FORMULATION HANDBOOK



4282-067

Valsartan **Direct Compression**

Key Words: Valsartan, Poor Flowability, Poor **Compactibility, Direct Compression** JRS Products: PROSOLV® SMCC HD 90, VIVASTAR® P, PRUV®

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Summary

Valsartan is an angiotensin II antagonist for hypertensive treatment. For many patients, it serves as an alternative to beta-blockers. Common dosages of valsartan are 80 and 160 mg per unit.

There are different qualities of valsartan available. The following formulation was done with a very amorphous, poorflowing powder.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Valsartan	80.0	80.0	50.0
Colloidal Silicone Dioxide		1.1	0.7
PROSOLV® SMCC HD 90 (Silicified Microcrystalline Cellulose)		72.0	45.0
VIVASTAR® P (Sodium Starch Glycolate)		5.3	3.3
PRUV [®] (Sodium Stearyl Fumarate)		1.6	1.0
Total		160.0	100.0

Procedure

Blending:

All ingredients, except PRUV®, were blended for 15 minutes. Then PRUV® was added and the powder mixture was mixed for another 3 minutes. The powder mixture was ready for direct compression.

Equipment:	
Tablet Press:	Kilian Pressima, 10 mm punch
Turbula Mixer:	Type T2A
Hardness Tester:	Schleuniger Tablet Tester 6D

Tablet Characteristics

Compression Force:	13.5 - 14.5 kN
Tablet diameter:	10 mm
Tablet weight:	160 mg
Crushing Strength:	120 - 130 N
Disintegration Time:	120 s

Disclaimer: The information provided is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.



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