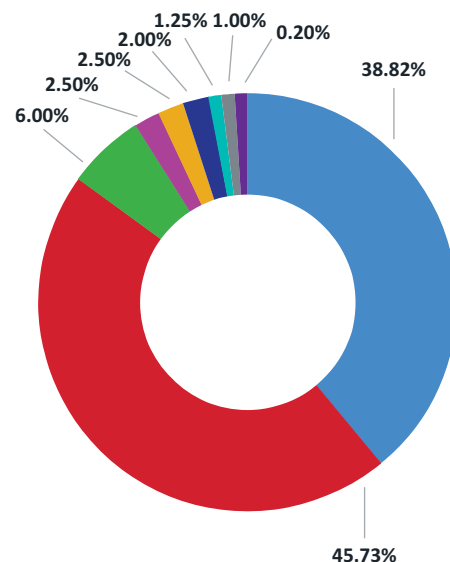




Formulation Recommendation

500 mg APAP Orally Disintegrating Tablet (ODT)

Composition	% (By Weight)	mg / Tablet
1 Actimask® APAP 92M	38.82	543.48
2 Pharmaburst® 500	45.73	640.22
3 Crospovidone XL	6.00	84.00
4 Lubripharm® SSF	2.50	35.00
5 MCC-101	2.50	35.00
6 Peppermint Flavoring	2.00	28.00
7 Sucralose	1.25	17.50
8 Silicon Dioxide	1.00	14.00
9 FD&C Blue #2	0.20	2.80
Final Tablet Weight		1400.00



General Tablet Characteristics

500 mg APAP ODT	Tablet Thickness (mm)	Tablet Hardness (kP)	Tablet Disintegration (s)	Friability (%)
Average	5.94	6.94	19.40	1.19
St. Dev.	0.01	0.73	1.14	

Method

1. Weigh the components individually and screen all non-lubricant and non-colorants using a #20-mesh sieve. Separately, take the Lubripharm and FD&C Blue and co-screen using a #20-mesh sieve.
2. Mix all ingredients, with the exception of Lubripharm and FD&C Blue co-screen in an 8-qt V-blender at 25rpm for 15 minutes.
3. Add the Lubripharm and FD&C Blue co-screen to the first mixture and blend for an additional 5 minutes at 25rpm.
4. Compress the formulation to 1.4 g tablets on a rotary tablet press outfitted with 0.6693" FFBE type "D" punches, operated at 25rpm with a pre-compression force of 1.5kN to a tablet hardness of 7kP.

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