

Master Production Record

MPR #: 5503

Product Code: Chewable Vitamin C	Drug Name: Chewable Vitamin C Tablets	Strength: 250 mg	Number: 147 1
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Cover Page

Manufacturing Date:	Author: Sam Ops	Formulation Id: 5503	Batch Size: 105000.000 ea
Theoretical Yield: 1050 kg	MPR Version #: 1	Purpose: Production for Distribution	
Scope: Commercial Supply in North America			

Bill of Materials

Part	Ver	Material	Qty/Batch	Unit	Composition	Unit
158	1	DIPAC	477.48	kg		
159	1	F.D. & C. Yellow #6	6.72	kg		
160	1	F.D. & C. Yellow #3	0.63	kg		
161	1	Orange Flavor	10.10	kg		
162	1	Orange Juice Oil	0.34	kg		
163	1	OilVeltol	0.11	kg		
164	1	Vanillin	2.63	kg		
165	1	Candex	196.88	kg		
166	1	Sodium Ascorbate	259.64	kg		
167	1	Ascorbic Acid	59.23	kg		

Equipment

Equipment #:	Equipment Name
PK001	2 Cu. Ft. V Blender
PK010	10 Cu. Ft. Twin Cone Blender
TP16	Manesty Beta Press Rotary Tablet Press, 16 station

In-Process Testing

Step	Test	Method	Purpose	Specifications
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MPR Approvals

Approver	Job Function	Date/Time
KWagner01	Production Supervisor	

Master Production Record

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Manufacturing Instructions

Step	100.00		
Material		Part: 0	Ver. 0
Action:	WEIGHING	Target:	
Inventory:	Performer:	Verifier:	
Step	101.00		
Material		Part: 0	Ver. 0
Action:	Weigh two portions of DIPAC of 75.000 kg each and one portion of 327.478 kg	Target: 477.48	Range: 477-478
Inventory:	Performer:	Verifier:	
Step	102.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 6.72 kg of F.D. & C Yellow #6	Target: 6.75	Range: 6-7
Inventory:	Performer:	Verifier:	
Step	104.00		
Material		Part: 0	Ver. 0
Action:	Weigh 10.101 kg of Orange Flavor S.D.	Target: 10.101	Range: 10.0-10.2
Inventory:	Performer:	Verifier:	
Step	105.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 0.63 kg of F.D. & C. Yellow 3	Target: 0.63	Range: 0.60-0.65
Inventory:	Performer:	Verifier:	
Step	107.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 0.340 kg of Orange Juice Oil	Target: 0.340	Range: 0.33-0.35
Inventory:	Performer:	Verifier:	
Step	108.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 0.105 kg of OilVeltol Plus	Target: 0.105	Range: 0.100-0.110
Inventory:	Performer:	Verifier:	
Step	109.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 2.625 kg of Vanillin	Target: 2.625	Range: 2.620-2.630
Inventory:	Performer:	Verifier:	
Step	110.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 196.875 kg of Candex	Target: 196.875	Range: 196-197
Inventory:	Performer:	Verifier:	
Step	120.00		
Material		Part: 0	Ver. 0
Action:	Weigh out 259.644 kg of Sodium Ascorbate	Target: 259.644	Range: 259-260
Inventory:	Performer:	Verifier:	

Master Production Record

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Step	130.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Weigh out 59.231 kg of Ascorbic Acid	<u>Target:</u> 59.231	<u>Range:</u> 59-60
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	200.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	BLENDING	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	210.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Preblend #1	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	211.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Load 75 kg DIPAC into suitable blender	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	212.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Pass the F.D. & C. Yellow 6, F.D. & C. Yellow 3 and Orange Flavor S.D. through a #20 screen	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	212.05		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Load the screened F.D. & C. Yellow 6, F.D. & C. Yellow 3 and Orange Flavor S.D. into the blender	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	213.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Load the second container of DiPAC (75 kg) into the blender and blend for 15 minutes	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	215.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Discharge into suitable lined containers. Record: Gross WT Tare WT Net Wt.	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	220.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Preblend #2	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	

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Step	222.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Charge the Dipac, Orange Juice Oil, Veltol Plus, and Vanillin into a suitable P.K. blender		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	223.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 15 minutes		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	224.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Discharge into a suitable lined container		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	230.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	FINAL BLENDING		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	231.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Weigh 327.478 kg DIPAC and charge into a suitable blender.		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	232.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Add Premix #1 and Premix #2 to the contents of the blender.		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	233.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Charge the blende with Candex (196.875 kg), Sodium Ascorbate (259.644 kg) and Ascorbic Acid (59.231 kg)		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	234.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 15 minutes		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	235.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Pass 21.00 kg Stearic Acid through a #20 mesh screen and charge into the blender.		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	236.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 5 minutes		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	

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Step	237.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Discharge the blend into suitable containers		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	300.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	COMPRESSION		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	301.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Set up rotary tablet machine using 1/2" round standard concave tooling		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	301.05		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Compress tablets to a target hardness of 7 kp		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	302.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Collect the tablets in double lined cartons with a desiccant bag between the liners.		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	303.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	When compression is complete, record Gross wt., Tare wt., Net wt. of the compressed tablets.		<u>Target:</u>
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	