

Aspartame Effervescent Tablets (20 mg)

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
00.00	1	Aspartame	20.00
10.40	2	Sorbitol crystalline	10.40
14.30	3	Tartaric acid powder	14.30
18.70	4	Sodium carbonate	18.70
1.70	5	Kollidon 25	1.70
1.10	6	PEG 6000 powder	1.10

Manufacturing Directions

1. Mix all components and pass through a 0.5-mm sieve.

2. Press to tablets at 66 mg.

Aspartame Tablets (25 mg), DC

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
27.00	1	Aspartame	27.00
76.00	2	Ludipress	76.00
12.00	3	Kollidon® CL	12.00
1.00	4	Magnesium stearate	1.00
3.00	5	Lutrol F68	3.00

Manufacturing Directions

1. Mix all components and pass through a 0.8-mm sieve.

2. Press to tablets with low-compression force at 120 mg.

Aspartame Tablets

Bill of Materials			
Scale (mg/tablet)	Item	Material Name	Quantity/1000 Tablets (g)
20.00	1	Aspartame	20.00
4.00	2	Cellulose (microcrystalline) (Avicel™ PH101), NF	4.00
4.00	3	Sodium starch glycolate (pH 5.5–7.5), NF International	4.00
0.50	4	Silicon dioxide (colloidal)	0.50
0.50	5	Povidone (PVP K-29-32), USP	0.50
14.00	6	Anhydrous alcohol (isopropyl, refined) USP	~14.00
34.00	7	Lactose (granulated)	34.00
4.00	8	Leucine, USP	4.00
3.00	9	Sodium benzoate (powder), NF	3.00

Manufacturing Directions

- Charge aspartame, cellulose microcrystalline, sodium starch glycolate, silicon dioxide, and Povidone in a suitable mixer.
- Blend for 20 minutes or until uniform.
- While mixing, slowly add isopropyl alcohol to blended powders until a suitable granulating mass is obtained. Avoid overwetting.
- Pass wet mass through a 2.38-mm screen on an oscillating granulator and spread onto paper-lined trays.
- Oven dry at 45°C to 50°C until LOD is NMT 1.2%.

- Pass dried granulation through an 840-µm screen on an oscillating granulator.
- Charge dried granulation into a suitable mixer.
- Add granulated lactose, leucine, and sodium benzoate, and blend for ~10 minutes.
- Discharge into polyethylene-lined drums.
- Compress tablets in a low-humidity area not to exceed 40% relative humidity at 23°C.
- Compress, using 7/32-in. concave punches, to the following specifications: weight of 10 tablets is 0.7 g; thickness of a tablet is 2.9 to 3.3 mm.