

4282-045

Simethicone Chewable Tablet Direct Compression

Key Words: Liquid API, Poor Flowability, Direct Compression, Chewable Tablet

JRS Products: EMDEX®, PRUV®

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Summary

Simethicone is an oral anti-foaming agent used to reduce bloating, discomfort, and pain caused by excess gas in the gastrointestinal tract. Its neutral taste makes it a suitable API

for chewable solid dosage forms. We used Simethicone as a model API to prepare chewable 50 mg tablets with oily active on the base of **EMDEX®** (Dextrate).

Formulation

	Active content [mg]	mg/tablet	Contribution [%]
Simethicone Mix*	42.0	42.0	8.54
EMDEX® (Dextrate)		440.0	89.43
PRUV® (Sodium Stearyl Fumarate)		10.0	2.03
Total		492.0	100.0

* The simethicone mixture: 150 g of Q7-9120 + 100 g of ANTIFOAM M Compound + 1 g Peppermint oil were mixed intensively; the Dimethicone / Silicium ratio of the prepared mixture is 97:3.

Procedure

Blending:

To the preliminary prepared simethicone mixture, **EMDEX®** and **PRUV®** were added in small portions until the formation of a homogeneous, free-flowing powder. The tablet mass was sieved and blended for 20 minutes. The powder mixture was ready for direct compression.

Equipment:

Tablet Press:	Korsch EK 0
Turbula Mixer:	Type T2A
Hardness Tester:	Schleuniger 6D
Disintegration Tester:	Pharmatest Standard PTZ

Tablet Characteristics

Tablet Weight:	492 mg
Tablet Diameter:	13 mm
Compaction Force:	15 kN
Crushing Strength:	70 N

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.