

Master Production Record

MPR #: WPI-BC

Product Code: B Complex with Vitamin C	Drug Name: B Complex with Vitamin C	Strength: 20 mg B Complex	Number: 169 1
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Cover Page

Manufacturing Date:	Author: Sam Ops	Formulation Id: 5657	
Theoretical Yield: 500000		Batch Size: 500000.000 ea	
Purpose: Resupply Northeast Distribution Center		MPR Version #: 1	
		Scope: Retail Pharmacy Stock	

Bill of Materials

Part	Ver	Material	Qty/Batch	Unit	Composition	Unit
154	1	Stearic Acid, NF	6.50	kg	13.00	mg
155	1	Magnesium Stearate, NF	6.50	kg	13.00	mg
156	1	Purified Water	14.04	kg	0	mg
172	1	Thiamine Mononitrate	8.10	kg	16.20	mg
173	1	Calcium Pantothenate	18.50	kg	37.00	mg
174	1	Riboflavin	9.18	kg	18.36	mg
176	1	Povidone	1.91	kg	3.82	mg
177	1	Starch 1500	15.00	kg	30.00	mg
178	1	Opadry Orange	7.71	kg	15.43	mg
179	1	Ethyl Vanillin	0.50	kg	1.00	mg
180	1	Aerosil P-200	1.50	kg	3.00	mg
181	1	Syloid 244 FP	2.40	kg	4.80	mg
182	1	Niacimamide	52.50	kg	105.00	mg
183	1	Pyridoxine HCl	15.96	kg	31.91	mg
184	1	Carbowax 8000	5.80	kg	11.60	mg
185	1	Ascorbic Acid 95%	433.70	kg	867.40	mg
186	1	Avicel PH	23.82	kg	47.64	mg
187	1	dl Alpha Tocopheryl Acetate	45.45	kg	90.90	mg
188	1	Cyancobalamin	0.78	kg	1.56	mg
189	1	Sodium Starch Glycolate	8.00	kg	16.00	mg
190	1	Talc	6.50	kg	13.00	mg

Equipment

Equipment #:	Equipment Name
TP16	Manesty Beta Press Rotary Tablet Press, 16 station
DC-100	KE Double Cone Blender (150 kg capacity)
DC-300	KE Double Cone Blender (500 kg capacity)
QC-194	Quadra Comil
SC-20	20 Mesh Screen
JS3	Neptune Propeller Mixer
AC-60	Thomas Accela Cota - 60" Pan

In-Process Testing

Step	Test	Method	Purpose	Specifications
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MPR Approvals

Approver	Job Function	Date/Time
GRizor01	Project Manager	

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Manufacturing Instructions

Step	10.00		
<u>Material</u> :		<u>Part</u> : 0	<u>Ver</u> : 0
<u>Action</u> :	WEIGHING	<u>Target</u> :	
<u>Inventory</u> :		<u>Performer</u> :	<u>Verifier</u> :
Step	15.00		
<u>Material</u> :		<u>Part</u> : 0	<u>Ver</u> : 0
<u>Action</u> :	Check room for QA approval.	<u>Target</u> :	
<u>Inventory</u> :		<u>Performer</u> :	<u>Verifier</u> :
Step	20.00		
<u>Material</u> :		<u>Part</u> : 0	<u>Ver</u> : 0
<u>Action</u> :	Weigh the ingredients in steps 30-70 and load into a suitable wet mixer	<u>Target</u> :	
<u>Inventory</u> :		<u>Performer</u> :	<u>Verifier</u> :
Step	30.00		
<u>Material</u> :	Thiamine Mononitrate	<u>Part</u> : 172	<u>Ver</u> : 1
<u>Action</u> :	Weigh out Thiamine Mononitrate (8.10 kg) and add to blender	<u>Target</u> : 8.10 <u>Range</u> : 8.00-8.20	
<u>Inventory</u> :	X	<u>Performer</u> : X	<u>Verifier</u> : X
Step	40.00		
<u>Material</u> :	Riboflavin	<u>Part</u> : 174	<u>Ver</u> : 1
<u>Action</u> :	Weigh out Riboflavin (9.18 kg) and add to blender	<u>Target</u> : 9.18 <u>Range</u> : 9.10-9.26	
<u>Inventory</u> :	X	<u>Performer</u> : X	<u>Verifier</u> : X
Step	50.00		
<u>Material</u> :	Niacinamide	<u>Part</u> : 182	<u>Ver</u> : 1
<u>Action</u> :	Weigh out Niacinamide (52.50 kg) and add to blender	<u>Target</u> : 52.50 <u>Range</u> : 52.0-53.0	
<u>Inventory</u> :	X	<u>Performer</u> : X	<u>Verifier</u> : X
Step	60.00		
<u>Material</u> :	Pyridoxine HCl	<u>Part</u> : 183	<u>Ver</u> : 1
<u>Action</u> :	Weigh out Pyridoxine HCL (15.957 kg) and add to blender	<u>Target</u> : 15.957 <u>Range</u> : 15.500-16.000	
<u>Inventory</u> :	X	<u>Performer</u> : X	<u>Verifier</u> : X
Step	70.00		
<u>Material</u> :	Carbowax 8000	<u>Part</u> : 184	<u>Ver</u> : 1
<u>Action</u> :	Weigh out Carbowax 8000 (2.549 kg) and add to blender	<u>Target</u> : 2.549 <u>Range</u> : 2.500-2.600	
<u>Inventory</u> :	X	<u>Performer</u> : X	<u>Verifier</u> : X
Step	100.00		
<u>Material</u> :		<u>Part</u> : 0	<u>Ver</u> : 0
<u>Action</u> :	GRANULATION	<u>Target</u> :	
<u>Inventory</u> :		<u>Performer</u> :	<u>Verifier</u> :
Step	110.00		
<u>Material</u> :		<u>Part</u> : 0	<u>Ver</u> : 0
<u>Action</u> :	After all ingredients are added, mix for 10 minutes	<u>Target</u> : 10 <u>Range</u> : 9-15	
<u>Inventory</u> :		<u>Performer</u> :	<u>Verifier</u> :

