. LOSS ON DRYING : 16.1% TO 17.1%
10. ASSAY : NLT 98.0% and NMT 102.0% of
(By HPLC) $C_4H_{12}NNaO_7P_2, 3H_2O$ on dried basis.

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ADDITIONAL SPECIFICATION

1. BULK DENSITY :

a) Untapped. : Limit : 0.72 to 0.76 gm / ml.
Result : 0.74 gm/ml.

b) Tapped : Limit : 0.94 to 1.05 gm/ml.
Result : 0.95 gm/ml.

2. PARTICLE SIZE :

Not more than 90 micron : 30%

Not more than 180 micron: 70%