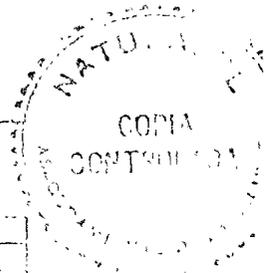


P.O. S.M.A.R.A. VIRA TAB. LOTE No. _____

Orde: _____ Fecha: _____ Cantidad a producir: _____

PROCEDIMIENTO DE MANUFACTURA



PUNTO CONTROL	HORA		FIRMA Y C.O.A.	
	INICIA	TERMINA	PERSONA	C.O.A.
<p>1. Equipo de manufactura, debe estar en buen estado: Bascula Mezclador ribbon Balarza Gramora Tableteadora Manesty Engomadora Píntora de Termoencogible S. Ilustradora Termoencogible</p>				
<p>2. Los envasadosamente, todo el procedimiento tenerlo en cuenta, utilizar el uniforme completo e implementos de seguridad industrial.</p>				
<p>3. Monitorear la correcta identificación y cantidad de los cigaretes materias primas: Almendra _____ Vira Vira _____ Caramelo de leche _____ Esencia de _____</p>				
<p>4. Verificar el buen estado de los equipos</p>				
<p>5. Verificar la temperatura de control de calidad.</p>				
<p>6. Colocar en el mezclador los excipientes de la receta, la goma y la mezcla en la goma y el azúcar, y disolver en () L de agua fría. Previamente se han calentado () L de agua caliente para la goma y la mezcla anterior.</p>				
<p>7. Colocar en el mezclador vira vira en la goma y el azúcar que del que halla en el punto 6 y mezclar durante 30 min.</p>				
<p>8. Verificar la temperatura de control de calidad.</p>				
<p>9. Colocar en el horno de secado o reducción en la goma y el azúcar un tiempo de 4 horas, a una temperatura de 60 C.</p>				
<p>10. Después de transcurrido este tiempo dejar enfriar.</p>				

(TRANSLATION)
S.O.P. VIRA VIRA TAB LOT. #

Code: _____ Date _____ Quantity: _____

MANUFACTURING PROCEDURE

PROCEDURE	TIME		SIGNATURE AND DATE	
	Start	Finish	Effectuates	Verifies

1. Manufacturing equipment, must be in good state:
Scale
Ribbon Mixer
Gram scale
Manesty tablet press
Glucr
Heat shrink tubing gun
Plastic wrap sealer

- 2 Read procedure carefully taking into account complete uniform must be worn and industrial security implements must be used.

- 3 Verify correct identification and quantity of the following materials
Starch _____
Vira vira _____
Arabic gum _____
Magnesium stearate _____

- 4 Verify cleanliness of equipment.

- 5 Solicit inspection from quality control.

- 6 Agglutinate, dissolving the excipients in the following manner: dry mix the gum and starch, and dissolve in () L of cold water. Previously, () L of water have been heated, which is added to the previous mix.

- 7 Place the vira vira powder in the mixer, add agglutinant in point 6 and mix for 30 min
- 8 Granulate through netting No. 20

- 9 Move to drying area and introduce for 8 hours, at 40° C After the time has passed let cool.

- 10 Mix the previous powder with magnesium stearate in the mixer for 15 min. Solicit process and approval control according to
Smell _____
Color _____
Appearance _____
Humidity % _____

(TRANSLATION)

PROCEDURE

TIME

SIGNATURE AND DATE

Start Finish

Effectuates Verifies

11. Transfer powder in plastic containers with a properly sealed plastic bag.

12. Press tablets in 16 station Manesty machine with proper care and proceed to:
Weight and consistency control (register in PD.FR.72 format)
Diameter, height, and disintegration control (register in CC.FR.1 format)

13. Solicit conditioning order (PD FR.65)

14. Transfer to solids bottling area (tablets) in white PVC bottle Ref. 150 tablet and control the number of tablets on the counting scale by weight. Place push down cap on each bottle

15. Transfer to labeling area in plastic containers.

16. Verify the labels
Code Lot # _____
Exp Date _____
Label color _____
Print quality _____

17. Proceed to label each bottle and place heat shrink tubing

18. Seal using heat shrinking pistol, avoiding excess heat

19. Plastic wrap in groups of 6 and place plastic containers (register CC.FR.2)

20 Deliver to finished product warehouse.
Performance
Expected bottles _____
Obtained bottles _____
Performance % _____

Elaborated:

Supervised:

Approved:

Operator:

P.L

T.C.