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Step	120.00		
Material	Purified Water	Part: 156	Ver. 1
Action:	In another suitable mixing tank, weigh Purified Water (14.04 kg)	Target: 14.04 Range: 14.00-14.10	
Inventory:	X	Performer: X	Verifier: X
Step	130.00		
Material	Povidone	Part: 176	Ver. 1
Action:	Weigh out Povidone (1.91 kg)	Target: 1.91 Range: 1.90-1.92	
Inventory:	X	Performer: X	Verifier: X
Step	140.00		
Material		Part: 0	Ver. 0
Action:	Start a propeller mixer to create a vortex in the tank of water and slowly add the Povidone	Target:	
Inventory:		Performer:	Verifier:
Step	150.00		
Material		Part: 0	Ver. 0
Action:	Start the wet mixer and slowing add the Povidone Solution (15.14 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	152.00		
Material		Part: 0	Ver. 0
Action:	Continue mixing for 30 minutes until the Povidone is completely dissolved	Target: 30 Range: 30-40	
Inventory:		Performer:	Verifier:
Step	154.00		
Material		Part: 0	Ver. 0
Action:	Continue mixing until a handful of the wet granulation will form a "snowball" when squeezed by hand	Target:	
Inventory:		Performer:	Verifier:
Step	155.00		
Material		Part: 0	Ver. 0
Action:	If necessary while mixing, add small increments of purified water to achieve this wetness endpoint	Target:	
Inventory:		Performer:	Verifier:
Step	170.00		
Material		Part: 0	Ver. 0
Action:	Pass the wet granulation through a Comil running at 700 rpm (without a screen)	Target:	
Inventory:		Performer:	Verifier:

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Step	180.00		
Material		Part: 0	Ver. 0
Action:	Transfer the sized granulation onto paper lined trays and place in an air dryer	Target:	
Inventory:		Performer:	Verifier:
Step	185.00		
Material		Part: 0	Ver. 0
Action:	Dry at 120° F for 8 to 12 hours or until the L.O.D. is less than 1%	Target:	
Inventory:		Performer:	Verifier:
Step	190.00		
Material		Part: 0	Ver. 0
Action:	Pass the dry granulation through Comil running at 700 rpm using a 12 mesh screen into lined containers	Target:	
Inventory:		Performer:	Verifier:
Step	200.00		
Material		Part: 0	Ver. 0
Action:	PREBLEND	Target:	
Inventory:		Performer:	Verifier:
Step	210.00		
Material	Starch 1500	Part: 177	Ver. 1
Action:	Weigh out and load into blender: Starch 1500 (15 kg)	Target: 15 Range: 14.5-15.5	
Inventory:	X	Performer: X	Verifier: X
Step	220.00		
Material	Ethyl Vanillin	Part: 179	Ver. 1
Action:	Weigh out and load into blender: Ethyl Vanillin (0.50 kg)	Target: 0.50 Range: 0.45-0.55	
Inventory:	X	Performer: X	Verifier: X
Step	230.00		
Material	Cyanocobalamin	Part: 188	Ver. 1
Action:	Weigh out and load into blender: Cyanocobalamin (0.78 kg)	Target: 0.78 Range: 0.76-0.80	
Inventory:	X	Performer: X	Verifier: X
Step	240.00		
Material		Part: 0	Ver. 0
Action:	Blend for 10 minutes	Target: 10 Range: 10-12	
Inventory:		Performer:	Verifier:
Step	250.00		
Material		Part: 0	Ver. 0
Action:	Discharge the blend into lined containers and record: Gross Weight, Net Weight, Tare Weight	Target:	
Inventory:		Performer:	Verifier:

