FORMULATION HANDBOOK



4282-063

Key Words: Theophyllin,

Good Solubility, Poor Flowability,

Direct Compression

JRS Products: VIVAPUR® 102, VIVASTAR® P

Theophylline Direct Compression

Page 1

Summary

Theophylline is an antiasthmatic agent, cardiac stimulant, and diuretic. It is used to reduce the frequency and severity of breathing problems in people with asthma, emphysema, bronchitis, and other pulmonary disorders. It works by relaxing the smooth muscle tissue in the bronchial passages that go

into bronchospasm, thus widening the constricted airways. It is available as a prescription drug product; small quantities are found in some herbal teas as well. Dosages commonly range from 50 to 300 mg per unit.

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Theophylline	100.0	100.0	55.5
VIVAPUR® 102 (Microcrystalline Cellulose)		72.0	40.0
VIVASTAR® P (Sodium Starch Glycolate)		7.2	4.0
Magnesium Stearate		0.8	0.5
Total		180.0	100.0

Procedure

Blending:

All excipients, except Magnesium Stearate, were blended for 15 minutes. Afterwards Magnesium Stearate was added to the blend and mixed for an additional 5 minutes. The powder mixture was ready for direct compression.

Equipment:		
Tablet Press:	Korsch EK 0 eccentric press, 7 mm punch, biplane	
Turbula Mixer:	Type T2A	
Hardness Tester:	Pharmatest PTB 311	
Disintegration Tester:	ERWEKA ZT 3	
Dissolution Tester:	Pharmatest PTW II	
Spectrophotometer:	Shimadzu UV-2101 PC	

Tablet Characteristics

Compaction force:	18 kN
Tablet diameter:	7 mm
Tablet weight:	180 mg
Crushing strength:	75 N
Disintegration time:	10 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.



Excipients • Coatings
Biopharma Services • Technical Services

WORLDWIDE HEADQUARTERS
JRS PHARMA GMBH & CO. KG

73494 Rosenberg (Germany) Phone: + 49 (0) 7967 / 152 312 Fax: + 49 (0) 7967 / 152 345

ExcipientsService@jrspharma.de