



## Quality Start-Up Checklist

Date: 12/07/23 Team Lead: ML Room #: 11 EL#: STB0635 Lot#: 2312J013

- Cleaning Logs have been completed.  
Employee Initial: DP Team Lead Initial: ML
  
- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.  
Employee Initial: DP Team Lead Initial: ML
  
- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.  
Employee Initial: DP Team Lead Initial: ML
  
- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready).  
Employee Initial: DP Team Lead Initial: ML
  
- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.  
Employee Initial: DP Team Lead Initial: ML
  
- Ensure that active Lot #'s match what's on the Batch Record and Drum.  
Employee Initial: DP Team Lead Initial: ML
  
- "In Process Production" sheet has been posted with correct BPR information.  
Employee Initial: DP Team Lead Initial: ML
  
- Retains have been collected:  
Employee Initial: V/A Team Lead Initial: MLA
  
- QA Approval Initial/Date: YR 12/07/23.

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: DP Team Lead Initial: MV
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: DP Team Lead Initial: MV
- Equipment Cleaning Log completed.  
Employee Initial: DP Team Lead Initial: MV
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: DP Team Lead Initial: MV
- Product is properly sealed, and hoppers covered.  
Employee Initial: DP Team Lead Initial: MV
- Restock all PPE and components needed for next day.  
Employee Initial: N/A Team Lead Initial: N/A
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: N/A Team Lead Initial: N/A
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: N/A Team Lead Initial: N/A
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: SP Team Lead Initial: MV
  
- QA Approval Initial/Date: VR 12/07/23



## Quality Start-Up Checklist

Date: 12/07/23 Team Lead: VR Room #: 12 EL#: 635 Lot#: 2312T010

- Cleaning Logs have been completed.  
Employee Initial: MV Team Lead Initial: VR
- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.  
Employee Initial: MV Team Lead Initial: VR
- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.  
Employee Initial: MV Team Lead Initial: VR
- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready).  
Employee Initial: MV Team Lead Initial: VR
- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.  
Employee Initial: MV Team Lead Initial: VR
- Ensure that active Lot #'s match what's on the Batch Record and Drum.  
Employee Initial: MV Team Lead Initial: VR
- "In Process Production" sheet has been posted with correct BPR information.  
Employee Initial: MV Team Lead Initial: VR
- Retains have been collected:  
Employee Initial: MV Team Lead Initial: VR
- QA Approval Initial/Date: ARS 12/07/23

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: MV Team Lead Initial: JR
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: MV Team Lead Initial: JR
- Equipment Cleaning Log completed.  
Employee Initial: MV Team Lead Initial: JR
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: MV Team Lead Initial: JR
- Product is properly sealed, and hoppers covered.  
Employee Initial: MV Team Lead Initial: JR
- Restock all PPE and components needed for next day.  
Employee Initial: MV Team Lead Initial: JR
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: MV Team Lead Initial: JR
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: MV Team Lead Initial: JR
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: MV Team Lead Initial: JR
  
- QA Approval Initial/Date: ARS 12/07/23



**STANDARD OPERATING INSTRUCTIONS**

Line #2

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

**Filler:** 30CT

**Target Count:** 30  
**Max Count:** 32

**Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.**

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>Desiccant</i>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
6:15 AM	30	30	30	30	30	30	yes	yes	yes	NA	yes	yes	ME	ARS 12/07/23
6:47 am	30	30	30	30	30	30	yes	yes	yes	NA	yes	yes	ME	ARS 12/07/23
7:20 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	PP 12/07/23
7:53 am	30	30	30	30	30	30	yes	yes	yes	ME	yes	yes	ME	ARS 12/07/23
8:25 am	30	30	30	30	30	30	yes	yes	yes	ME	yes	yes	ME	ARS 12/07/23
8:55 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	ARS 12/07/23
9:24 AM	30	30	30	30	30	30	yes	yes	yes	12/07/23	yes	yes	ME	ARS 12/07/23
9:57 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	ARS 12/07/23
10:30 am	30	30	30	30	30	30	yes	yes	yes	12/07/23	yes	yes	ME	ARS 12/07/23
11:05 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	PP 12/07/23
11:37 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	PP 12/07/23
12:10 pm	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	PP 12/07/23
Lunch														
1:05 pm	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	ARS 12/07/23
1:37 pm	30	30	30	30	30	30	yes	yes	yes		yes	yes	ME	ARS 12/07/23

**Note:** Any failure should be immediately reported to the QA Manager & Production Manager

**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

Filler: 30ct

Target Count: 30

Max Count: 32

Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <u>Desiccant</u>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
<u>2:10 pm</u>	<u>30</u>	<u>30</u>	<u>30</u>	<u>30</u>	<u>30</u>	<u>30</u>	<u>Yes</u>	<u>Yes</u>	<u>Yes</u>	<u>N/A</u>	<u>Yes</u>	<u>Yes</u>	<u>HE</u>	<u>ARS 12/02/23</u>
<div style="position: absolute; top: 50%; left: 50%; transform: translate(-50%, -50%); border: 1px solid black; width: 100%; height: 100%; pointer-events: none;"> <div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border: 1px solid black; width: 100%; height: 100%;"></div> </div>														

Note : Any failure should be immediately reported to the QA Manager & Production Manager





**STANDARD OPERATING INSTRUCTIONS**

Form 11

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

**Filler:** 30 ct

**Target Count:** 30  
**Max Count:** 32

**Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.**

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other	Completed By	QA Signature & Date
	1	2	3	4	5	6								
2:31 PM	30	30	31	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/06/23
3:00 PM	31	30	30	30	30	31	Yes	Yes	Yes		Yes	Yes	MV	YK 12/06/23
3:32 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/06/23
4:05	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/06/23
<b>Stop Production</b>														
6:30 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
7:00 AM	30	30	30	30	30	30	Yes	Yes	Yes	N/A	Yes	Yes	MV	YK 12/07/23
7:35 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
8:02 AM	30	30	30	30	31	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
8:29 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
9:00 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
9:30 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
10:02 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
10:31 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23
11:00 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YK 12/07/23

**Note : Any failure should be immediately reported to the QA Manager & Production Manager**





## Quality Start-Up Checklist

Date: 12/06/23 Team Lead: MV Room #: 11 EL#: 0635 Lot#: 2312T013

- Cleaning Logs have been completed.

