



EXCIPIENTS STARCH 1500[®]

PARTIALLY PREGELATINIZED MAIZE STARCH

Formulation

Direct Compression

Aspirin 325 mg Tablets

Direct Compression Formulation Used to Produce Aspirin (325 mg) Tablets

Formulations and Tablet Properties

Ingredients	Mg/Tablet	Percent (w/w)
Aspirin	325.00	85.98
Starch 1500	25.52	6.77
Microcrystalline Cellulose (50µm)	21.33	5.66
Powdered cellulose	6.33	1.68
Total	378.00	100.00

Tablet Properties

Compaction Force	10-14 kN
Tablet Properties (3/8" standard concave tooling)	
Weight	378.0 mg
Diameter	9.5 mm
Thickness	4.4 mm
Hardness	8-9 kp
Friability	0.53 %
Disintegration Time	< 2 min
Dissolution I, T ₈₀ %	12.0 min

Process (Direct Compression)

(Twin-shell blender)

- All ingredients were blended for 15 minutes in a twin-shell blender.
- Tablets were compressed using a Manesty Betapress 16 station tablet machine equipped with a gravity feed frame.

Stability

- The aspirin tablets were packaged in foil sealed HDPE bottles and stored at 3 separate environmental conditions for three months.
- The tablets were tested for % free salicylic acid content and disintegration time. The USP limit for % free salicylic acid in coated aspirin tablets is 0.30%.

Stability Test Results

Time Point	Storage Condition	% Free Salicylic Acid	Disintegraton Time (min:sec)
0 Time	n/a	0.03	1:42
3 Months	25° C	0.05	1:58
	37°C	0.04	1:47
	40°C/75% RH	0.05	1:40

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