

## MASTER FORMULA CARD



Form No.: FDF013/00

Reference SOP No.: FD044

<b>Product Name</b> : Nicotine Chewing Gum 2 mg and 4 mg (Mint Flavor)	
<b>Generic Name</b> : Nicotine Chewing Gum	
<b>Product Code</b> : NECTI2 and NECTI4	<b>Market</b> : Europe
<b>MFC Number</b> : MFC/0251/05	<b>Supersedes</b> : MFC/0251/04
<b>Effective Date</b> : 23 APR 2021	<b>Page No.</b> : 1 of 14

### 1.0 Label claim:

#### For Nicotine Chewing Gum 2mg:

Each coated gum contains Nicotine Resinate 10 mg equivalent to Nicotine 2 mg.

#### For Nicotine Chewing Gum 4mg:

Each coated gum contains Nicotine Resinate 20 mg equivalent to Nicotine 4 mg.

### 2.0 Packing information:

Refer current PDS.

### 3.0 Shelf life:

24 Months\*

\*Tentative and shall be ascertained on the basis of real time stability data.

### 4.0 Storage Conditions:

Do not store above 25°C

### 5.0 Precautions:

5.1 Wear nose mask, head cap, gloves, primary and secondary gowning to avoid contact with Nicotine Resinate during manufacturing.

5.2 Possible effects of overexposure in the workplace include: Skin irritation, Eye irritation and Respiratory arrest.

5.3 Wash hands and arms thoroughly after handling.

### 6.0 Reasons for issue:





Revision

### 7.0 Reasons for revision: (Refer CCN/FD/033/2021)

7.1 In section 1.0, 5.0, 8.2, 11.2.1, 11.2.2 and 11.2.3 the name of the API was updated to Nicotine Resinate.

7.2 In section 8.0- Foot note, Nicotine Resinate is also known as Nicotine Polacrilex was updated.

7.3 In section 8.0 and 9.0 API name was updated to Nicotine Resinate (Nicotine content 20%).

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## 8.0 Unit composition:

S. No	Ingredients	Grade/Brand Name	Specific ation No. <sup>5</sup>	Pharmaco peial Reference	Functional category	2 mg strength		4 mg strength	
						mg per gum	% m/m	mg per gum	% m/m
API dispersion stage									
1	Nicotine Resinate (Nicotine content 20%)	Nicotine Resinate (Nicotine content 20%)	RS727	Pb.Eur	Active pharmaceutical ingredient	10.00 <sup>1</sup>	0.694	20.00 <sup>2</sup>	1.389
2	Mint Flavor	Mint Flavor 1109501181	RS731	IH	Flavor	12.00	0.833	12.00	0.833
Intra granular stage									
3	Health In Gum base	Health In Gum PWD-04	RS638	IH	Gum base	216.17 <sup>3</sup>	15.012	214.17 <sup>4</sup>	14.873
4	Silica, colloidal hydrated	Syloid 244 FP	RS722	Ph.Eur	Adsorbent	8.00	0.556	8.00	0.556
Extra granular stage									
5	Health In Gum base	Health In Gum PWD-04	RS638	IH	Gum base	864.68	60.047	856.68	59.492
6	Menthol	L-Menthol	RS758	USP	Flavor enhancer	6.00	0.417	6.00	0.417
7	Sucralose	Sucrex	RS725	Ph.Eur	Sweetener	2.00	0.139	2.00	0.139
8	Acesulfame potassium	Sunett particle size D pharma	RS584	Ph.Eur	Sweetener	4.00	0.278	4.00	0.278
9	Sodium carbonate anhydrous	Sodium carbonate anhydrous	RS726	Ph.Eur	Buffering agent	14.75	1.024	14.75	1.024
10	Sodium hydrogen carbonate	Sodium hydrogen carbonate	RS421	Ph.Eur	Buffering agent	7.40	0.514	7.40	0.514
11	Refreshing flavor	Refreshing flavor	RS721	IH	Flavor	15.00	1.042	15.00	1.042
12	Silica, colloidal hydrated	Syloid 244 FP	RS722	Ph.Eur	Glidant	16.00	1.111	16.00	1.111
Lubrication									
13	Magnesium stearate	LIGAMED MF-2-V	RS032	Ph.Eur	Lubricant	24.00	1.667	24.00	1.667
Core gum weight						1200.00	-	1200.00	-