Employee Initial: DP Team Lead Initial: MV

- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.

Employee Initial: DP Team Lead Initial: MV

- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.

Employee Initial: SP Team Lead Initial: MV

- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.

Employee Initial: DP Team Lead Initial: MV

- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.

Employee Initial: DP Team Lead Initial: MV

- Ensure that active Lot #'s match what's on the Batch Record and Drum.

Employee Initial: DP Team Lead Initial: MV

- "In Process Production" sheet has been posted with correct BPR information.

Employee Initial: DP Team Lead Initial: MV

- Retains have been collected:

Employee Initial: N/A Team Lead Initial: N/A

- QA Approval Initial/Date: JR 12/06/23

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: DP Team Lead Initial: MU
  
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: DP Team Lead Initial: MU
  
- Equipment Cleaning Log completed.  
Employee Initial: DP Team Lead Initial: MU
  
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: DP Team Lead Initial: MU
  
- Product is properly sealed, and hoppers covered.  
Employee Initial: DP Team Lead Initial: MU
  
- Restock all PPE and components needed for next day.  
Employee Initial: DP Team Lead Initial: MU
  
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: DP Team Lead Initial: MU
  
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: MA Team Lead Initial: MA
  
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: DP Team Lead Initial: MU
  
  
- QA Approval Initial/Date: VR 12/06/23



**STANDARD OPERATING INSTRUCTIONS**

Room 11

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

Filler: 30 ct

Target Count: 36  
Max Count: 32

Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>De-sticker</i>	Completed By	QA Signature & Date	
	1	2	3	4	5	6									
4:10 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/05/23	
Stop Production															
6:15 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
6:35 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
7:07 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
7:31 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
8:00 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
8:20 AM	stop Production - n/a														
11:45 AM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
12:11 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
12:35 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
12:55 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
lunch															
1:35 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	
2:03 PM	30	30	30	30	30	30	yes	yes	yes	yes	yes		MV	YK 12/06/23	

Note : Any failure should be immediately reported to the QA Manager & Production Manager



## Quality Start-Up Checklist

Date: 12/06/23 Team Lead: VR Room #: 12 EL#: 635 Lot#: 2312T013

- Cleaning Logs have been completed.  
Employee Initial: OR Team Lead Initial: VR
  
- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.  
Employee Initial: OR Team Lead Initial: VR
  
- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.  
Employee Initial: OR Team Lead Initial: VR
  
- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready).  
Employee Initial: OR Team Lead Initial: VR
  
- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.  
Employee Initial: OR Team Lead Initial: VR
  
- Ensure that active Lot #'s match what's on the Batch Record and Drum.  
Employee Initial: OR Team Lead Initial: VR
  
- "In Process Production" sheet has been posted with correct BPR information.  
Employee Initial: OR Team Lead Initial: VR
  
- Retains have been collected:  
Employee Initial: OR Team Lead Initial: VR
  
  
- QA Approval Initial/Date: ARS 12/06/23

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: OA Team Lead Initial: VR
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: OA Team Lead Initial: VR
- Equipment Cleaning Log completed.  
Employee Initial: OA Team Lead Initial: VR
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: OA Team Lead Initial: VR
- Product is properly sealed, and hoppers covered.  
Employee Initial: OA Team Lead Initial: VR
- Restock all PPE and components needed for next day.  
Employee Initial: OA Team Lead Initial: VR
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: OA Team Lead Initial: VR
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: OA Team Lead Initial: VR
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: OA Team Lead Initial: VR
  
- QA Approval Initial/Date: ARS 12/06/23



STANDARD OPERATING INSTRUCTIONS

Line #12

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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QA In-Process Packaging Checks

In-Process Inspection Check

Filler: 30ct

Target Count: 30

Max Count: 32

Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>Desiccant</i>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
8:25 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
9:05 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
9:40 am	30	30	30	30	30	30	Yes	Yes	Yes	O/A	Yes	Yes	HE	PP 12/06/23
10:15 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
10:50 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
11:25 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
12:00 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
12:30 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
Lunch														
1:05 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
1:37 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
2:10 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
2:42 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
3:15 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23
3:48 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/06/23

Note : Any failure should be immediately reported to the QA Manager & Production Manager

S( **DARD OPERATING INSTRUCTIONS** )

Line #12

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 2312T013
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

Filler: 30ct

Target Count: 30  
Max Count: 32

Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>Desiccant</i>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
11:52 am	30	30	30	30	30	30	Yes	Yes	Yes	NA	Yes	Yes	HE	ARS 12/05/23
12:25 pm	30	30	30	30	30	30	Yes	Yes	Yes	NA	Yes	Yes	HE	ARS 12/05/23
Lunch														
1:05 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/05/23
1:32 pm	30	30	30	30	30	30	yes	yes	yes	HE	yes	yes	HE	ARS 12/05/23
2:05 pm	30	30	30	30	30	30	yes	yes	yes		yes	yes	HE	ARS 12/05/23
2:36 pm	30	30	30	30	30	30	yes	Yes	Yes		Yes	Yes	HE	ARS 12/05/23
3:10 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	ARS 12/05/23
3:47 pm	30	30	30	30	30	30	Yes	Yes	Yes	12/05/23	Yes	Yes	HE	PP 12/05/23
Stop Production														
6:15 am	30	30	30	30	30	30	Yes	Yes	Yes	12/06/23	Yes	Yes	HE	PP 12/06/23
6:46 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	HE	PP 12/06/23
7:10 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	HE	YK 12/06/23
7:35 am	30	30	30	30	30	30	yes	yes	yes		yes	yes	HE	YK 12/06/23
8:03 am	30	30	30	50	30	30	yes	yes	yes		yes	yes	HE	YK 12/06/23

Note : Any failure should be immediately reported to the QA Manager & Production Manager





# Quality Start-Up Checklist

Line # 11

Date: 12/05/23 Team Lead: MV Room #: 11 EL#: STB0635 Lot#: 2312T013

- Cleaning Logs have been completed.  
Employee Initial: SP Team Lead Initial: MV
- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.  
Employee Initial: DP Team Lead Initial: MV
- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.  
Employee Initial: SP Team Lead Initial: MV
- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready).  
Employee Initial: DP Team Lead Initial: MV
- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.  
Employee Initial: DP Team Lead Initial: MV
- Ensure that active Lot #'s match what's on the Batch Record and Drum.  
Employee Initial: DP Team Lead Initial: MV
- "In Process Production" sheet has been posted with correct BPR information.  
Employee Initial: N/A Team Lead Initial: N/A
- Retains have been collected:  
Employee Initial: N/A Team Lead Initial: N/A
- QA Approval Initial/Date: VB 12/05/23



## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: DP Team Lead Initial: MU
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: DP Team Lead Initial: MU
- Equipment Cleaning Log completed.  
Employee Initial: DP Team Lead Initial: MU
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: DP Team Lead Initial: MU
- Product is properly sealed, and hoppers covered.  
Employee Initial: DP Team Lead Initial: MU
- Restock all PPE and components needed for next day.  
Employee Initial: DP Team Lead Initial: MU
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: DP Team Lead Initial: MU
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: N/A Team Lead Initial: N/A
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: DP Team Lead Initial: MU
  
- QA Approval Initial/Date: YB 12/05/23



## Quality Start-Up Checklist

Line #2

Date: 12/05/23 Team Lead: VR Room #: 12 EL#: 035 Lot#: 2312 T013

- Cleaning Logs have been completed.

Employee Initial: MV Team Lead Initial: VR

- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.

Employee Initial: MV Team Lead Initial: VR

- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.

Employee Initial: MV Team Lead Initial: VR

- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.

Employee Initial: MV Team Lead Initial: VR

- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.

Employee Initial: MV Team Lead Initial: VR

- Ensure that active Lot #'s match what's on the Batch Record and Drum.

Employee Initial: MV Team Lead Initial: VR

- "In Process Production" sheet has been posted with correct BPR information.

Employee Initial: MV Team Lead Initial: VR

- Retains have been collected:

Employee Initial: MV Team Lead Initial: VR

- QA Approval Initial/Date: ARS 12/05/23

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: MV Team Lead Initial: VR
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: MV Team Lead Initial: VR
- Equipment Cleaning Log completed.  
Employee Initial: MV Team Lead Initial: VR
- Filling machine has been tagged with a status identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: MV Team Lead Initial: VR
- Product is properly sealed, and hoppers covered.  
Employee Initial: MV Team Lead Initial: VR
- Restock all PPE and components needed for next day.  
Employee Initial: MV Team Lead Initial: VR
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: MV Team Lead Initial: VR
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: MV Team Lead Initial: VR
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: MV Team Lead Initial: VR
  
- QA Approval Initial/Date: ARS 12/05/23



## Quality Start-Up Checklist

Date: 12/04/23 Team Lead: VR Room #: 12 EL#: 635 Lot#: 2312T013

- Cleaning Logs have been completed.

Employee Initial: OR Team Lead Initial: VR

- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.

Employee Initial: OR Team Lead Initial: VR

- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.

Employee Initial: OR Team Lead Initial: VR

- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.

Employee Initial: OR Team Lead Initial: VR

- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.

Employee Initial: OR Team Lead Initial: VR

- Ensure that active Lot #'s match what's on the Batch Record and Drum.

Employee Initial: OR Team Lead Initial: VR

- "In Process Production" sheet has been posted with correct BPR information.

Employee Initial: OR Team Lead Initial: VR

- Retains have been collected:

Employee Initial: OR Team Lead Initial: VR

- QA Approval Initial/Date: ARS 12/04/23

### Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: OA Team Lead Initial: VR
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: OA Team Lead Initial: VR
- Equipment Cleaning Log completed.  
Employee Initial: OA Team Lead Initial: VR
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: OA Team Lead Initial: VR
- Product is properly sealed, and hoppers covered.  
Employee Initial: OA Team Lead Initial: VR
- Restock all PPE and components needed for next day.  
Employee Initial: OA Team Lead Initial: VR
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: OA Team Lead Initial: VR
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: OA Team Lead Initial: VR
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: OA Team Lead Initial: VR
- QA Approval Initial/Date: ARS 12/04/23



### Quality Start-Up Checklist

Line #11

Date: 12/04/23 Team Lead: MV Room #: 11 EL#: 635 Lot#: 2312T073

- Cleaning Logs have been completed.

Employee Initial: DP Team Lead Initial: MV

- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.

Employee Initial: DP Team Lead Initial: MV

- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.

Employee Initial: DP Team Lead Initial: MV

- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.

Employee Initial: DP Team Lead Initial: MV

- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.

Employee Initial: DP Team Lead Initial: MV

- Ensure that active Lot #'s match what's on the Batch Record and Drum.

Employee Initial: DP Team Lead Initial: MV

- "In Process Production" sheet has been posted with correct BPR information.

Employee Initial: N/A Team Lead Initial: N/A

- Retains have been collected:

Employee Initial: N/A Team Lead Initial: N/A

- QA Approval Initial/Date: YB 12/04/23



## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.  
Employee Initial: DP Team Lead Initial: MV
- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.  
Employee Initial: DP Team Lead Initial: MV
- Equipment Cleaning Log completed.  
Employee Initial: DP Team Lead Initial: MV
- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.  
Employee Initial: DP Team Lead Initial: MV
- Product is properly sealed, and hoppers covered.  
Employee Initial: DP Team Lead Initial: MV
- Restock all PPE and components needed for next day.  
Employee Initial: DP Team Lead Initial: MV
- In-Process partial box to be identified as "partial" with quantity (initial and dated)  
Employee Initial: MA Team Lead Initial: N/A
- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:  
Employee Initial: MA Team Lead Initial: MA
- All "Reworks" completed. Damaged components documented and signed off by QA unit.  
Employee Initial: DP Team Lead Initial: MV
  
- QA Approval Initial/Date: YR 12/04/23



## Quality Start-Up Checklist

Line # 11

Date: 11/30/23 Team Lead: MV Room #: 11 EL#: 0635 Lot#: 2312T013

- Cleaning Logs have been completed.  
Employee Initial: DP Team Lead Initial: MV
  
- Room is cleared of all materials, packaging, and product from the previous batch, if not a continuation.  
Employee Initial: DP Team Lead Initial: MV
  
- Verify that packaging and Labels are correct/Box Labels have been verified with 2 initials as well.  
Employee Initial: DP Team Lead Initial: MV
  
- Filling machine has been tagged with a status (Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready).  
Employee Initial: DP Team Lead Initial: MV
  
- Check the cleanliness and proper set-up of all required equipment, room, and ancillaries, including online sieves on tank valve mesh and Torer filler pump mesh.  
Employee Initial: DP Team Lead Initial: MV
  
- Ensure that active Lot #'s match what's on the Batch Record and Drum.  
Employee Initial: DP Team Lead Initial: MV
  
- "In Process Production" sheet has been posted with correct BPR information.  
Employee Initial: N/A Team Lead Initial: N/A
  
- Retains have been collected:  
Employee Initial: DP Team Lead Initial: MV
  
- QA Approval Initial/Date: YR 11/30/23

## Post-Line Clearance Checklist

- Empty all garbage cans/breakdown cardboard. Sweep and Mop clean room.

