

4282-022

Key Words: Diazepam, Low Dosage, Direct Compression

JRS Products: VIVAPUR® 12, EMCOMPRESS®, VIVASTAR® P, PRUV®

Diazepam Direct Compression

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Summary

Diazepam, better known under the brand name Valium™, is a benzodiazepine derivative. It is prescribed for the short-term management of moderate anxiety, tension, agitation, fear or aggressiveness. It is often used during certain medical

procedures (e.g., surgery or dental work) to reduce anxiety. Dosages commonly range between 2 and 10 mg. This formulation is an example for a low-dosage active ingredient, suitable for direct compression.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Diazepam	10.0	10.0	7.1
VIVAPUR® 12 (Microcrystalline Cellulose)		59.0	42.1
EMCOMPRESS® (Calcium Hydrogen Phosphate Dihydrate)		65.5	46.8
VIVASTAR® P (Sodium Starch Glycolate)		4.0	2.9
PRUV® (Sodium Stearyl Fumarate)		1.5	1.1
Total		140.0	100.0

Procedure

Blending:

All excipients except **PRUV®** were blended for 30 minutes. Afterwards, **PRUV®** was added to the blend and mixed for an additional 3 minutes. The powder mixture was ready for direct compression.

Equipment:

Tablet Press:	Korsch EK 0, instrumented
Turbula Mixer:	Type T2A
Hardness Tester:	Schleuniger 2E
Friability Tester:	ERWEKA TAP
Disintegration Tester:	Pharmatest Standard PTZ
Dissolution Tester:	Pharmatest PTW 2
Spectrophotometer:	Cecil CE 1021

Tablet Characteristics

Tablet Weight:	140 mg
Tablet Diameter:	8 mm
Compression Force:	22 kN
Crushing Strength:	75 N
Disintegration Time:	20 s
Friability:	0.1 %

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Dissolution Test:

Dissolution Medium: 900 mL 0.1 N HCl, 37°C, n=6
 Samples were taken after 1, 5, 10, 20, 30 and 60 minutes. The sample volume was 3 mL.
 The determination of the active ingredient was done by an UV-spectrometer at $\lambda = 242 \text{ nm}$.

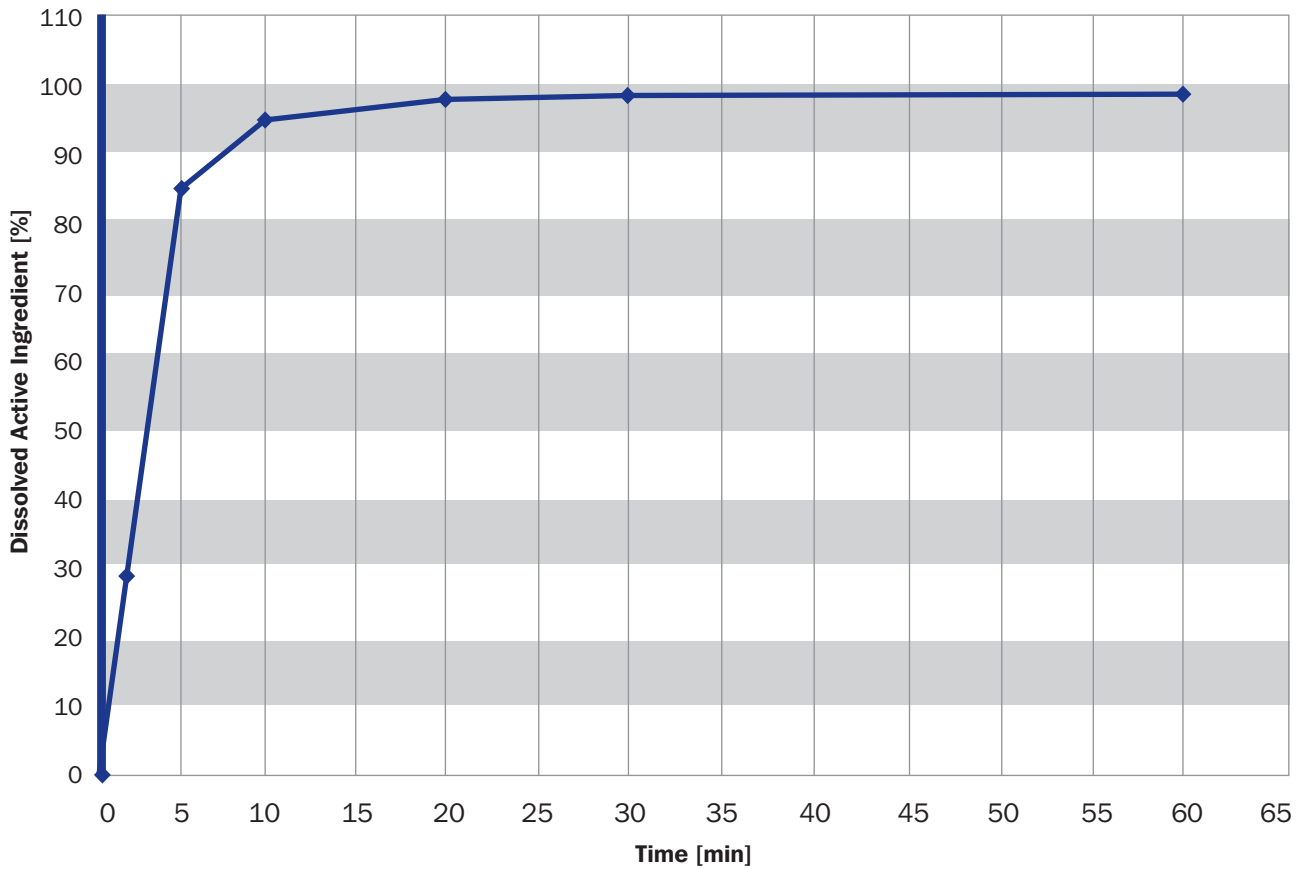


Diagram 1:

Typical dissolution profile of a Diazepam tablet. Produced according to the above formulation.

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