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



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S. No	Ingredients	Grade/Brand Name	Specific ation No. <sup>5</sup>	Pharmaco peial Reference	Functional category	2 mg strength		4 mg strength	
						mg per gum	% m/m	mg per gum	% m/m
Sub-coating <sup>6</sup>									
14	Xylitol	Xylisorb 90	RS724	Ph.Eur	Sweetener	166.81	11.584	166.81	11.584
15	Xanthan gum	Xanthural 75	RS058	Ph.Eur	Binder	0.86	0.060	0.86	0.060
16	Talc	Talc Luzenac PharmaM	RS137	Ph.Eur	Dispersing agent	2.94	0.204	2.94	0.204
17	Titanium dioxide	KRONOS 1171	RS131	Ph.Eur	Opacifying agent	4.39	0.305	4.29	0.298
18	Ferric oxide (yellow)	Iron oxide sicovit yellow 10	RS752	NF	Coloring agent	-	-	0.10	0.007
19	Purified water <sup>7</sup>	Purified water	RS014	Ph.Eur	Dispersant	213.88	-	213.88	-
Flavored coating <sup>6</sup>									
20	Mint Flavor	Mint Flavor 1109501181	RS731	IH	Flavor	10.00	0.694	10.00	0.694
21	Xylitol	Xylisorb 90	RS724	Ph.Eur	Sweetener	39.00	2.708	39.00	2.708
22	Hypromellose	Methocel E5 premium LV	RS226	Ph.Eur	Binder	9.00	0.625	9.00	0.625
23	Talc	Talc Luzenac PharmaM	RS137	Ph.Eur	Dispersing agent	0.50	0.035	0.50	0.035
24	Titanium dioxide	KRONOS 1171	RS131	Ph.Eur	Opacifying agent	1.50	0.104	1.40	0.097
25	Ferric oxide (yellow)	Iron oxide sicovit yellow 10	RS752	NF	Coloring agent	-	-	0.10	0.007
26	Purified water <sup>7</sup>	Purified water	RS014	Ph.Eur	Dispersant	73.33	-	73.33	-
Glow coating <sup>6</sup>									
27	Insta Glow	Insta Glow IG 001	RS658	IH	Polishing agent	5.00	0.347	5.00	0.347
28	Purified water <sup>7</sup>	Purified water	RS014	Ph.Eur	Dispersant	20.00	-	20.00	-
Coated gum weight						1440.00	100.00	1440.00	100.00

<sup>1,2,3,4</sup> Refer section 8.1 and 8.2; <sup>5</sup> Follow current version; <sup>6</sup> Based on 100% coating efficiency; <sup>7</sup> Appears in trace amount in finished product; IH: In-House; Note: Nicotine Resinate is also known as Nicotine Polacrilex.

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### 8.1 In put basis:

<sup>1,2</sup> The API quantity is based on 100% m/m assay on dried basis and %LOD.

<sup>3,4</sup> Intra granular Health in gum base is adjusted to maintain constant unit weight.

### 8.2 Calculations:

Calculate quantity of the Nicotine Resinate (Equivalent to 2mg and 4mg of Nicotine) based on actual assay on dried basis and %LOD as per the following formula and adjust the weight with intra-granular Health in gum base:

#### For 2mg (Lower Strength)

$$^1 \text{Actual quantity of Nicotine Resinate (A)} = \frac{10 \times 100 \times 100}{\% \text{ Assay on dried Basis} \times 100 - \% \text{ LOD}}$$

$$^3 \text{Intra-granular Health in gum base} = (10 + 216.17) - (A)$$

#### For 4mg (Higher Strength)

$$^2 \text{Actual quantity of Nicotine Resinate (B)} = \frac{20 \times 100 \times 100}{\% \text{ Assay on dried Basis} \times 100 - \% \text{ LOD}}$$





$$^4 \text{Intra-granular Health in gum base} = (20 + 214.17) - (B)$$

### 8.3 Overages (if any):

Not applicable.

### 8.4 Excess (if any):

30% excess coating materials to be provided to compensate the losses during coating process.