Employee Initial: DP Team Lead Initial: MV

- All tabletops have been cleaned and properly sanitized with multi-Quat sanitizer.

Employee Initial: DP Team Lead Initial: MV

- Equipment Cleaning Log completed.

Employee Initial: DP Team Lead Initial: MV

- Filling machine has been tagged with a status Identifying previous/present product tagged as Partial Clean/In-Process, needs to be cleaned or Major Clean Ready.

Employee Initial: DP Team Lead Initial: MV

- Product is properly sealed, and hoppers covered.

Employee Initial: DP Team Lead Initial: MV

- Restock all PPE and components needed for next day.

Employee Initial: DP Team Lead Initial: MV

- In-Process partial box to be identified as "partial" with quantity (initial and dated)

Employee Initial: DP Team Lead Initial: MV

- Labels to be returned to Label Room by the Supervisor/Lead or QA Unit:

Employee Initial: N/A Team Lead Initial: N/A

- All "Reworks" completed. Damaged components documented and signed off by QA unit.

Employee Initial: DP Team Lead Initial: MV

- QA Approval Initial/Date: DP 11/30/23

**STANDARD OPERATING INSTRUCTIONS**

Room 11

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

**Filler:** 30ct

**Target Count:** 30  
**Max Count:** 32

**Fill bottles** - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>Desigan</i>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
10:20 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	YR 11/30/23
11:00 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	YR 11/30/23
11:32 AM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
12:00 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
12:30 PM	30	30	30	30	30	30	yes	yes	yes	YR	yes	yes	MV	YR 11/30/23
1:00 PM	30	30	30	30	30	30	yes	yes	yes	YR	yes	yes	MV	YR 11/30/23
Lunch										N/A				
1:35 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
2:03 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
2:27 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
3:00 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
3:30 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
4:01 PM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/30/23
Stop the production														
11:40 AM	30	30	30	30	30	30	yes	yes	yes	N/A	yes	yes	MV	YR 11/04/23

Note : Any failure should be immediately reported to the QA Manager & Production Manager



**STANDARD OPERATING INSTRUCTIONS**

Line #2

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

**Target Count:** 30  
**Max Count:** 32

**Filler:** 30ct

**Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.**

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other <i>Desiccant</i>	Completed By	QA Signature & Date
	1	2	3	4	5	6								
2:12 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
2:45 pm	30	30	30	30	30	30	Yes	Yes	Yes	N/A	Yes	Yes	ME	ARS 12/04/23
3:20 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
3:55 pm	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
Stop Production														
6:15 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	PP 12/05/23
6:47 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	PP 12/05/23
7:20 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	PP 12/05/23
7:53 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
8:25 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
9:10 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
9:42 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
10:15 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
10:46 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23
11:20 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/05/23

**Note : Any failure should be immediately reported to the QA Manager & Production Manager**

**STANDARD OPERATING INSTRUCTIONS**

Form 11

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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### QA In-Process Packaging Checks

**In-Process Inspection Check**

**Target Count:** 30

**Filler:** 30 ct

**Max Count:** 32

**Fill bottles** - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other	Completed By	QA Signature & Date
	1	2	3	4	5	6								
9:00 AM	30	30	30	31	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
9:31 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
10:05 AM	30	30	30	31	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
10:37 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
11:03 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
11:27 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
12:03 PM	30	31	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
12:31 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
1:00 PM	30	30	31	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
— stop the production —														
1:40 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
2:11 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
2:41 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
3:10 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23
3:41 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	MV	YR 12/05/23

**Note :** Any failure should be immediately reported to the QA Manager & Production Manager



**STANDARD OPERATING INSTRUCTIONS**

*Room # 11*

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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**QA In-Process Packaging Checks**

**In-Process Inspection Check**

**Filler:** *30 ct*

**Target Count:** *30*  
**Max Count:** *32*

**Fill bottles** - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other	Completed By	QA Signature & Date
	1	2	3	4	5	6								
12:12 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
12:40 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
<i>stop the production</i>														
1:35 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
2:02 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
2:29 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
2:58 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
3:28 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
4:00 PM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/04/23
<i>Stop Production</i>														
6:30 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/05/23
7:00 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/05/23
7:28 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/05/23
8:00 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	YK	<i>YK</i> 12/05/23
8:30 AM	30	30	30	30	30	30	yes	yes	yes		yes	yes	MV	<i>YK</i> 12/05/23

Note : Any failure should be immediately reported to the QA Manager & Production Manager

STANDARD OPERATING INSTRUCTIONS

Line #2

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 23121013
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QA In-Process Packaging Checks

In-Process Inspection Check

Filler: 30ct

Target Count: 30  
Max Count: 32

Fill bottles - 6 containers from the filler are checked approximately every 30 minutes and after each stoppage.

