

Wagner Pharmaceutica Master Production Record

MPR #: 5245

Product Code:	Drug Name:	Strength:	Number:
Calcium Tablet	Oyster Shell Calcium Tablet	250 mg	146 1

Cover Page

Manufacturing Date:	Author: Sam Ops	Formulation Id:	5245
Theoretical Yield:	2000000	Batch Size:	1616.000 kg
Purpose:	Production	MPR Version #:	1
		Scope:	Scale-Up

Bill of Materials

Part	Ver	Material	Qty/Batch	Unit	Composition	Unit
148	1	Oyster Shell Granulation	1428.60	kg		
149	1	Vitamin D2	0.38	kg		
150	1	Calcium Carbonate	51.27	kg		
151	1	Emcosoy	16.16	kg		
152	1	Microcrystalline Cellulose	63.27	kg		
153	1	Crospovidone, NF	32.32	kg		
154	1	Stearic Acid, NF	16.00	kg		
155	1	Magnesium Stearate, NF	8.00	kg		
156	1	Purified Water	76.50	kg		
157	1	Opadry Light Green	13.50	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
AC60	60" Accela Cota

In-Process Testing

Step	Test	Method	Purpose	Specifications
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MPR Approvals

Approver	Job Function	Date/Time
KWagner01	Production Supervisor	
GRazor01	Quality Manager	

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Manufacturing Instructions

Step	100.00		
Material		Part: 0	Ver. 0
Action:	WEIGHING		
Inventory:	Performer:	Verifier:	
Step	110.00		
Material		Part: 0	Ver. 0
Action:	Check Room Preparation		
Inventory:	Performer:	Verifier:	
Step	120.00		
Material	Oyster Shell Granulation	Part: 148	Ver. 1
Action:	Weigh out Oyster Shell granulation as two weighing: 28.600 kg and 1400 kg		
Inventory:	Performer:	Verifier:	
Step	130.00		
Material	Vitamin D2	Part: 149	Ver. 1
Action:	Weigh out 375 g of Vitamin D2		
Inventory:	Performer:	Verifier:	
Step	140.00		
Material	Calcium Carbonate	Part: 150	Ver. 1
Action:	Weigh out 51.272 kg of Calcium Carbonate		
Inventory:	Performer:	Verifier:	
Step	150.00		
Material	Emcosoy	Part: 151	Ver. 1
Action:	Weigh out 16.160 kg of Emcosoy		
Inventory:	Performer:	Verifier:	
Step	160.00		
Material	Microcrystalline Cellulose	Part: 152	Ver. 1
Action:	Weigh out 63.273 kg of Microcrystalline Cellulose		
Inventory:	Performer:	Verifier:	
Step	170.00		
Material	Crospovidone, NF	Part: 153	Ver. 1
Action:	Weigh out 32.32 kg of Crospovidone, NF		
Inventory:	Performer:	Verifier:	
Step	180.00		
Material	Stearic Acid, NF	Part: 154	Ver. 1
Action:	Weigh out 16.00 kg of Stearic Acid, NF		
Inventory:	Performer:	Verifier:	
Step	190.00		
Material	Magnesium Stearate, NF	Part: 155	Ver. 1
Action:	Weigh out 8.00 kg of Magnesium Stearate, NF		
Inventory:	Performer:	Verifier:	

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Step	200.00		
Material		Part: 0	Ver. 0
Action:	BLENDING	Target:	
Inventory:		Performer:	Verifier:
Step	202.00		
Material		Part: 0	Ver. 0
Action:	Load OYSTER SHELL GRAN and VITAMIN D2 into a 2 cu. ft. "V" blender	Target:	
Inventory:		Performer:	Verifier:
Step	203.00		
Material		Part: 0	Ver. 0
Action:	Blend for 10 minutes then load into double polyethylene lined drum	Target: 10 Range: 8-12	
Inventory:		Performer:	Verifier:
Step	205.03		
Material		Part: 0	Ver. 0
Action:	Load into a suitable blender: OYSTER SHELL GRAN (1400.000 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	205.04		
Material		Part: 0	Ver. 0
Action:	Add to blender: CALCIUM CARBONATE PREMIX from Step 204 (51.272 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	205.05		
Material		Part: 0	Ver. 0
Action:	Add to blender: EMCOSOY (16.160 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	205.06		
Material		Part: 0	Ver. 0
Action:	Add to blender: AVICEL PH 101 (63.273 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	205.07		
Material		Part: 0	Ver. 0
Action:	Add to blender: POLYPLASDONE (32.320 kg)	Target:	
Inventory:		Performer:	Verifier:
Step	206.00		
Material		Part: 0	Ver. 0
Action:	Blend for 15 minutes	Target: 15 Range: 14-17	
Inventory:		Performer:	Verifier:
Step	207.00		
Material		Part: 0	Ver. 0
Action:	Pass STEARIC ACID and MAGNESIUM STEARATE through a # 20 mesh screen and charge into blender	Target:	
Inventory:		Performer:	Verifier:

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Step	208.00		
Material		Part: 0	Ver. 0
Action:	Blend for 5 minutes	Target: 5	Range: 4-6
Inventory:	Performer:	Verifier:	
Step	209.00		
Material		Part: 0	Ver. 0
Action:	Discharge blend into suitable containers	Target:	
Inventory:	Performer:	Verifier:	
Step	300.00		
Material		Part: 0	Ver. 0
Action:	COMPRESSION	Target:	
Inventory:	Performer:	Verifier:	
Step	300.05		
Material		Part: 0	Ver. 0
Action:	Set up rotary tablet machine using shallow cup capsule shaped tooling	Target:	
Inventory:	Performer:	Verifier:	
Step	310.00		
Material		Part: 0	Ver. 0
Action:	Compress tablets at the theoretical tablet weight of 1616 mg	Target:	
Inventory:	Performer:	Verifier:	
Step	320.00		
Material		Part: 0	Ver. 0
Action:	Collect compressed tablets in poly lined containers	Target:	
Inventory:	Performer:	Verifier:	
Step	400.00		
Material		Part: 0	Ver. 0
Action:	COATING	Target:	
Inventory:	Performer:	Verifier:	
Step	401.00		
Material	Purified Water	Part: 156	Ver. 1
Action:	Load 76.5 kg Purified Water into a suitable stainless steel container	Target:	
Inventory:	Performer:	Verifier:	
Step	401.05		
Material	Opadry Light Green	Part: 157	Ver. 1
Action:	Load 13.5 kg Opadry Light Green into stainless steel container above	Target:	
Inventory:	Performer:	Verifier:	
Step	402.00		
Material		Part: 0	Ver. 0
Action:	Gently mix for 60 minutes to insure uniform dispersion, adjust mixer speed to avoid foaming	Target:	
Inventory:	Performer:	Verifier:	

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Step	403.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Set-up 60" Accela Cota and load approximately 250 kg of Oyster shell Calcium Tablets	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	404.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Preheat pan to approximately 40 degrees C.	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	405.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Spray 90 kg coating suspension at appropriate pan speed, inlet and exhaust temperatures and spray rate	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	406.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Discharge tablets into suitable containers	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	407.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>	Repeat coating sub-batches of core tablets to complete the batch	<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	500.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>		<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	510.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>		<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	520.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>		<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	
Step	530.00		
<u>Material</u>		<u>Part:</u> 0	<u>Ver.</u> 0
<u>Action:</u>		<u>Target:</u>	
<u>Inventory:</u>	<u>Performer:</u>	<u>Verifier:</u>	