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## 9.0 Ingredient details:

S. No	Material name	Grade/Brand Name	Material code	Monograph reference	Vendor / Manufacturer
1	Nicotine Resinate (Nicotine content 20%)	Nicotine Resinate (Nicotine content 20%)	10000306	Ph.Eur	Siegfried
2	Mint Flavor	Mint Flavor I 109501181	25000860	IH	Silesia Gerhard hanke GmbH & Co.KG
3	Health In Gum base	Health In Gum PWD-04	25000708	IH	CAFOSA
4	Silica, colloidal hydrated	Syloid 244 FP	25000770	Ph.Eur	Grace
5	Menthol	L-Menthol	25000199	USP	Spectrum chemicals & laboratory products
6	Sucralose	Sucrex	25000857	Ph.Eur	Gangwal chemicals pvt. Ltd.
7	Acesulfame potassium	Sunett particle size D pharma	25000184	Ph.Eur	Nutrinova
8	Sodium carbonate anhydrous	Sodium carbonate anhydrous	25000859	Ph.Eur	Merck KGaA
9	Sodium hydrogen carbonate	Sodium hydrogen carbonate	25000265	Ph.Eur	Merck KGaA
10	Refreshing flavor	Refreshing flavor	25000727	IH	Bell flavours & Fragrances GmbH
11	Magnesium stearate	LIGAMED MF-2-V	25000104	Ph.Eur	Peter greven Nederland C.V.
12	Xylitol	Xylisorb 90	25000858	Ph.Eur	Roquette
13	Xanthan gum	Xanthural 75	25000084	Ph.Eur	CP Kelco
14	Talc	Talc Luzenac PharmaM	25000233	Ph.Eur	Imerys Talc, Italy
15	Titanium dioxide	KRONOS 1171	25000225	Ph.Eur	Kronos international Inc
16	Ferric oxide (yellow)	Iron oxide sicovit yellow 10	25000865	NF	Huntsman
17	Hypromellose	Methocel E5 premium LV	25000078	Ph.Eur	Dow chemical company
18	Insta Glow	Insta Glow IG 001	25000802	IH	Ideal cures
19	Purified water	Purified water	25000001	Ph.Eur	In-house

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### 10.0 Environmental Conditions:

Temperature: NMT 25°C;  
 Relative Humidity: NMT 60%RH  
**Compression area:**  
 Temperature: NMT 25 °C;  
 Relative Humidity: NMT 45% RH





### 11.0 Brief manufacturing process:

#### 11.1 Intra-granular gum base sifting:

11.1.1 Sift the Intra granular Health In Gum base through # 16 sieve.

#### 11.2 Nicotine dispersion and dry mixing (For both 2mg and 4mg strength):

S. No.	Manufacturing stage	For 2mg strength	For 4mg strength
11.2.1	Nicotine Resinate dispensing	Weigh the Nicotine Resinate.	Weigh the Nicotine Resinate and divide into two equal portions.
11.2.2	Nicotine dispersion preparation	Disperse the total Nicotine Resinate in Mint flavor in a suitable container manually for sufficient time until uniform dispersion is formed.	Disperse the first portion of Nicotine Resinate in Mint flavor in a suitable container by manually for sufficient time until uniform dispersion is formed.
11.2.3	Dry mixing	Place the step no. 11.1.1 material into SMG bowl.	Place the step no. 11.1.1 material and second portion of Nicotine Resinate of step no. 11.2.1 in SMG bowl and mix the blend at slow speed (95 RPM) for 1 minute.

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### 11.3 Nicotine dispersion adsorption:

11.3.1 Adsorb the Nicotine dispersion of step no. 11.2.2 on dry mixing stage material of step no. 11.2.3 in RMG for 3 to 6 minutes with Impeller at slow speed (95RPM) and chopper off.

11.3.2 After addition, clean the Nicotine dispersion container and API poly bags with sufficient quantity of blend of 11.3.1 and transferred to RMG.

Note: Please ensure that total quantity of API gets transferred.

11.3.3 Continue the mixing for about 1 to 3 minutes with Impeller at slow speed (95 RPM) and chopper at slow speed (1440 RPM).

11.3.4 Add Silica, colloidal hydrated (Intra granular) to the step no. 11.3.3 in RMG and knead for 15 seconds to 90 seconds with Impeller at slow speed (95RPM) and chopper at slow speed (1440 RPM).

11.3.5 Unload the materials from RMG at slow speed (95RPM) and chopper off and sift through # 16 sieve.





### 11.4 Milling:

11.4.1 Mill the Menthol using Mobile cone mill fitted with 1.2 mm screen at 500 – 1500 RPM and collect into double polythene bags.

### 11.5 Extra granular materials sifting:

11.5.1 Sift the extra-granular Health in gum base through # 16 sieve and divided it into two equal portions.

11.5.2 Co-sift the milled Menthol (step no. 11.4.1), Sucralose, Acesulfame potassium, Sodium carbonate, Sodium hydrogen carbonate, Refreshing flavor and Silica, colloidal hydrated (Extra-granular) through #20 sieve.