Time	Bottle Count*						Cap Seal Intact (Yes/No)	Neckband/Full Body Sleeve (Yes/No)	Batch # / Exp Date legible and Correct (Yes/No)	Bottle Label present and correctly orientated (Yes/No)	Shipping label applied (Yes/No)	Other Desiccant	Completed By	QA Signature & Date
	1	2	3	4	5	6								
6:20 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	YK 12/04/23
7:01 AM	30	30	30	30	30	30	Yes	Yes	Yes	N/A	Yes	Yes	ME	YK 12/04/23
7:35 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	YK 12/04/23
8:03 AM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	YK 12/04/23
8:35 AM	30	30	30	30	30	30	Yes	Yes	Yes	N/A	Yes	Yes	ME	YK 12/04/23
9:07 AM	30	30	30	30	30	30	Yes	Yes	Yes	N/A	Yes	Yes	ME	YK 12/04/23
9:40 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	PP 12/04/23
10:12 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
10:43 am	30	30	30	30	30	30	Yes	Yes	Yes	12/04/23	Yes	Yes	ME	ARS 12/04/23
11:15 am	30	30	30	30	30	30	Yes	Yes	Yes	12/04/23	Yes	Yes	ME	ARS 12/04/23
11:47 am	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
12:20 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
Lunch														
1:05 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23
1:38 PM	30	30	30	30	30	30	Yes	Yes	Yes		Yes	Yes	ME	ARS 12/04/23

Note : Any failure should be immediately reported to the QA Manager & Production Manager



## Case Pack(s) & Case Pack Label

<b>PRODUCT #:</b>  EL635	<b>EL635 Blood Sugar Support Chewable Tablets</b>	<b>EFFECTIVE DATE:</b>  12/04/2023
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<b>Product Code</b>
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STB0635-01-30
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Bottle Size	Box Dimensions		
	L (in)	W(in)	H(in)
100cc	16	12	12

<b>Packout</b>
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Bottle Size	Qty/Master	TI	HI	Master Case Per Pallet	Bottles Per Pallet
100cc	180	8	3	24	4320

Blood Sugar Support Chewable Tablets

Item Code: STB0635- 01- 30

LOT#:YYMMTXXX (Unlabeled)

EXP Date:MM/YYYY

Qty/case: 180

Packed By: \_\_\_\_\_

Checked By: \_\_\_\_\_





**Blood Sugar Support Chewable Tablets**

**Item Code: STB0635 – 01 – 30**

**LOT#: 2312T013 (Unlabeled)**

**EXP Date: 11/2025**

**Q'ty/case: 180**

Packed By:

Checked By:

*N/A*

*VB 11/30/23*

## STANDARD OPERATING INSTRUCTIONS

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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Average Empty Bottle Weight:

The average of ten measurements of empty Bottles:

$$\begin{array}{r}
 12.3 + 12.4 + 12.4 + 12.3 + 12.8 + 12.3 + 12.2 + 12.3 + 12.2 + 12.2 = 123.4 \\
 \hline
 \div \qquad \qquad \qquad 10 \qquad \qquad \qquad = \qquad 12.3
 \end{array}$$

Product Size: 30 g

Target Weight: 16.2 g

Max Weight: 17.0 g

**Set the first 6 units to ensure per weight are maintained, before weighing tare the bottle weight and leave it on the scale for all in-process weight checks for this product.**

From the first filling of each size of Bottles calculate the average of the first 6 filled bottles, without a cap or a seal

$$\begin{array}{r}
 16.7 + 16.5 + 15.9 + 16.2 + 16.3 + 15.9 = 97.5 \\
 \hline
 \div \qquad \qquad \qquad 6 \qquad \qquad \qquad = \qquad 16.2 \qquad \qquad \qquad (F)
 \end{array}$$

**6 bottles will be checked initially and every 30 minutes**





**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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<b>TABLETING</b>		<b>Performed By/ Date (MM/DD/YY)</b>	<b>QA Checked By/ Date (MM/DD/YY)</b>
Check the deduster and tablet compression equipment for cleanliness, mechanical set-up and correct tooling. Check the room for cleanliness.		MS 11/28/23	IR 11/28/23
Assure that equipment log for previous batch shows that room/equipment has been cleaned.		MS 11/28/23	IR 11/28/23
Punch Size and Shape:      Asset#0827		MS 11/28/23	IR 11/28/23
Check and record the temperature of room # <u>6</u>  Temperature: 68° - 86°F      Actual: <u>68.8</u> °F		MS 11/28/23	IR 11/28/23
Transfer the container(s) from to the "Compression Area" and check labeling for product name, batch #, total number of containers, total net weight and physical appearance of containers. Tablet Press #: <u>0339</u> Scale: <u>0562</u> # of Containers: <u>31</u> Total net weight: <u>1499.82</u> kg		MS 11/28/23	IR 11/28/23
<p>After set-up of the tablet press is complete, the In-Process Testing parameters should be accomplished as follows: Compact the blend into tablets employing a rotary tablet press.</p> <p>Press Speed (Range 15 - 30RPM)      Actual: <u>22</u> RPM</p> <p>At the beginning of the run, the average of 10 tablets</p> <p><u>528</u> + <u>531</u> + <u>526</u> + <u>530</u> + <u>536</u> + <u>527</u> + <u>532</u> + <u>535</u> + <u>537</u> + <u>529</u> = <u>5311</u> / 10 = <u>531</u> mg (G)</p> <p>Target Weight – <u>525</u> ①</p> <p><b>For avg tablet weight of 1 tablet, the acceptable range= 500mg</b></p> <p>Hardness Tester ID#: <u>0500</u></p> <p>Hardness: (using 10 tablets) NLT 5KP</p> <p>Actual Hardness: <u>6.5</u> kp</p> <p>Friability Tester ID#: <u>0455</u></p> <p>Friability: (using 20 tablets) Not more than (NMT) 2% in 100 drops Actual: <u>0.2</u> %</p>		MS 11/28/23	IR 11/28/23
		MS 11/28/23	IR 11/28/23

① N/A MS 11/28/23



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
11/28/23	AM 3:00	528	6.3	0.3	MS	11/28/23	AM 3:00	522	7.8	0.5	JK
11/28/23	AM 3:30	533	7.2	0.3	MS	11/28/23	PM 4:08	520	6.5	0.3	JR.
11/28/23	AM 4:00	527	7.2	0.3	MS	11/28/23	PM 5:08	525	6.9	0.3	LO
11/28/23	AM 4:20	528	6.8	0.3	DLF	11/28/23	PM 6:08	527	6.8	0.4	LO
11/28/23	AM 5:00	530	6.6	0.3	DLF	11/28/23	PM 7:08	523	6.8	0.4	LO
11/28/23	AM 5:30	528	6.5	0.3	DLF	11/28/23	PM 8:08	528	7.2	0.3	LO
11/28/23	AM 6:00	530	7.1	0.3	DLF	11/28/23	PM 9:03	530	6.9	0.3	LO
11/28/23	AM 6:30	528	6.9	0.3	DLF	11/28/23	PM 10:08	525	6.9	0.4	LO
11/28/23	AM 7:00	526	7.7	0.3	DLF	11/28/23	PM 11:08	528	7.2	0.4	LO
11/28/23	AM 7:30	526	5.9	0.3	DLF						
11/28/23	AM 8:00	526	7.6	0.3	DLF						
11/28/23	AM 8:30	534	5.1	0.3	DLF						
11/28/23	AM 9:00	529	7.8	0.3	DLF						
11/28/23	AM 9:30	529	7.9	0.3	DLF						
11/28/23	AM 10:00	525	7.5	0.3	DLF						
11/28/23	AM 10:30	525	8.1	0.3	DLF						
11/28/23	AM 11:00	535	6.7	0.3	DLF						
11/28/23	AM 11:30	525	7.4	0.3	DLF						

