

4282-050

Key Words: Amlodipine Besylate, Good Flowability, Direct Compression
JRS Products: PROSOLV® EASYtab SP

Amlodipine Direct Compression

Page 1/2

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® EASYtab SP** is used as a binder in direct compression.

Common dosages 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® EASYtab SP		113.1	94.25
Total		120.0	100.0

Procedure

Blending:

The API was blended with **PROSOLV® EASYtab SP** 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

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Page 2/2

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 $\lambda = 360 \text{ nm}$.

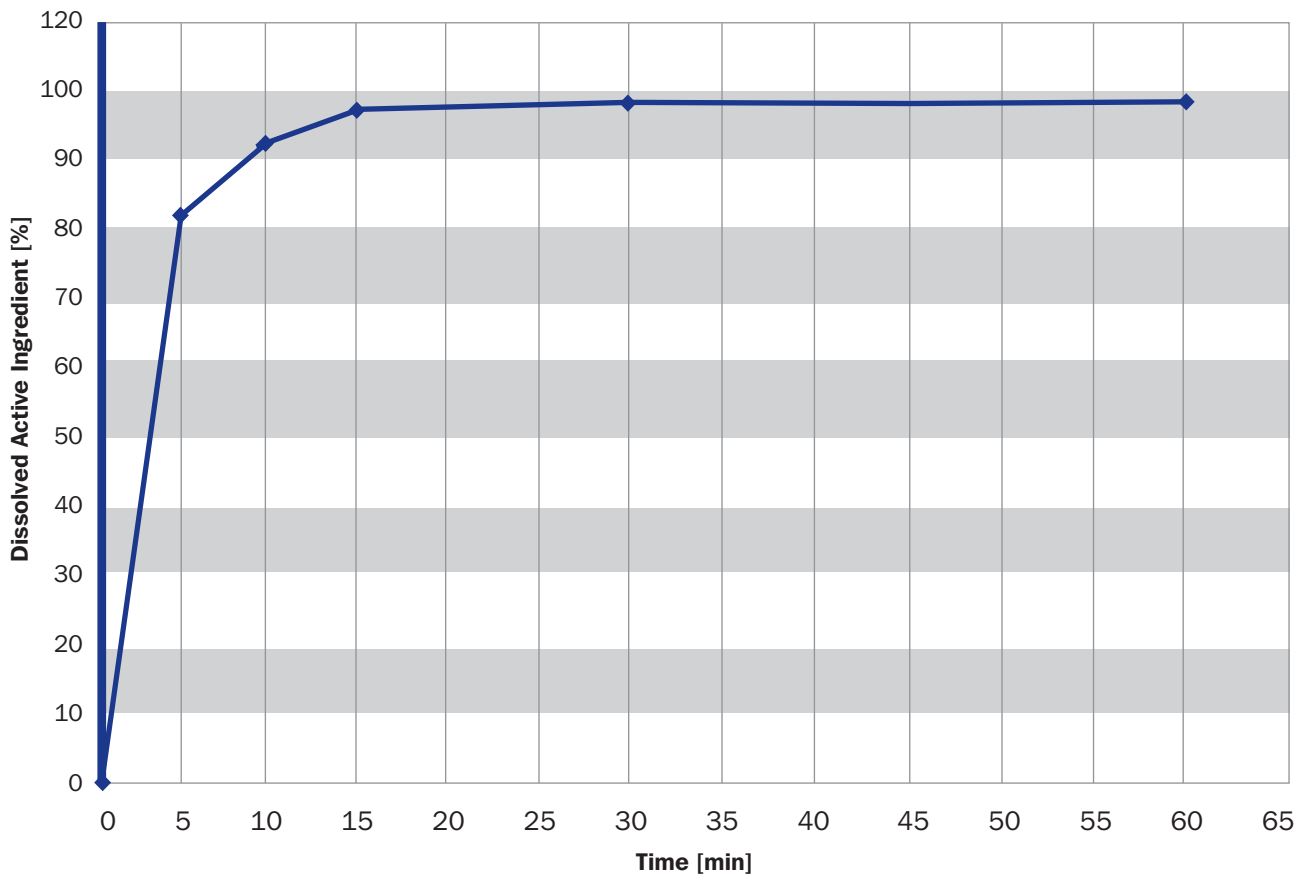


Diagram 1:

Typical dissolution profile of an Amlodipine tablet. Produced according to the above formulation.

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