**YMC** SEPARATION TECHNOLOGY

## アムロジピンベシル酸塩口腔内崩壊錠
## Amlodipine Besilate Orally Disintegrating Tablets

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Amlodipine besilate
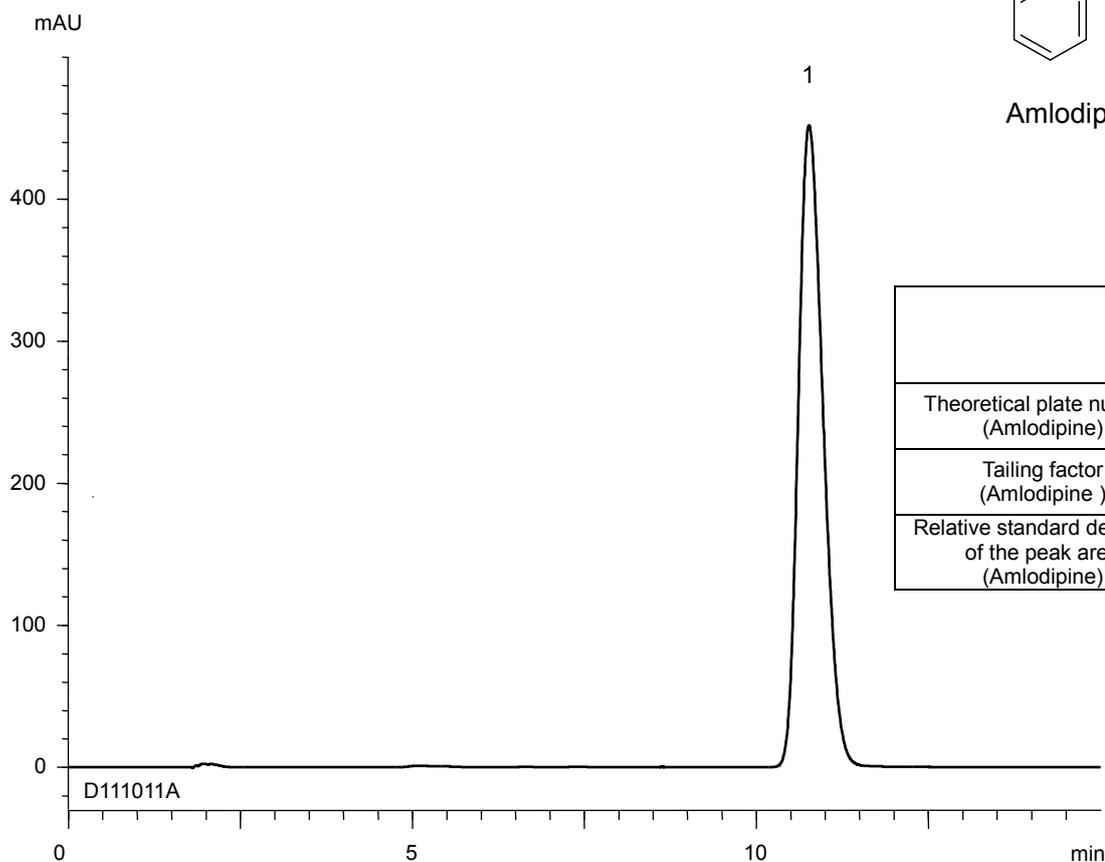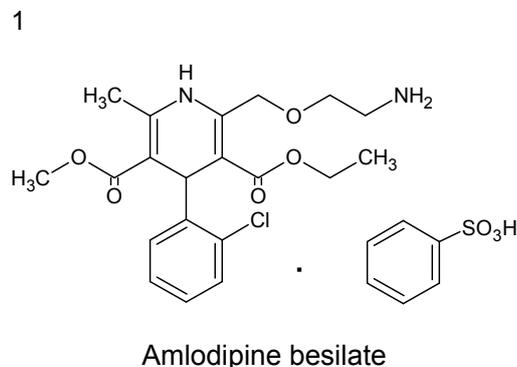


|  | System suitability requirement | result |
|---|---|---|
| Theoretical plate number (Amlodipine) | ≧3000 | 4200 |
| Tailing factor (Amlodipine ) | ≦2.0 | 1.26 |
| Relative standard deviation of the peak area (Amlodipine) | ≦1.0% | 0.12% |

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| Column | : YMC-Triart C18 (5 μm, 12 nm) |
|---|---|
| | 150 X 4.6 mmI.D. |
| Eluent | : phosphate buffer (pH 6.0)*/methanol (40/60) |

*Dissolve 4.1 g of $KH_2PO_4$ in 1000 mL of water and adjust pH 6.0 with 30 mM $Na_2HPO_4$*

| Flow rate | : 0.8 mL/min *(adjust the flow rate so that the retention time of amlodipine is about 10 min)* |
|---|---|
| Temperature | : 25℃ |
| Detection | : UV at 237 nm |
| Injection | : 30 μL (0.14 mg/mL) |

(The draft for the Japanese Pharmacopoeia; Assay)