**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
11/29/23	12:00 AM	521	6.4	0.3	OLF	11/29/23	12:01 AM	534	6.7	0.4	LO
11/29/23	12:30 AM	529	6.4	0.3	OLF	11/29/23	11:00 AM	530	6.5	0.4	LO
11/29/23	1:00 AM	527	8.0	0.3	OLF	<del>STOP MACHINE</del>					
11/29/23	1:30 AM	528	7.5	0.3	OLF	11/29/23	6:35 AM	536	7.4	0.4	IR
<del>STOP MACHINE</del>						11/29/23	7:36 AM	526	7.0	0.3	IR
11/29/23	6:30 AM	533	6.8	0.3	MS	11/29/23	8:30 AM	528	9.1	0.3	IR
11/29/23	7:00 AM	536	6.1	0.3	MS	11/29/23	9:32 AM	521	7.0	0.3	IR
11/29/23	7:30 AM	530	7.6	0.3	MS	11/29/23	10:31 AM	534	8.9	0.3	IR
11/29/23	8:00 AM	530	6.2	0.3	MS	11/29/23	11:33 AM	530	7.6	0.3	IR
11/29/23	8:30 AM	527	7.1	0.3	MS	11/29/23	12:35 PM	531	6.6	0.3	IR
11/29/23	9:00 AM	537	6.9	0.3	MS	<del>IR</del> <del>N/A 11/29/23</del>					
11/29/23	9:30 AM	529	9.1	0.3	MS						
11/29/23	10:00 AM	534	8.0	0.3	MS						
11/29/23	10:30 AM	541	7.6	0.3	MS						
11/29/23	11:00 AM	538	8.6	0.3	MS						
11/29/23	11:30 AM	538	7.1	0.3	MS						
11/29/23	12:00 PM	530	7.2	0.3	MS						
11/29/23	12:30 PM	527	6.6	0.3	MS						



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check						
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials	
11/29/23	1:00 PM	526	6.3	0.3	MS	11/29/23	1:32 PM	530	6.7	0.3	JR	
11/29/23	1:30 PM	533	7.2	0.3	MS	11/29/23	2:30 PM	523	6.0	0.3	JR	
11/29/23	2:00 PM	537	6.9	0.3	MS	11/29/23	3:35 PM	528	7.1	0.3	JR	
11/29/23	2:30 PM	530	6.6	0.3	MS	11/29/23	4:30 PM	532	6.2	0.4	LO	
11/29/23	3:00 PM	537	8.4	0.3	MS	11/29/23	5:33 PM	537	6.8	0.3	LO	
11/29/23	3:30 PM	529	7.1	0.3	MS	11/29/23	6:3 PM	530	6.5	0.3	LO	
11/29/23	4:00 PM	536	6.3	0.3	MS	11/29/23	7:30 PM	534	7.2	0.3	LO	
11/29/23	4:30 PM	532	7.0	0.3	DLF	11/29/23	8:32 PM	526	7.1	0.3	LO	
11/29/23	5:00 PM	528	7.1	0.3	DLF	11/29/23	9:30 PM	525	6.9	0.3	LO	
11/29/23	5:30 PM	531	8.0	0.3	DLF	/						
11/29/23	6:00 PM	520	6.7	0.3	DLF							
11/29/23	6:30 PM	523	5.7	0.3	DLF							
11/29/23	7:00 PM	525	5.7	0.3	DLF							
11/29/23	7:30 PM	530	8.0	0.3	DLF							
11/29/23	8:00 PM	525	7.7	0.3	DLF							
11/29/23	8:30 PM	528	6.9	0.3	DLF							
11/29/23	9:00 PM	531	5.0	0.3	DLF							
11/29/23	9:30 PM	532	5.0	0.3								



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
11/29/23	10:00 <sup>AM</sup>	525	7.2	0.3	OLF	11/29/23	10:30 <sup>PM</sup>	523	5.9	0.3	LO
11/29/23	10:30 <sup>PM</sup>	525	7.5	0.3	OLF	11/29/23	11:30 <sup>PM</sup>	530	6.1	0.3	LO
11/29/23	11:00 <sup>AM</sup>	533	5.6	0.3	OLF	11/30/23	12:32 <sup>AM</sup>	536	6.4	0.3	LO
11/29/23	11:30 <sup>PM</sup>	525	5.2	0.3	OLF	11/30/23	1:30 <sup>AM</sup>	528	6.7	0.3	LO
11/30/23	12:00 <sup>AM</sup>	530	6.0	0.3	OLF	<del>STOP MACHINE</del>					
11/30/23	12:30 <sup>AM</sup>	525	6.5	0.3	OLF	11/30/23	6:37 <sup>AM</sup>	520	10.5	0.3	IR
11/30/23	1:00 <sup>AM</sup>	535	7.2	0.3	OLF	11/30/23	7:34 <sup>AM</sup>	539	8.4	0.3	IR
11/30/23	1:30 <sup>AM</sup>	525	7.0	0.3	OLF	11/30/23	8:33	532	9.0	0.3	IR.
<del>STOP MACHINE</del>						11/30/23	9:30 <sup>AM</sup>	525.	7.6	0.3	IR.
11/30/23	6:30 <sup>AM</sup>	526	6.6	0.3	MS	11/30/23	10:32 <sup>AM</sup>	530	6.0	0.3	IR
11/30/23	7:00 <sup>AM</sup>	537	7.3	0.3	MS	<del>IR N/A 11/30/23</del>					
11/30/23	7:30 <sup>AM</sup>	543	7.9	0.3	MS						
11/30/23	8:00 <sup>AM</sup>	531	6.2	0.3	MS						
11/30/23	8:30 <sup>AM</sup>	523	6.9	0.3	MS						
11/30/23	9:00 <sup>AM</sup>	527	8.0	0.3	MS						
11/30/23	9:30 <sup>AM</sup>	521	6.4	0.3	MS						
11/30/23	10:00 <sup>AM</sup>	525	7.0	0.3	MS						
11/30/23	10:30 <sup>AM</sup>	536	5.6	0.3	MS						