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Step	300.00		
Material		Part: 0	Ver. 0
Action:	FINAL BLEND		Target:
Inventory:		Performer:	Verifier:
Step	310.00		
Material	dl Alpha Tocopheryl Acetate	Part: 187	Ver. 1
Action:	Weigh out and load into blender: dl Alpha Tocopheryl Acetate (45.45 kg)		Target: 45.5 Range: 45.0-46.0
Inventory:	X	Performer: X	Verifier: X
Step	311.00		
Material	Avicel PH	Part: 186	Ver. 1
Action:	Weigh out and load into blender: Avicel PH 101 (23.82 kg)		Target: 23.82 Range: 23.80-23.84
Inventory:	X	Performer: X	Verifier: X
Step	312.00		
Material	Calcium Pantothenate	Part: 173	Ver. 1
Action:	Weigh out and load into blender: Calcium Pantothenate (18.5 kg)		Target: 18.5 Range: 18.0-19.0
Inventory:		Performer:	Verifier:
Step	313.00		
Material	Aerosil P-200	Part: 180	Ver. 1
Action:	Weigh out and pass through a #20 mesh screen and add to blender: Aerosil P-200 (1.50 kg)		Target: 1.50 Range: 1.49-1.51
Inventory:	X	Performer: X	Verifier: X
Step	314.00		
Material	Syloid 244 FP	Part: 181	Ver. 1
Action:	Weigh out and pass through a #20 mesh screen and add to blender: Syloid 244 FP (2.40 kg)		Target: 2.40 Range: 2.39-2.41
Inventory:	X	Performer: X	Verifier: X
Step	315.00		
Material	Carbowax 8000	Part: 184	Ver. 1
Action:	Weigh out and pass through a #20 mesh screen and add to blender: Carbowax 8000 (3.25 kg)		Target: 3.25 Range: 3.24-3.26
Inventory:	X	Performer: X	Verifier: X
Step	316.00		
Material	Sodium Starch Glycolate	Part: 189	Ver. 1
Action:	Weigh out and pass through a #20 mesh screen and add to blender: Sodium Starch Glycolate (8.00 kg)		Target: 8.00 Range: 7.98-8.02
Inventory:	X	Performer: X	Verifier: X
Step	318.00		
Material		Part: 0	Ver. 0
Action:	Load the ingredients from GRANULATION (step 190 and PREMIX (Step 250) into the mixer		Target:
Inventory:		Performer:	Verifier:

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Step	320.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 15 minutes.	<u>Target:</u> 15	<u>Range:</u> 14 - 17
<u>Inventory:</u>		<u>Performer:</u>	<u>Verifier:</u>
Step	330.00		
<u>Material</u>	Ascorbic Acid 95%	<u>Part:</u> 185	<u>Ver.</u> 1
<u>Action:</u>	Weigh out and load into blender: Ascorbic Acid 95% (433.70 kg)	<u>Target:</u> 433.70	<u>Range:</u> 433.00-434.40
<u>Inventory:</u>	X	<u>Performer:</u> X	<u>Verifier:</u> X
Step	335.00		
<u>Material</u>	Stearic Acid, NF	<u>Part:</u> 154	<u>Ver.</u> 1
<u>Action:</u>	Weigh out and pass through a #20 mesh screen and add to blender: Stearic acid (6.5 kg)	<u>Target:</u> 6.5	<u>Range:</u> 6.45-6.55
<u>Inventory:</u>	X	<u>Performer:</u> X	<u>Verifier:</u> X
Step	340.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 10 minutes	<u>Target:</u> 10	<u>Range:</u> 10-12
<u>Inventory:</u>		<u>Performer:</u>	<u>Verifier:</u>
Step	350.00		
<u>Material</u>	Talc	<u>Part:</u> 190	<u>Ver.</u> 1
<u>Action:</u>	Weigh out and pass through a #20 mesh screen and add to blender: Talc (6.5 kg)	<u>Target:</u> 6.5	<u>Range:</u> 6.45-6.55
<u>Inventory:</u>	X	<u>Performer:</u> X	<u>Verifier:</u> X
Step	355.00		
<u>Material</u>	Magnesium Stearate, NF	<u>Part:</u> 155	<u>Ver.</u> 1
<u>Action:</u>	Weigh out and pass through a #20 mesh screen and add to blender: Magnesium Stearate (6.5 kg)	<u>Target:</u> 6.5	<u>Range:</u> 6.45-6.55
<u>Inventory:</u>	X	<u>Performer:</u> X	<u>Verifier:</u> X
Step	360.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Blend for 5 minutes.	<u>Target:</u> 5	<u>Range:</u> 5-6
<u>Inventory:</u>		<u>Performer:</u>	<u>Verifier:</u>
Step	370.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Discharge the blend into suitable containers. Record: Gross Weight, Net Weight, Tare Weight	<u>Target:</u>	
<u>Inventory:</u>		<u>Performer:</u>	<u>Verifier:</u>
Step	400.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	TABLET COMPRESSION	<u>Target:</u>	
<u>Inventory:</u>		<u>Performer:</u>	<u>Verifier:</u>

