

Amlodipine Besylate (Cas No 111470-99-6.)

Taj Active Pharmaceuticals Ingredients

TAJNW-KKWAQ345

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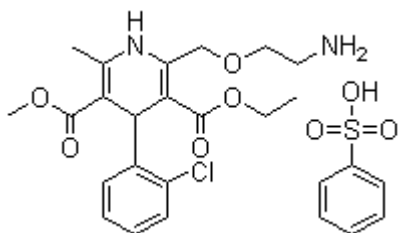
Active Pharmaceutical Ingredients
TAJ PHARMACEUTICALS LIMITED INDIA



Raw Material / Chemicals Index

Amlodipine Besylate

Cas No. 111470-99-6.



Chemical Structure:

Identification

Synonyms Amlodipine besilate; 2-[(2-Aminoethoxy)methyl]-4-(2-chlorophenyl)-3-ethoxycarbonyl-5-methoxycarbonyl-6-methyl-1,4-dihydropyridine benzenesulfonate.

Molecular Formula : C₂₀H₂₅ClN₂O₅ · C₆H₆O₃S Molecular Weight 567.05 CAS Registry Number 111470-99-6.

Amlodipine Besylates Description

Amlodipine besylate is the besylate salt of amlodipine, a long-acting calcium channel blocker.

Amlodipine besylate is chemically described as 3-Ethyl-5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulphonate. Its molecular formula is C₂₀ H₂₅ ClN₂ O₅ · C₆ H₆ O₃ S, and its structural formula is:

Amlodipine besylate is a white crystalline powder with a molecular weight of 567.1. It is slightly soluble in water and sparingly soluble in ethanol. Amlodipine besylate tablets are formulated as white tablets equivalent to 2.5, 5 and 10 mg of amlodipine for oral administration. In addition to the active ingredient, amlodipine besylate, each tablet contains the following inactive ingredients: colloidal silicon dioxide, dibasic calcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, and stearic acid.

Amlodipine Besylate Precautions.

General

Since the vasodilation induced by amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering amlodipine, particularly in

patients with severe aortic stenosis.

QUALITY CONTROL AND ASSURANCE PRODUCT : AMLODIPINE BESILATE

MSDS no. TPLM 055614
SPECIFICATION NO. TAJNW-KKWAQ345

NOMENCLATURE: Amlodipine besylate;: 3-Ethyl 5-methyl (4RS)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulphonate.

MOL. WT. : 567.1

DESCRIPTION : White or almost White Powder.
: Slightly soluble in water.

THERAPEUTIC USE : Calcium antagonist.

1. DESCRIPTION : White or almost White Powder.

2. SOLUBILITY : Freely soluble in Methanol;
Sparingly soluble in Ethanol;
Slightly soluble in Water, and in 2-Propanol

3. IDENTIFICATION : 1. IR absorption spectrophotometry
comparision : Amlodipine Besilate
CRS.

2. 0.005% Solution of Test in 1% v/v
solution of 0.1%M HCL in Methanol R.
Examin between 300 nm to 400 nm.
The solution shows an absorption
maximum at 360 nm. The specific
absorbance at maximum is 113 to
121.

4. RELATED SUBSTANCES : A. By TLC
Individual Impurity : NMT 0.1%
Total Impurity : NMT 0.3%
B. By HPLC
Impurity D : NMT 0.3%
Total of other : NMT 0.3%
Impurities

5. OPTICAL ROTATION : -0.10° to $+0.10^{\circ}$
at 589 nm [1% sol. in Methanol]

6. HEAVY METALS : Not more than 20 ppm.

7. LOSS ON DRYING : NMT 0.5%.
(WATER CONTENT)

8. IRON : NMT 20 ppm.

9. SULPHATED ASH : NMT 0.2% w/w

10. Residual Solvents :

1. Ethyl Acetate : NMT 5000 ppm
2. Methanol : NMT 2000 ppm
3. Toluene : NMT 800 ppm

11. ASSAY (By HPLC) : Not less than 97.0% w/w and not more than 102.0% w/w on Anhydrous Basis

**M/S. TAJ PHARMACEUTICALS. LTD.
MUMBAI (INDIA)**

FINISHED PRODUCT

SPECIFICATIONS

QUALITY CONTROL AND ASSURANCE PRODUCT : AMLODIPINE BESILATE



MSDS no. TPLM 055614

SPECIFICATION NO. TAJNW-KKWAQ345

Assay:99%



**Packing: 1kg,5kg, 10kg, 25kg/Drum
Usage: pharmaceutical material**

**Shelf life of API
24 Months**

Origin: INDIA

We have experience in Exporting and Manufacturing of all Countries and Overseas medicines in quick reliable manner and we are very interested to start collaboration with your company or organisation!



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