

4282-001

Key Words: Acetylsalicylic Acid, High Dosage, Direct Compression

JRS Products: VIVAPUR® 102, VIVASTAR® P, PRUV®

Acetylsalicylic Acid Direct Compression

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Summary

Acetylsalicylic Acid (ASA) is an old and very well known API substance with analgesic (pain-relieving) and antipyretic (fever-reducing) properties. It is a non-steroidal anti-inflammatory drug that also inhibits platelet aggregation. The

common Acetylsalicylic Acid (ASA) dosage is 500 mg. In the following formulation, **VIVAPUR® 102** is used as a filler and binder, and **VIVASTAR® P** as a disintegrant. Acetylsalicylic Acid is not compatible with Magnesium Stearate so **PRUV®** (Sodium Stearyl Fumarate) was used as a lubricant.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Acetylsalicylic Acid (ASA)	500.0	500.0	74.6
VIVAPUR® 102 (Microcrystalline Cellulose)		140.0	20.9
VIVASTAR® P (Sodium Starch Glycolate)		23.4	3.5
PRUV® (Sodium Stearyl Fumarate)		6.6	1.0
Total		670.0	100.0

Procedure

Blending:

Acetylsalicylic Acid (ASA), **VIVAPUR® 102** and **VIVASTAR® P** were blended to homogeneity for 15 minutes. Then **PRUV®** was added and mixed for another 5 minutes. The powder mixture was ready for direct compression.

Equipment:

Tablet Press:	Korsch EK 0, instrumented
Turbula Mixer:	Type T2A
Hardness Tester:	Pharmatest PTB 311, n=6
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:	670 mg
Tablet Diameter:	13 mm
Compaction Force:	28 kN
Crushing Strength:	79 N
Disintegration Time:	40 s

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Dissolution Test:

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

Samples were taken after 5, 10, 15, 30, 45 and 60 minutes. The sample volume was 3 mL.

The determination of the active ingredient was done by an UV-spectrophotometer at $\lambda = 232 \text{ nm}$.

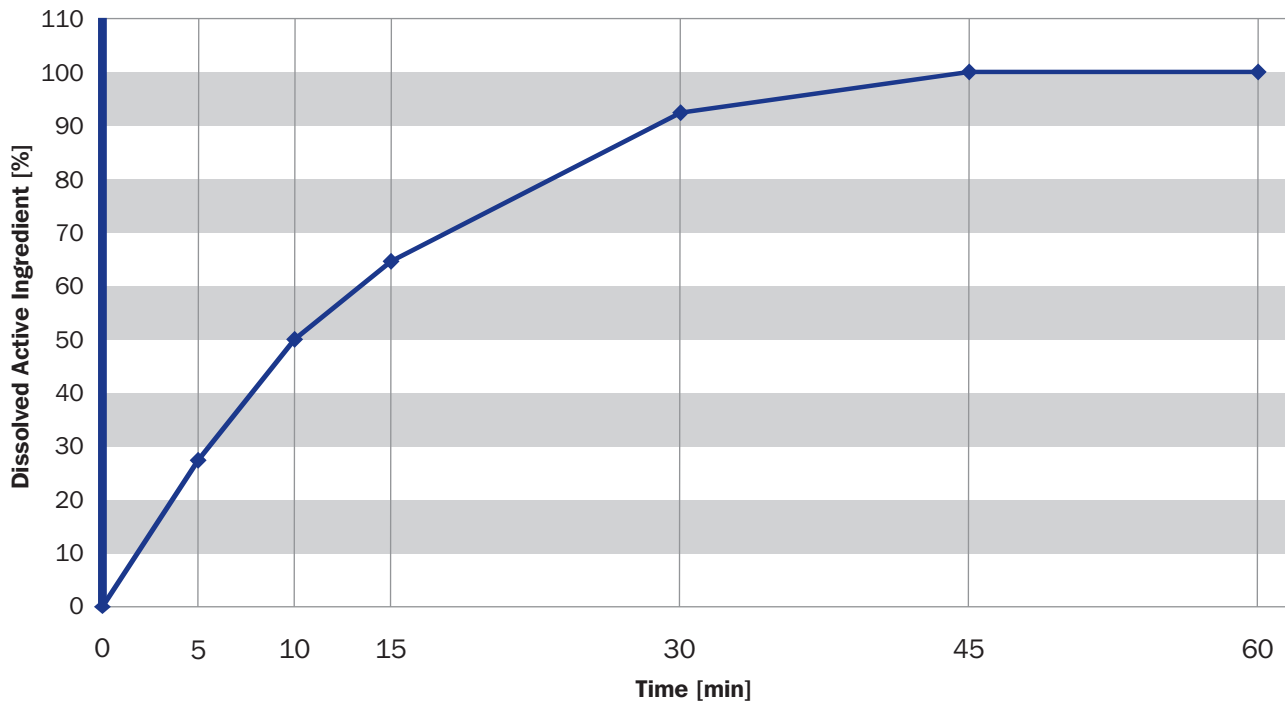


Diagram 1:

Typical dissolution profile diagram of an Acetylsalicylic Acid 500 mg tablet. Produced according to the above formulation.

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