**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
11/30/23	AM 11:00	531	6.7	0.3	MS	11/30/23	Am 11:35	510	6.1	0.3	IR
11/30/23	AM 11:30	520	9.1	0.3	MS	11/30/23	Pm 12:37	525	7.4	0.3	IR
11/30/23	PM 12:00	533	7.9	0.3	MS	11/30/23	Pm 1:35	532	6.8	0.3	IR
11/30/23	PM 12:30	526	7.5	0.3	MS	11/30/23	Pm 2:31	524	9.8	0.3	IR
11/30/23	PM 1:00	527	8.7	0.3	MS	11/30/23	① 5:38	538	8.5	0.3	IR
11/30/23	PM 1:30	520	7.0	0.3	MS	11/30/23	4:30 Pm	525	8.7	0.3	LO
11/30/23	PM 2:00	525	7.4	0.3	MS	11/30/23	5:32 Pm	521	7.9	0.3	LO
11/30/23	PM 2:30	532	6.8	0.3	MS	11/30/23	6:34 Pm	520	6.7	0.3	LO
11/30/23	PM 3:00	526	7.2	0.3	MS	11/30/23	7:30 Pm	534	6.4	0.3	LO
11/30/23	PM 3:30	533	7.7	0.3	MS						
11/30/23	PM 4:00	524	7.0	0.3	MS						
11/30/23	PM 4:30	537	7.4	0.3	OLF						
11/30/23	PM 5:00	529	8.0	0.3	OLF						
11/30/23	PM 5:30	520	6.3	0.3	OLF						
11/30/23	PM 6:00	537	7.2	0.3	OLF						
11/30/23	PM 6:30	537	8.4	0.3	OLF						
11/30/23	PM 7:00	526	5.8	0.3	OLF						
11/30/23	PM 7:30	525	5.9	0.3	OLF						

① W.E: 3:31 Pm IR 11/30/23



## STANDARD OPERATING INSTRUCTIONS

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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### Tablet Batch Data Record

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
11/30/23	8:00 PM	525	7.4	0.3	DLF	11/30/23	8:30 PM	526	7.4	0.3	LO
11/30/23	8:30 PM	525	5.1	0.3	DLF	11/30/23	9:30 PM	529	6.9	0.3	LO
11/30/23	9:00 PM	530	5.8	0.3	DLF	11/30/23	10:30 PM	525	7.0	0.3	LO
11/30/23	9:30 PM	521	7.4	0.3	DLF	11/30/23	11:30 PM	528	7.2	0.3	LO
11/30/23	10:00 PM	525	5.2	0.3	DLF	12/01/23	12:34 AM	530	6.7	0.3	LO
11/30/23	10:30 PM	525	5.4	0.3	DLF	— STOP Machine —					
11/30/23	11:00 PM	536	6.3	0.3	DLF	12/04/23	6:32 AM	539	7.4	0.3	IR
11/30/23	11:30 PM	529	7.5	0.3	DLF	— Stop Machine —					
12/01/23	12:00 AM	537	7.6	0.3	DLF	12/04/23	9:37 AM	540	6.8	0.3	IR
12/01/23	12:30 AM	529	6.5	0.3	DLF	12/04/23	10:02 AM	529	6.5	0.4	IR
12/01/23	1:00 AM	530	6.0	0.3	DLF	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;"> <p>— STOP MACHINE —</p> <p>12/04/23 6:30 AM 536 7.1 0.3 MS</p> <p>12/04/23 7:00 AM 523 8.3 0.3 MS</p> <p>— STOP MACHINE —</p> <p>12/04/23 9:30 AM 538 8.4 0.3 MS</p> <p>12/04/23 10:00 AM 523 8.0 0.3 MS</p> <p>12/04/23 10:30 AM 527 6.7 0.3 MS</p> </div> <div style="text-align: center;"> <p>IR</p> <p>N/A</p> <p>12/04/23</p> </div> </div>					
— STOP MACHINE —											
12/04/23	6:30 AM	536	7.1	0.3	MS						
12/04/23	7:00 AM	523	8.3	0.3	MS						
— STOP MACHINE —											
12/04/23	9:30 AM	538	8.4	0.3	MS						
12/04/23	10:00 AM	523	8.0	0.3	MS						
12/04/23	10:30 AM	527	6.7	0.3	MS						



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 2312T013
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
12/04/23	AM 11:00	526	7.7	0.3	MS	12/04/23	AM 11:07	519	5.3	0.3	IR
12/04/23	AM 11:30	510	8.8	0.3	MS	12/04/23	PM 12:08	510	8.8	0.4	IR
12/04/23	PM 12:00	526	6.3	0.3	MS	12/04/23	PM 1:00	527	7.2	0.3	IR
12/04/23	PM 12:30	515	7.6	0.3	MS	12/04/23	PM 2:09	518	7.9	0.4	IR
12/04/23	PM 1:00	531	6.8	0.4	MS	12/04/23	PM 3:00	521	6.3	0.3	IR
12/04/23	PM 1:30	525	6.4	0.4	MS	12/04/23	PM 4:01	542	6.9	0.3	IR
12/04/23	PM 2:00	529	8.3	0.3	MS	12/04/23	PM 5:00	519	8.3	0.3	MR
12/04/23	PM 2:30	523	10.1	0.3	MS	12/04/23	PM 6:00	524	5.5	0.3	JM
12/04/23	PM 3:00	528	7.2	0.3	MS	12/04/23	PM 7:00	520	9.7	0.3	NRM
12/04/23	PM 3:30	526	7.4	0.3	MS						
12/04/23	PM 4:00	535	7.9	0.3	MS						
12/04/23	PM 4:30	526	7.7	0.3	OLF						
12/04/23	PM 5:00	520	7.5	0.3	OLF						
12/04/23	PM 5:30	520	8.1	0.3	OLF						
12/04/23	PM 6:00	530	6.8	0.3	OLF						
12/04/23	PM 6:30	525	6.5	0.3	OLF						
12/04/23	PM 7:00	532	6.0	0.3	OLF						
12/04/23	PM 7:30	522	7.9	0.3	OLF						