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### 11.6 Blending Step I:

- 11.6.1 Load the sifted Nicotine adsorbed granules of step no.11.3.5 and first portion of step no. 11.5.1 extra-granular Health in gum base into Pillar Type Bin Blender (200 L) and blend for 20 minutes at fast speed (23 RPM).
- 11.6.2 Unload the above blend into double polythene lined bag in HDPE containers.

### 11.7 Blending Step II:

- 11.7.1 Load the second portion of step no.11.5.1 extra-granular Health in gum base and step no.11.5.2 excipients and materials of step no. 11.6.2 into Conta blender (400 L) and blend for 20 minutes at 20 RPM.
- 11.7.2 Unload the above blend into double polythene lined bag in HDPE containers.

### 11.8 Magnesium stearate sifting:

- 11.8.1 Sift the magnesium stearate through # 60 sieve.

### 11.9 Sifting :

- 11.9.1 Co-sift ¼ scoop of Magnesium stearate step no. 11.8.1 with 10 scoops of step no. 11.7.2 through # 16 sieve.

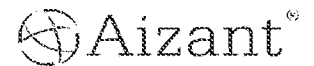
### 11.10 Lubrication:

- 11.10.1 Load the materials of step no. 11.9.1 into Conta blender (400 L) and blend for 20 minutes at 20 RPM.
- 11.10.2 Unload the above blend into double polythene lined bag in HDPE containers.

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### 11.11 Compression:

**Note:** Jogg the compression machine with 50g of Magnesium stearate for 10 min at 20RPM and remove the peripheral magnesium stearate with vaccum cleaner before initiation of compression activity.

11.11.1 Compress the lubricated blend of step no. 11.10.2 as per the compression parameters mentioned in section 12.0, using tooling as described in section 13.0.

### 11.12 Coating

#### 11.12.1 Sub-coating:

11.12.1.1 Take required quantity of purified water (quantity of purified water equal to 45% m/m solid content) in a stainless steel/suitable vessel equipped with stirrer.

11.12.1.2 **For 2 mg strength:** Dissolve the weighed quantity of xanthan gum in the step no. 11.12.1.1 purified water and stir continuously until clear viscous solution is formed.

**For 4mg strength:** Sift the Ferric oxide (yellow) through # 100 sieve and disperse in the step no. 11.12.1.1 purified water under continuous stirring and stir for 10 minutes. Then dissolve the weighed quantity of xanthan gum and stir continuously until yellow colored clear viscous solution is formed.

11.12.1.3 **For 2 mg strength:** Dissolve the weighed quantity of xylitol into the step no.11.12.1.2 and stir continuously until clear viscous solution is formed.

**For 4 mg strength:** Dissolve the weighed quantity of xylitol into the step no.11.12.1.2 and stir continuously until yellow colored clear viscous solution is formed.

11.12.1.4 Co-sift the Titanium dioxide and Talc through # 60 sieve, added to the step no.11.12.1.3 and stir for 30 minutes.

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



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11.12.1.5 Transfer the core gums of step no.11.11.1, into the coating pan. Jog the pan intermittently for 5 minutes or more to remove any adhering powder and pre-warm the core gums at inlet temperature of  $45^{\circ}\text{C} \pm 5^{\circ}\text{C}$  with pan speed of 2 - 5 RPM for 15 - 30 minutes (Bed temperature should not be more than  $40^{\circ}\text{C}$ ).

11.12.1.6 Set the process parameters as mentioned in the below table and start the coating dispersion spraying on to the core gums bed by selecting sugar coating process and continue the process until the % weight gain of 14.58% m/m (range 14.08% m/m to 15.08% m/m) to the average weight of pre-warmed core gums is achieved.

Parameters	Specification		
No of Phases	Spray time (Sec)	Pause time (Sec)	Dry time (Sec)
Phase-1 (Up to 5% m/m Weight gain)	10 - 55	10 - 45	10 - 90
Phase-2 (Up to 10% m/m Weight gain)	10 - 35	10 - 70	10 - 65
Phase-3 (Up to 14.58% m/m Weight gain)	10 - 25	10 - 90	10 - 45
Inlet Temperature	$60^{\circ}\text{C} \pm 10^{\circ}\text{C}$		
Exhaust temperature	$25^{\circ}\text{C} - 60^{\circ}\text{C}$		
Bed temperature	$20^{\circ}\text{C} - 50^{\circ}\text{C}$		
Atomization pressure ( $\text{kg}/\text{cm}^2$ )	1 - 3		
Gun to bed distance (cm)	12 - 28		
Pan speed (RPM)	1 - 15		
Nozzle size (mm)	1		
No. of guns	2		
Curing	Inlet temperature of $50^{\circ}\text{C} \pm 10^{\circ}\text{C}$ , for 15 - 30 minutes with pan speed of 2 - 5 RPM		

Note: Parameters of phase-1, phase-2 and phase-3 can be altered as required to get optimum coating performance.