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Step	410.00		
Material		Part: 0	Ver. 0
Action:	Set up rotary tablet machine fitted with capsule shaped shallow cup tooling	Target:	
Inventory:		Performer:	Verifier:
Step	420.00		
Material		Part: 0	Ver. 0
Action:	Compress tablets to target Weight: 1325 mg.	Target: 1325	Range: 1298-1352
Inventory:		Performer:	Verifier:
Step	500.00		
Material		Part: 0	Ver. 0
Action:	TABLET COATING	Target:	
Inventory:		Performer:	Verifier:
Step	510.00		
Material	Purified Water	Part: 156	Ver. 1
Action:	Load into a suitable stainless steel container equipped with a propeller mixer: Purified Water (43.714 kg)	Target: 43.714	Range: 43-44
Inventory:	X	Performer: X	Verifier: X
Step	512.00		
Material		Part: 0	Ver. 0
Action:	Run the mixer at a speed to create small vortex	Target:	
Inventory:		Performer:	Verifier:
Step	515.00		
Material	Opadry Orange	Part: 178	Ver. 1
Action:	Weigh out and add Opadry Orange (7.714 kg) slowly to the vortex	Target: 7.714	Range: 7.710-7.720
Inventory:	X	Performer: X	Verifier: X
Step	517.00		
Material		Part: 0	Ver. 0
Action:	Continue mixing at a slow speed to avoid foaming for 60 minutes	Target: 60	Range: 55-65
Inventory:		Performer:	Verifier:
Step	520.00		
Material		Part: 0	Ver. 0
Action:	Set up a 60" Accela Cota	Target:	
Inventory:		Performer:	Verifier:
Step	522.00		
Material		Part: 0	Ver. 0
Action:	Specifications: Spray System Co. 5 spray guns, Fluid Cap: 0.040 Inches, Air Cap: 45°	Target:	
Inventory:		Performer:	Verifier:

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Step	524.00		
Material		Part: 0	Ver. 0
Action:	Space guns evenly to provide a uniform spray. (No Gaps)		Target:
Inventory:	Performer:	Verifier:	
Step	526.00		
Material		Part: 0	Ver. 0
Action:	Guns approximately 12" from cascading bed of tablets		Target:
Inventory:	Performer:	Verifier:	
Step	528.00		
Material		Part: 0	Ver. 0
Action:	Adjust pan speed to provide a gentle cascading tablet flow		Target:
Inventory:	Performer:	Verifier:	
Step	530.00		
Material		Part: 0	Ver. 0
Action:	Load into the Accela Coated pan: B Complex with Vitamin C (approximately 200,000 core tablets)		Target:
Inventory:	Performer:	Verifier:	
Step	540.00		
Material		Part: 0	Ver. 0
Action:	Preheat cores to 40° C while the bed is rotating.		Target:
Inventory:	Performer:	Verifier:	
Step	550.00		
Material		Part: 0	Ver. 0
Action:	Spray Color Coating Suspension (51.4 kg) onto the cores at a rate to maintain the exhaust temperature at 40°C.		Target:
Inventory:	Performer:	Verifier:	
Step	555.00		
Material		Part: 0	Ver. 0
Action:	When coating is complete, reduce exhaust temperature to 25°C and dry tablets for an additional 5 minutes		Target:
Inventory:	Performer:	Verifier:	
Step	560.00		
Material		Part: 0	Ver. 0
Action:	Repeat the coating cycle until the entire batch has been coated.		Target:
Inventory:	Performer:	Verifier:	

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Attachments

PublicTempStorage/Pricing Spreadsheet for 5657 B Complex_18996309.xlsx