

Betamethasone Tablets (0.50 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
0.50	1	Betamethasone base, 10% excess	0.55
20.00	2	Maize starch	20.00
85.90	3	Lactose monohydrate	85.95
3.00	4	Maize starch	3.00
0.50	5	Magnesium stearate	0.50
QS	6	Purified water	25.00

Manufacturing Directions

1. Pass item 2 through a 250- μ m sieve, and make a homogeneous slurry in cold purified water (5 kg) to assure it is free of lumps.
2. Add the slurry to a container with water (20 kg) at 80°C, stir until completely gelatinized, and cool to 50°C.
3. Mix item 1 gradually with item 3 and pass through a 250- μ m sieve; pass item 4 through a similar sieve and mix the powders for 15 minutes.
4. Add starch paste and mix for 10 minutes; pass the wet mass through a FitzMill sieve 24205 at medium speed.
5. Dry granules at 55°C for 10 hours; do not exceed a moisture content of 2%. Pass dried granules through a 1-mm sieve into a double-cone blender.
6. Pass item 5 through a 250- μ m sieve, mix with granules, and mix for 1 minute.
7. Compressed average tablet weight is 1.10 g; hardness not less than 2.0 kPa.

Beta Carotene Effervescent Tablets (7 mg)

Formulation: Lucarotin[®] dry powder 10% CWD (BASF), 70 g; Ludipress, 113 g; citric acid, anhydrous, 200 g; sodium bicarbonate, 120 g; sodium carbonate, 12 g; sodium cyclamate, 20 g; aspartame, 15 g; orange flavor, 20 g; polyethylene glycol 6000, powder, 30 g.

Manufacturing Directions

Pass all components through an 0.8-mm sieve, mix, and press with medium- or high-compression force at maximum 30% of relative atmospheric humidity.

Beta-Carotene Effervescent Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
7.00 mg	1	Beta-carotene; use Lucarotin [®] CWD (dry powder, 10%) (BASF)	70.00
113.00 mg	2	Ludipress [®]	113.00
200.00 mg	3	Anhydrous citric acid	200.00
120.00 mg	4	Sodium bicarbonate	120.00
12.00 mg	5	Sodium carbonate	12.00
20.00 mg	6	Sodium cyclamate	20.00
15.00 mg	7	Aspartame	15.00
20.00 mg	8	Orange flavor	20.00
30.00 mg	9	PEG-6000 (powder)	30.00

Manufacturing Directions

1. Pass all components through an 0.8-mm sieve and mix.
2. Press with medium- or high-compression force at maximum 30% relative humidity.
3. Use 12-mm biplanar punches for 602-mg tablets.