

4282-020

Key Words: Ranitidine HCl,
High Dosage, Direct Compression

Ranitidine HCl Direct Compression

JRS Products: VIVAPUR® 102, VIVASTAR® P

Page 1/2

Summary

Ranitidine HCl is a histamine receptor antagonist, which reduces the stomach's release of hydrochloric acid. It is used to prevent and treat ulcers of the stomach and duodenum, erosive esophagitis, and gastroesophageal reflux disease.

Formulations for direct compression with an API content of more than 50 % of the tablet mass can be made using **VIVAPUR® 102** for good tablet hardness and **VIVASTAR® P** for short disintegration time. Oral tablets come in 150 and 300 mg dosages.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Ranitidine HCl	150.0	167.4	69.75
VIVAPUR® 102 (Microcrystalline Cellulose)		60.0	25
VIVASTAR® P (Sodium Starch Glycolate)		10.2	4.25
Magnesium Stearate		2.4	1.0
Total		240.0	100.0

Procedure

Blending:

Ranitidine HCl, **VIVAPUR® 102** and **VIVASTAR® P** were blended to homogeneity for 15 minutes. Then a sieved mixture of Magnesium Stearate was added and mixed for another 5 minutes. The powder mix was ready for direct compression.

Equipment:

Tablet Press:	Korsch EK 0 eccentric press, 9 mm punch, biplane
Turbula Mixer:	Type T2A
Hardness Tester:	Pharmatest PTB 311
Friability Tester:	ERWEKA TAP
Disintegration Tester:	ERWEKA ZT 3
Dissolution Tester:	Pharmatest PTW II, with 6 vessels, flat blade paddle
Spectrophotometer:	Shimadzu UV-2101 PC

Tablet Characteristics

Tablet Weight:	240 mg
Tablet Diameter:	9 mm
Compaction Force:	29 kN
Crushing Strength:	110 N
Disintegration Time:	315 s
Friability:	0.9 %

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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, 20, and 30 minutes. The sample volume was 3 mL.

The determination of the active ingredient was done by an UV-spectrophotometer at $\lambda = 313$ nm.

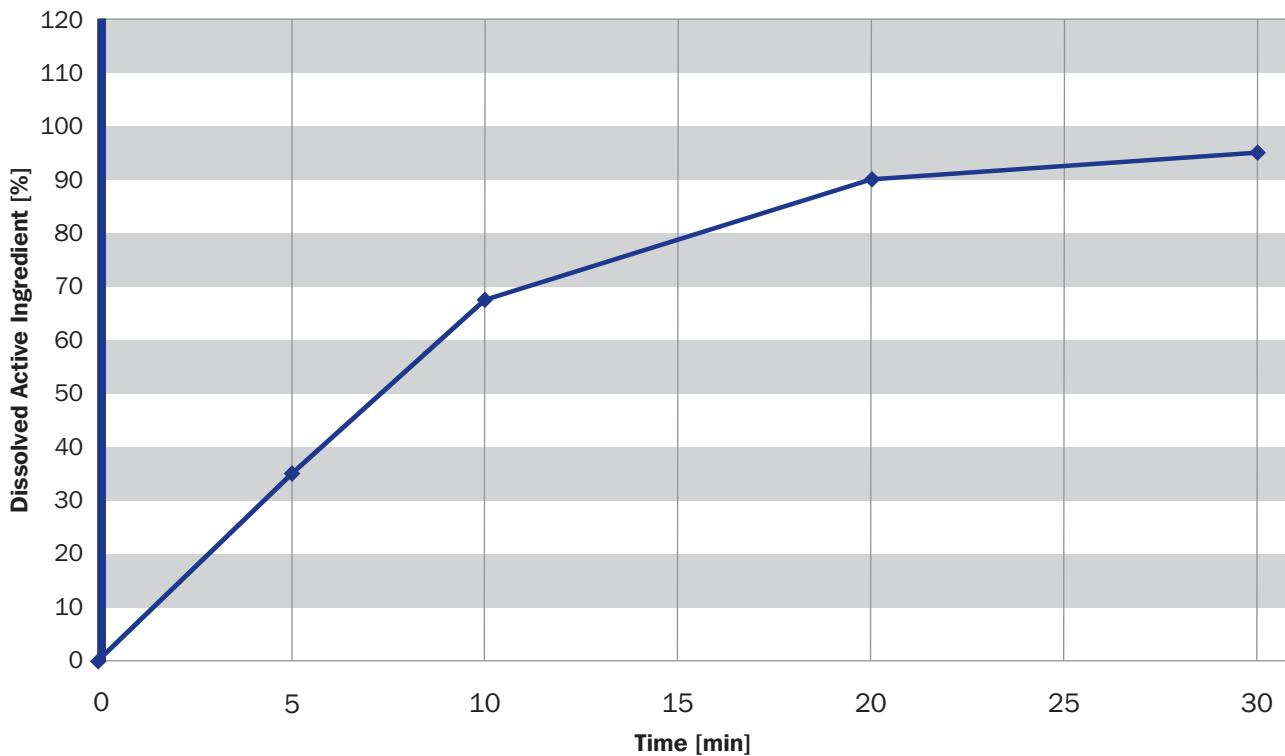


Diagram 1:

Typical dissolution profile diagram of a Ranitidine tablet, produced according to the above formulation.

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