

4282-025

Key Words: Cimetidine, High Dosage, Direct Compression
JRS Products: VIVAPUR® 12, VIVASTAR® P, PRUV®

Cimetidine Direct Compression

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Summary

Cimetidine is a histamine H₂-receptor antagonist for treatment of *ulcus duodeni* and *ulcus ventriculi*. Normally, this active is wet-granulated to improve solubility, as the active ingredient Cimetidine is only slightly water soluble.

Adding **VIVAPUR® 12** as a binder allows Cimetidine to be formulated as a direct compression tablet with good dissolution profiles.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Cimetidine	400.0	400.0	57.1
VIVAPUR® 12 (Microcrystalline Cellulose)		265.0	37.9
VIVASTAR® P (Sodium Starch Glycolate)		28.0	4.0
PRUV® (Sodium Stearyl Fumarate)		7.0	1.0
Total		700.0	100.0

Procedure

Blending:

The API, **VIVAPUR® 12**, **VIVASTAR® P** and **PRUV®** were blended for 10 minutes. The powder mixture was ready for direct compression.

Equipment:

Tablet Press:	Korsch EK 0, 13 mm punch
Turbula Mixer:	Type T2A
Hardness Tester:	Schleuniger, Type 2 E
Dissolution Tester:	Pharmatest, Type PTW 2
Disintegration Tester:	Pharmatest Standard, Type PTZ
Friability Tester:	Pharmatest, Typ PTF 1
Spectrophotometer:	Cecil CE 1021

Tablet Characteristics

Tablet Diameter:	13 mm
Tablet Weight:	700 mg
Compression Force:	15 kN
Crushing Strength:	100 N
Friability:	0.8 %
Disintegration Time:	50 s

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Dissolution Test:

Dissolution Medium: 900 mL 0.1 N HCl, 37°C, n=3.

Samples were taken after 1, 5, 10, 20, 30, 60, 90 and 120 minutes. The sample volume was 3 mL.

The determination of the active ingredient was done by an UV-spectrophotometer at $\lambda = 220 \text{ nm}$.

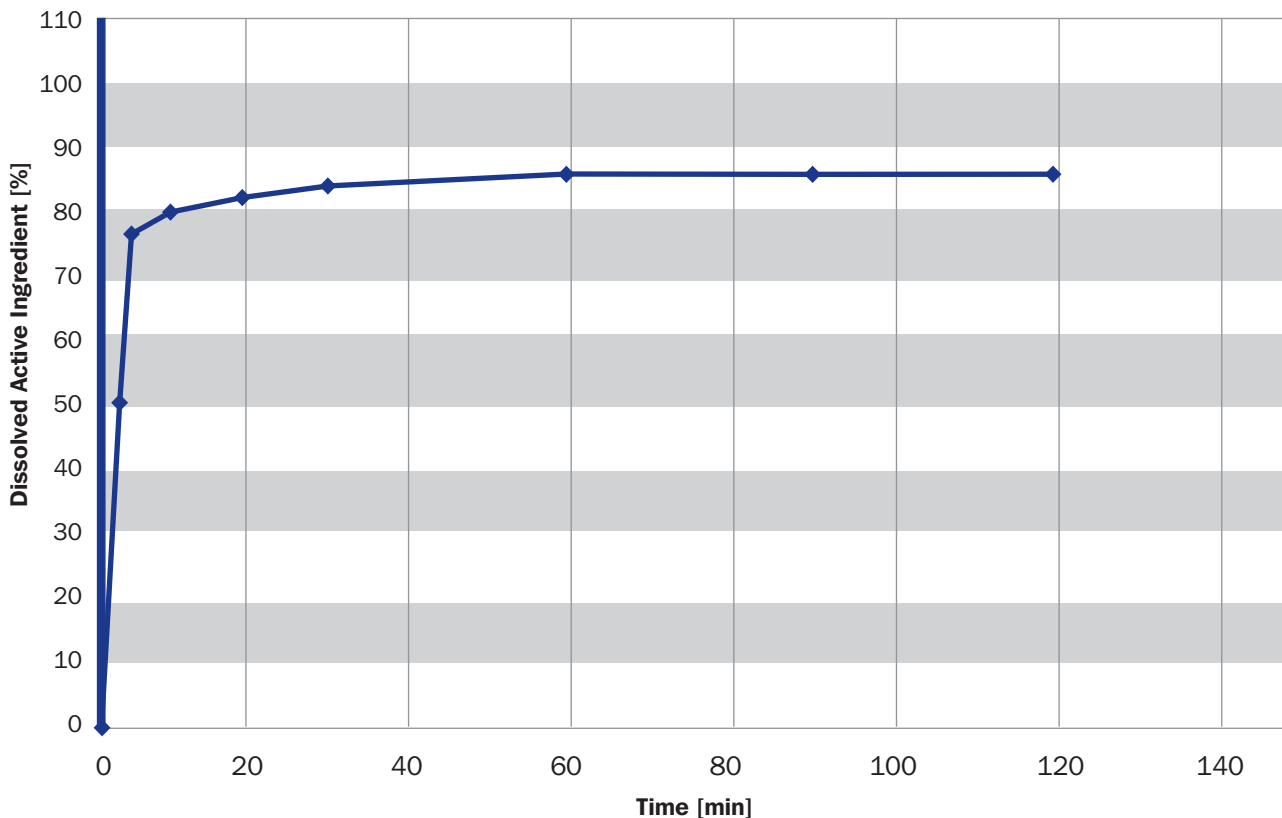


Diagram 1:

Typical dissolution profile of a Cimetidine 700 mg tablet. Produced according to the above formulation.

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