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## MASTER FORMULA CARD



Form No.: FDF013/00

Reference SOP No.: FD044

<b>Product Name</b> : Nicotine Chewing Gum 2 mg and 4 mg (Mint Flavor)	
<b>Generic Name</b> : Nicotine Chewing Gum	
<b>Product Code</b> : NECTI2 and NECTI4	<b>Market</b> : Europe
<b>MFC Number</b> : MFC/0251/05	<b>Supersedes</b> : MFC/0251/04
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11.12.1.7 After spraying of coating dispersion, dry the gums at an inlet temperature of  $50^{\circ}\text{C} \pm 10^{\circ}\text{C}$  with pan speed of 2 – 5 RPM for 15-30 minutes, once the buildup is achieved.

### 11.12.2 Flavored coating:

11.12.2.1 Take required quantity of purified water (quantity of purified water equal to 45% m/m solid content) in a stainless steel/suitable vessel equipped with stirrer.

11.12.2.2 **For 2 mg strength:** Dissolve the weighed quantity of Xylitol in the step no. 11.12.2.1 purified water and stir continuously until clear viscous solution is formed.

**For 4mg strength:** Sift the Ferric oxide (yellow) through # 100 sieve and disperse into the step no. 11.12.2.1 purified water under continuous stirring and stir for 10 minutes. Then dissolve the weighed quantity of Xylitol and stir continuously until yellow colored clear viscous solution is formed.

11.12.2.3 **For 2 mg strength:** Dissolve the weighed quantity of Hypromellose E5 LV premium into the solution of step no.11.12.2.2 and stir continuously until clear viscous solution is formed.

**For 4 mg strength:** Dissolve the weighed quantity of Hypromellose E5 LV premium into the step no.11.12.2.2 and stir continuously until yellow colored clear viscous solution is formed.

11.12.2.4 Disperse the Mint flavor to the step no.11.12.2.3 and stir continuously for 5 minutes.

11.12.2.5 Co-sift the Titanium dioxide and Talc through # 60 sieve, added to the step no.11.12.2.4 and stir for 30 minutes.

11.12.2.6 Pre-warm the sub-coated gums of step no. 11.12.1.7 at inlet temperature till to achieve the bed temperature reaches  $38^{\circ}\text{C}$  to  $42^{\circ}\text{C}$ .

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## MASTER FORMULA CARD



Form No.: FDF013/00

Reference SOP No.: FD044

<b>Product Name</b> : Nicotine Chewing Gum 2 mg and 4 mg (Mint Flavor)	
<b>Generic Name</b> : Nicotine Chewing Gum	
<b>Product Code</b> : NECTI2 and NECTI4	<b>Market</b> : Europe
<b>MFC Number</b> : MFC/0251/05	<b>Supersedes</b> : MFC/0251/04
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11.12.2.7 Set the process parameters as mentioned in the below table and start the coating dispersion spraying on to the sub-coated gums bed by selecting sugar coating process and continue the process until the % weight gain of 4.36 % m/m (range 3.86% m/m to 4.86% m/m) to the average weight of sub-coated gums is achieved.

Parameters	Specification		
No of Phases	Spray time (Sec)	Pause time (Sec)	Dry time (Sec)
Phase-1 (Upto 1.5% Weight gain)	10 - 35	10 - 45	10 - 90
Phase-2 (Upto 3.0% Weight gain)	10 - 30	10 - 70	10 - 65
Phase-3 (Upto 4.36% weight gain)	10 - 20	10 - 90	10 - 45
Inlet Temperature	60°C ± 10°C		
Exhaust temperature	25°C - 60°C		
Bed temperature	20°C - 50°C		
Atomization pressure (kg/cm <sup>2</sup> )	1 - 3		
Gun to bed distance (cm)	12 - 28		
Pan speed (RPM)	1 - 15		
Nozzle size (mm)	1		
No. of guns	2		
Curing	Inlet temperature of 50°C ± 10°C, for 15 - 30 minutes with pan speed of 2 - 5 RPM		

Note: Parameters of phase-1, phase-2 and phase-3 can be altered as required to get optimum coating performance.

