

HETERO DRUGS LIMITED (UNIT-I)

Survey.No's. 213,214 & 255, Bonthapally Village,
Gummadidala Mandal, Sangareddy District-502313, Telangana, INDIA.
Telephone : +91-9704432102 / 9704432103



CERTIFICATE OF ANALYSIS

| | | | |
|------------------------------|--|---------------------|-----------------------|
| Product: Amlodipine Besilate | | | |
| Batch No. | AL25080103 | Reference | Ph.Eur. |
| Analytical Report No. | HD01FP25006295 HD01FP25006312 | Batch Quantity | 501.19 Kg |
| Date Of Analysis | 17-08-2025 | Date of manufacture | 28-07-2025 |
| Storage condition | Store at 25°C (Excursions permitted between 15°C and 30°C) | Retest Date | 27-07-2030 |
| Reference STP No. | AL-013-00 AL-007-01 | Status | Initial Certification |

| S. No. | TEST | RESULT | SPECIFICATION |
|--------|---|---|---|
| 1 | \$ Appearance (Ref: Visual inspection) | White Powder. | White or almost White Powder. |
| 2 | Solubility (Ref: Visual inspection) | | |
| 2.1 | Solubility | Complies | Freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in water and in 2-propanol. |
| 3 | Identification by | | |
| 3.1 | \$ a) IR (Ref: Ph.Eur.<2.2.24>) | Matches with standard. | The infra-red absorption spectrum of the finely ground sample in mineral oil (liquid paraffin) dispersion should exhibit maxima only at the same wave numbers as that of a similar preparation of Amlodipine Besilate working standard. |
| 3.2 | \$ b) HPLC (Ref: Ph.Eur.<2.2.29>) | Matches with standard in the Assay by HPLC test | The retention time of the major peak in the chromatogram of the Assay preparation-1 should corresponds to that of the standard solution obtained as directed in the Assay on anhydrous basis by HPLC. |
| 4 | Optical Rotation (Ref: Ph.Eur.<2.2.7>) | 0.002 ° | Should be between (-) 0.10° and (+) 0.10° |
| 5 | \$ Related Substances by HPLC (Ref:Ph.Eur.<2.2.29>) | | |
| 5.1 | 3-Ethyl 5-methyl (4RS)-4-(2-chlorophenyl)-2-[[2-(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)ethoxy]methyl]-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate (Impurity-A*) | Not Detected | Not more than 0.10% |
| 5.2 | 3-Ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chloro phenyl)-6-methylpyridine-3,5-dicarboxylate (Impurity-D*) | 0.04 % | Not more than 0.20% |
| 5.3 | Diethyl(4RS)-2-[(2-aminoethoxy)methyl]-4-(2-chloro | Not Detected | Not more than 0.15% |

Remarks: APPROVED (Sample Conforms to above Specification)
Comments: * In-House specifications

Prepared By

Gopal.Ch

18-08-2025 09:41

Reviewed By

Satish Kumar.A

18-08-2025 10:14

Approved By

LAXMI NARASIMHA RAO.V

18-08-2025 11:40

Printed by: LAXMI NARASIMHA RAO.V

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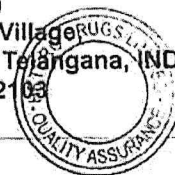
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CERTIFICATE OF ANALYSIS

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| | | | |
|------|--|----------------------|--|
| | phenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate(Impurity -E) | | |
| 5.4 | Dimethyl (4RS)-2-((2-aminoethoxy)methyl)-4-(2-chloro phenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate(Impurity -F) | Not Detected | Not more than 0.15% |
| 5.5 | Any unspecified impurity | Below 0.05% | Not more than 0.10% |
| 5.6 | *Total impurities | 0.04 % | Not more than 0.50% |
| 6 | \$ Water content by KF(Ref:Ph.Eur.<2.5.12>) | 0.21 % w/w | Not more than 0.5% w/w |
| 7 | Sulfated ash (Ref:Ph.Eur.<2.4.14>) | 0.04 %w/w | Not more than 0.2 % w/w |
| 8 | \$ Assay on anhydrous basis by HPLC (by using Assay of the standard) (Ref: Ph.Eur.<2.2.29>) | 101.9 %w/w | Not less than 97.0 % w/w and not more than 102.0 % w/w |
| 9 | Content of Methyl benzene Sulphonate by HPLC (Ref: In-House) | Not Detected | Not more than 80 ppm |
| 10 | Residual solvents by GC (Ref: In-House) | | |
| 10.1 | Methanol | Below QL (QL=60 ppm) | Not more than 300 ppm |
| 10.2 | Ethyl acetate | 44 ppm | Not more than 500 ppm |
| 11 | Besilate ion content by titration (Ref: In-House) | 27.8 % w/w | Should be between 27.0% w/w and 28.5% w/w |
| 12 | Particle size analysis (Ref : In-House) | | |
| 12.1 | d (0.10) | 1.9 µm | Should be less than 10 µm |
| 12.2 | d (0.50) | 6 µm | Should be less than 25 µm |
| 12.3 | d (0.90) | 18 µm | Should be less than 100 µm |

Remarks: APPROVED (Sample Conforms to above Specification)
Comments: * In-House specifications

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