MANUFACTURING PROCEDURES

CSP 590 **MPR #:** _____	**Production Run (Batch/Lot) #:** _____ **TID #:** _____	**Theoretical Lot Size[1]:** _____**kg/batch** **Theoretical # units/batch[2]:**_____	**Start Time:** _____ **Start Date:** _____ **End Time:** _____ **End Date:** _____

[1]*Batch size to be determined at time of manufacture (Procedures suitable for 1.5 Kg to3.375 K g batches)*
[2]*Theoretical No. of Tablets to be calculated at time of production (batch size divided by 0.375)*

Component ID, Weights and Measures Log

COMPONENT	TID	QUANTITY PER TABLET	FORMULA =	BULK QTY REQUIRED	QUANTITY ON HAND	CALC. PERFORMED BY	CALC. CHECKED BY	QM CHECK
PLACEBO 375 mg MYTHICAL tablets		1	Desired batch size (in Kg) X 1,000	_____g	_____g			
Opadry II orange (85F93265)		11.25 mg (3% of tab wt)	Batch size x 0.03*	_____g	_____g			
DI Water		N/A	Weight of Opadry required x 5	_____g	_____g			

**Target 3% weight gain*

Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
	Safety Precautions: normal personal protective gear; no special safety precautions required.				

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
1	Manually verify the calibration of each balance to be used with a set of certified masses prior to weighing active ingredient or excipients. • Only use scales calibrated for the unit of measure to be weighed o i.e. Kg scale for Kg weight, o mg scale for mg weight, o g scale for g weight. • Use one certified mass for each scale that weighs less than the lowest value to be weighed on that scale. • Use one certified mass for each scale that weighs more than the heaviest value to be weighed on that scale. • Attach a printout of the results to this page. • Actual results shall fall within ± 0.5% of the test mass.	Mettler Toledo No._____ Certified Low Mass Weight: _____g Certified High Mass Weight: _____g	Low Mass Range: Low: _____ g High: _____ g Actual:_____ g High Mass Range: Low:_____ g High: _____ g Actual: _____ g		
2	Weigh _____ g of Opadry. Record actual weight. Acceptable range ± 1% of the bulk quantity determined in the Component ID, Weights and Measures Log	Minimum : _____g to Maximum: _____g	**ACTUAL WEIGHT OF OPADRY:** **_____g (A)**		

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
3	Weigh _____ g of DI water. Record actual weight. Acceptable range ± 0.1 g of the bulk quantity determined in the Component ID, Weights and Measures Log	Minimum : _____g to Maximum: _____g	**ACTUAL WEIGHT OF DEIONIZED WATER:** **_____g**		
4	Using the variable-blade standard mixer, slowly add the Opadry powder to the water from step 3. Mix for at least 45 minutes prior to initiation of spraying. Continue mixing throughout the coating process to prevent sedimentation.	Required mix time: ≥ 45 minutes	Start Time: _____ Stop Time: _____ Total Mixing Time before initiating spraying: _____min.		
5	Weigh _____g of tablets. Record actual weight. Acceptable range ± 200 g of the bulk quantity determined in the Component ID, Weights and Measures Log	Minimum : _____g to Maximum: _____g	**ACTUAL WEIGHT OF UNCOATED TABLETS:** **_____g (B)**		
6	Place tablets in the O'Hara Labcoat M 15 inch pan..				

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
7	Turn on O'Hara coating apparatus and set processing parameters at the following settings: • Inlet temperature: 62 - 65°C • Inlet air volume: 160 cfm • Pan pressure (INWC): -10.0 -14.0 • Pan speed: 20 RPM (adjust if necessary to achieve an even mixing of the tablet bed) • Pan jog: 15 RPM • Pump speed: 15 - 20 grams/minute • Atomizing air: 10 – 15 psi • Pattern air: 15 – 22 psi Note that these are initial settings and may need to be adjusted during the coating process as described in step 8.				

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
8	Begin the coating process. Ensure spray nozzle is tilted to spray the upper third of the tablet bed. Adjust atomization air pressure if needed to create a fine mist. Adjust spray rate if necessary to prevent tablet sticking (to the pan or to each other) and spray drying. If necessary, adjust pan speed to ensure even mixing of the tablet bed. Record all changes on the addendum page. Continue spraying until all Opadry suspension has been sprayed.				
9	Pump DI water through the tubing for 2-3 minutes.	Required time = 2-3 minutes	Start Time: _____ Stop Time: _____ Total Spraying Time:_____min.		
10	Allow tablets to continue to tumble in the drum for an additional 4-5 minutes to ensure some degree of dryness has been achieved.	Required time = 4-5 minutes	Start Time: _____ Stop Time: _____ Total Spraying Time:_____min.		

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
11	Record total coating time.		**TOTAL COATING TIME:** **_____min.**		
12	Remove the coated tablets from the drum. Weigh coated tablets and record actual weight.		**ACTUAL WEIGHT OF COATED TABLETS:** **_____g (C)**		
13	Calculate a percent weight gain for the batch. [Weight of coated tablets (C)] divided by weight of uncoated tablets B (C) ÷ (B) = _____ (D) Determine the theoretical weight gain. Weight of uncoated tablets (B) x 1.03 = _____(E) Calculate the % of theoretical.	Acceptable range: 85-105% of theoretical	**PERCENT YIELD** **(% of theoretical weight gain):** $\frac{\_\_\_\_\_(D)}{\_\_\_\_\_(E)} x100 =$ **_____%**		
14	Visually examine the coated tablets. Set aside any chipped or damaged tablets for additional coating or destruction.				

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Step #:	Procedure Description	Specification – Tolerances	Value	Performed By:	Checked By:
15	Double bag and quarantine coated tablets until released by QCS				
16	Enter final inventory in DOSE.				