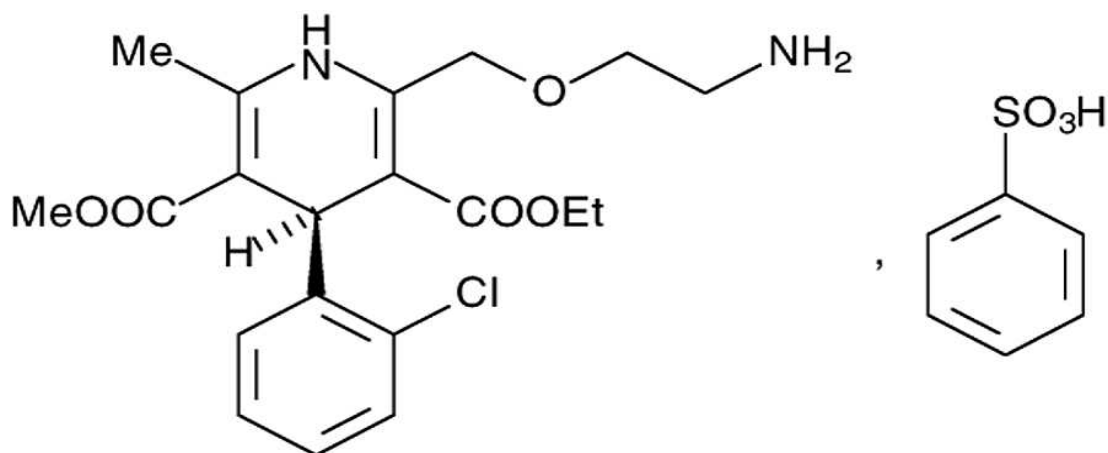


M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : AMLODIPINE BESILATE
MSDS no. BPPL 014	SPECIFICATION NO. FP-014

1. NOMENCLATURE : Amlodipine besylate;
: 3-Ethyl 5-methyl (4*R*)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate benzenesulphonate.
2. CAS NO. : 111470-99-6
3. EMPIRICAL FORMULA : C₂₀H₂₅ClN₂O₅, C₆H₆O₃S
4. MOL. WT. : 567.1
5. STRUCTURAL FORMULA :



and enantiomer

6. DESCRIPTION : White or almost White Powder.
: Slightly soluble in water.
7. THERAPEUTIC USE : Calcium antagonist.

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINISHED PRODUCT SPECIFICATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : AMLODIPINE BESILATE BP
MSDS no. BPPL 014	SPECIFICATION NO. FP-014

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 comparison : 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 Impurities : NMT 0.3%
5. OPTICAL ROTATION : -0.10° to + 0.10°
at 589 nm [1% sol. in Methanol]
6. HEAVY METALS : Not more than 20 ppm.

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QUALITY CONTROL AND ASSURANCE	PRODUCT : AMLODIPINE BESILATE
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7. LOSS ON DRYING (WATER CONTENT) : NMT 0.5%.
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