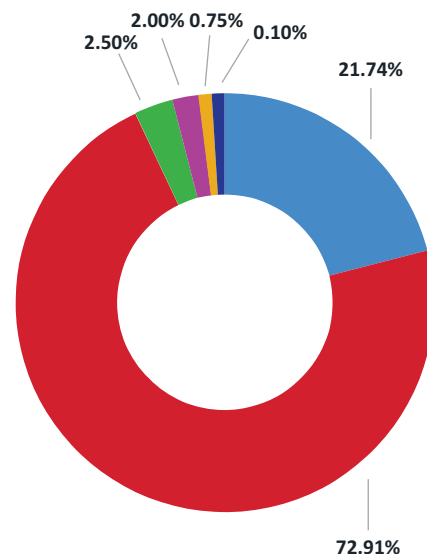




# Formulation Recommendation

## 80/160 mg APAP Orally Disintegrating Tablet (ODT)

Composition	% (By Weight)	mg / Tablet
1 Actimask® APAP 92M	21.74	86.96
2 Pharmaburst® 500	72.91	291.64
3 Lubripharm® SSF	2.50	10.00
4 Bubblegum Flavor	2.00	8.00
5 Sucralose	0.75	3.00
6 FD&C Red #27	0.10	0.40
<b>Final Tablet Weight</b>		<b>400.00</b>



### General Tablet Characteristics

80 mg APAP ODT	Tablet Thickness (mm)	Tablet Hardness (kP)	Tablet Disintegration (s)	Friability (%)
<b>Average</b>	5.87	3.30	12.60	0.25
<b>St. Dev.</b>	0.02	0.19	1.67	

160 mg APAP ODT	Tablet Thickness (mm)	Tablet Hardness (kP)	Tablet Disintegration (s)	Friability (%)
<b>Average</b>	6.36	5.16	27.00	0.6
<b>St. Dev.</b>	0.03	0.30	4.00	

### 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 Red and co-screen using a #20-mesh sieve.
2. Mix all ingredients, with the exception of Lubripharm and FD&C Red in an 8-qt V-blender at 25rpm for 15 minutes.
3. Add the Lubripharm and FD&C Red to the first mixture and blend for an additional 5 minutes at 25rpm.
4. Compress the formulation to 400mg tablets on a rotary tablet press outfitted with 0.4930" Arc Square type "D" punches, operated at 25rpm to a tablet hardness of 3kP. Alternatively, the 160mg APAP ODT can be manufactured by compressing 800mg tablets at 25rpm with 0.5" Arc Square type "D" punches to a tablet hardness of 5kP.

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