11.12.2.8 After spraying of coating dispersion, dry the gums at an inlet temperature of 50°C ± 10°C with pan speed of 2 - 5 RPM for 15 - 30 minutes, once the buildup is achieved.

### 11.12.3 Glow coating:

11.12.3.1 Dissolve the Insta glow in required quantity of purified water (20% m/m solid content) in a stainless steel/suitable vessel until clear solution formed by manually.

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Form No.: FDF013/00

Reference SOP No.: FD044


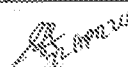
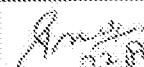

<b>Product Name</b> : Nicotine Chewing Gum 2 mg and 4 mg (Mint Flavor)	
<b>Generic Name</b> : Nicotine Chewing Gum	
<b>Product Code</b> : NECTI2 and NECTI4	<b>Market</b> : Europe
<b>MFC Number</b> : MFC/0251/05	<b>Supersedes</b> : MFC/0251/04
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11.12.3.2 Pre-warm the flavor coated gums of step no. 11.12.2.8 at inlet temperature of  $55^{\circ}\text{C} \pm 10^{\circ}\text{C}$  till to achieve the bed temperature reaches  $35^{\circ}\text{C}$  to  $40^{\circ}\text{C}$ .

11.12.3.3 Set the process parameters as mentioned in the below table and start the coating dispersion spraying on to the flavored coated gums bed by using continuous coating process and continue the process until the % weight gain of 0.35 % m/m (range 0.31% m/m to 0.39 % m/m) to the average weight of flavor coated gums is achieved.

Parameters	Specification
Inlet Temperature	$55^{\circ}\text{C} \pm 10^{\circ}\text{C}$
Exhaust temperature	$25^{\circ}\text{C} - 60^{\circ}\text{C}$
Bed temperature	$20^{\circ}\text{C} - 50^{\circ}\text{C}$
Pan RPM	1 - 15
Spray rate (gm/min/gun)	15 - 60
Atomization air ( $\text{kg}/\text{cm}^2$ )	1 - 3
Gun to bed distance (cm)	12 - 28
No. of guns	2
Curing	Inlet temperature of $50^{\circ}\text{C} \pm 10^{\circ}\text{C}$ , for 15 - 30 minutes with pan speed of 2 - 5 RPM

11.12.3.4 After spraying of glow coating, dry the gums at an inlet temperature of  $50^{\circ}\text{C} \pm 10^{\circ}\text{C}$  with pan speed of 2 - 5 RPM for 15-30 minutes, once the buildup is achieved.

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## MASTER FORMULA CARD



Form No.: FDF013/00

Reference SOP No.: FD044

<b>Product Name</b> : Nicotine Chewing Gum 2 mg and 4 mg (Mint Flavor)	
<b>Generic Name</b> : Nicotine Chewing Gum	
<b>Product Code</b> : NECTI2 and NECTI4	<b>Market</b> : Europe
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### 12.0 Critical process and product parameters:

S. No.	Parameters	Specifications	
		2mg Strength	4mg Strength
Core gums			
1	Appearance	White to off-white colored, round biconvex shaped gums plain on both sides	White to off-white colored, round biconvex shaped gums plain on both sides
2	Individual gum mass (mg)	1200.00 mg $\pm$ 5.0% (1140.00 mg – 1260.00 mg)	1200.00 mg $\pm$ 5.0% (1140.00 mg – 1260.00 mg)
3	Average gum mass (mg)	1200.00 mg $\pm$ 3.0% (1164.00 mg – 1236.00 mg)	1200.00 mg $\pm$ 3.0% (1164.00 mg – 1236.00 mg)
4	Thickness (mm)	7.60 $\pm$ 0.3 mm (7.30 mm – 7.90 mm)	7.60 $\pm$ 0.3 mm (7.30 mm – 7.90 mm)
Coated gums			
5	Appearance	White to off-white colored, round biconvex shaped coated gums plain on both sides	Light yellow colored, round biconvex shaped coated gums plain on both sides
6	Average gum mass (mg)	1440.00 $\pm$ 3.0% (1396.80 mg – 1483.20mg)	1440.00 $\pm$ 3.0% (1396.80 mg – 1483.20mg)

### 13.0 Tooling:

Upper punch: 14.5 mm, round, deep concave plain punch.

Lower punch: 14.5 mm, round, deep concave plain punch.

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