

Formulation Study

Amlodipine Direct Compression

Summary

Amlodipine is a well known calcium channel blocker, prescribed mainly to reduce blood pressure. It is a crystalline API with good flow properties, so PROSOLV® RX 90 is used as a binder in direct compression.

Common dosage are 5 and 10 mg Amlodipine or 6.9 and 13.8 mg Amlodipine Besylate respectively.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Amlodipine besylate	5.0	6.9	5.75
PROSOLV® RX 90		113.1	94.20
Total		120.0	100.00

Procedure

Blending

The API was blended with PROSOLV® RX 90 for 20 minutes. The powder mixture was ready for direct compression.

Equipment	
Tablet press	Kilian Pressima, 8 mm punch
Turbula mixer	Type T2A
Hardness tester	Schleuniger Tablet Tester 6D
Dissolution tester	Pharmatest PTW 2
Spectrophotometer	Cecil CE 1021

Tablet characteristics

Compaction force	4.5 kN
Tablet diameter	8 mm
Tablet weight	120 mg
Crushing strength	100 N
Friability	0.0 %
Disintegration time	25 s

Dissolution test

Dissolution medium 900 mL 0.1 N HCl, 37 °C, n=6

Samples were taken after 5, 10, 15, 30 and 60 minutes. The sample volume was 3 mL.

The determination of the active ingredient was done by an UV-spectrophotometer at $\lambda = 360$ nm.

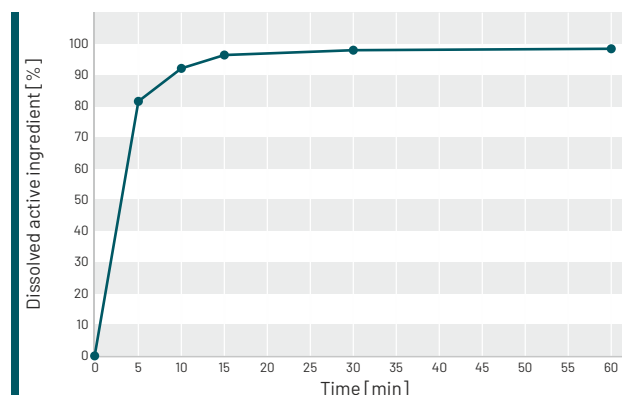


Fig. 1 Typical dissolution profile of an amlodipine tablet. Produced according to the above formulation.

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