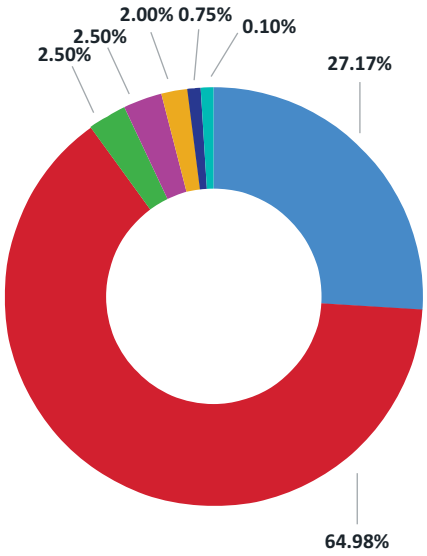
Formulation Recommendation

125/250 mg APAP Orally Disintegrating Tablet

Composition	% (By Weight)	mg / Tablet
1 Actimask® APAP 92M	21.17	135.87
2 Pharmaburst® 500	64.98	324.88
3 Lubripharm® SSF	2.50	12.50
4 Crospovidone XL	2.50	12.50
5 Cherry Flavor	2.00	10.00
6 Sucralose	0.75	3.75
7 FD&C Red #27	0.10	0.50
Final Tablet Weight		500.00



General Tablet Characteristics

125 mg APAP ODT	Tablet Thickness (mm)	Tablet Hardness (kP)	Tablet Disintegration (s)	Friability (%)
Average	3.53	4.68	19.20	0.16
St. Dev.	0.02	0.13	5.40	

250 mg APAP ODT	Tablet Thickness (mm)	Tablet Hardness (kP)	Tablet Disintegration (s)	Friability (%)
Average	4.78	5.80	31.80	0.58
St. Dev.	0.03	0.37	2.17	

Method

1. Weigh the components individually and screen all non-lubricant and non-colorants using a #20-mesh sieve. Seperately, take the Lubripharm and FD&C Red and co-screen using a #20-mesh sieve.
2. Mix all ingredients, with the exception of the Lubripharm and FD&C Red Co-Screen, in an 8-qt V-blender at 25rpm for 15 minutes.
3. Add the Lubripharm and FD&C Red Co-Screen to the first mixture and blend for an additional 5 minutes at 25rpm.
4. Compress the formulation to 500mg tablets on a rotary tablet press outfitted with 0.4375" FFBE type "D" punches, operated at 25rpm with a pre-compression force of 700N to a tablet hardness of 4.5kP. Alternatively, the 250mg APAP ODT can be manufactured by compressing 1000mg tablets at 25rpm with 0.625" FFBE type "D" punches to a tablet hardness of 6kP, using 700N of pre-compression.

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