NRM 12/04/23  
N/A

**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> 2312T013
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
12/04/23	8:00 <sup>PM</sup>	525	8.0	0.3	OLF	12/04/23	8:00 <sup>PM</sup>	519	8.1	0.3	NRM
12/04/23	8:30 <sup>PM</sup>	523	7.5	0.3	OLF	12/04/23	9:00 <sup>PM</sup>	523	6.6	0.4	NRM
12/04/23	9:00 <sup>PM</sup>	520	7.5	0.3	OLF	12/04/23	10:00 <sup>PM</sup>	519	7.8	0.4	NRM
12/04/23	9:30 <sup>PM</sup>	535	7.0	0.3	OLF	12/04/23	11:00 <sup>PM</sup>	528	7.6	0.4	NRM
12/04/23	10:00 <sup>PM</sup>	520	8.1	0.3	OLF	12/05/23	12:00 <sup>AM</sup>	523	8.5	0.3	NRM
12/04/23	10:30 <sup>PM</sup>	520	8.2	0.3	OLF	12/05/23	1:00 <sup>AM</sup>	526	7.6	0.3	NRM
12/04/23	11:00 <sup>PM</sup>	525	6.2	0.3	OLF	<del>STOP MACHINE</del>					
12/04/23	11:30 <sup>PM</sup>	540	7.2	0.3	OLF	12/05/23	6:35 <sup>AM</sup>	527	7.4	0.5	IR
12/05/23	12:00 <sup>AM</sup>	570	6.8	0.3	OLF	12/05/23	7:38 <sup>AM</sup>	542	10.0	0.4	IR
12/05/23	12:30 <sup>AM</sup>	535	7.0	0.3	OLF	12/05/23	8:30 <sup>AM</sup>	515	5.6	0.4	IR
12/05/23	1:00 <sup>AM</sup>	523	8.5	0.3	OLF	<del>IR N/A 12/5/23</del>					
12/05/23	1:30 <sup>AM</sup>	530	9.6	0.3	OLF						
<del>STOP MACHINE</del>											
12/05/23	6:30 <sup>AM</sup>	525	7.2	0.3	MS						
12/05/23	7:00 <sup>AM</sup>	537	8.5	0.3	MS						
12/05/23	7:30 <sup>AM</sup>	533	9.1	0.4	MS						
12/05/23	8:00 <sup>AM</sup>	526	8.8	0.4	MS						
12/05/23	8:30 <sup>AM</sup>	519	6.1	0.3	MS						



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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**Tablet Batch Data Record**

Tablet Operator Check						QA Check					
Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 abs) NLT 5KP	Friability NMT 2%	Initials	Date (MM/DD/YY)	Time (AM/PM)	Avg Wt (10 tabs) 500 to 550 mg	Hardness (10 tabs) NLT 5KP	Friability NMT 2%	Initials
12/05/23	9:00 AM	523	7.7	0.4	MS	12/05/23	9:31 AM	536	7.4	0.5	IR
12/05/23	9:30 AM	531	9.6	0.5	MS	12/05/23	10:37 AM	524	5.9	0.5	IR
12/05/23	10:00 AM	528	9.3	0.5	MS	12/05/23	11:35 AM	532	6.5	0.5	IR
12/05/23	10:30 AM	524	8.2	0.3	MS	12/05/23	12:30 PM	523	8.0	0.5	IR
12/05/23	11:00 AM	529	9.4	0.3	MS	12/05/23	1:30 PM	528	6.7	0.4	IR
12/05/23	11:30 AM	522	7.4	0.5	MS	12/05/23	2:38 PM	527	10.6	0.4	IR
12/05/23	12:00 PM	520	8.1	0.3	MS	12/05/23	3:31 PM	535	7.4	0.4	IR
12/05/23	12:30 PM	524	6.5	0.3	MS	— Stop Machine —					
12/05/23	1:00 PM	533	7.1	0.3	MS	12/05/23	4:30 PM	532	7.5	0.4	NRM
12/05/23	1:30 PM	529	6.7	0.3	MS	12/05/23	5:30 PM	523	8.4	0.4	NRM
12/05/23	2:00 PM	523	7.2	0.4	MS	<del>                     N/A                      12/05/23                      N/A                 </del>					
12/05/23	2:30 PM	529	7.0	0.3	MS						
12/05/23	3:00 PM	532	7.7	0.5	MS						
12/05/23	3:30 PM	530	7.4	0.4	MS						
12/05/23	4:00 PM	526	6.7	0.3	MS						
12/05/23	4:30 PM	522	5.5	0.3	DLF						
12/05/23	5:00 PM	528	7.9	0.3	DLF						
12/05/23	5:30 PM	525	5.1	0.4	DLF						





**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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<b>COMPRESSION</b>	<b>Performed By/ Date (MM/DD/YY)</b>	<b>QA Checked By/ Date (MM/DD/YY)</b>
Collect acceptable core tablets in clean, tared, properly identified, polyethylene bag lined containers. Record the individual container weights below.		
Actual weight <u>1499.82</u> Kg.	<u>MS</u> <u>11/28/23</u>	<u>IR</u> <u>11/28/23</u>
Average Tablet Weight <u>531</u> mg	<u>MS</u> <u>11/28/23</u>	<u>IR</u> <u>11/28/23</u>
Scale #: <u>0418</u> Location: <u>ROOM 6</u>	<u>MS</u> <u>11/28/23</u>	<u>IR</u> <u>11/28/23</u>
<b>Acceptable Capsules:</b>		
<b>Container #    Gross Weight (Kg)    Tare Weight (Kg)    Net Weight (Kg)</b>		
1                    17.0                    1.0                    16.0		
2                    17.0                    1.0                    16.0		
3                    17.0                    1.0                    16.0		
4                    17.0                    1.0                    16.0		
5                    17.0                    1.0                    16.0		
6                    17.0                    1.0                    16.0		
7                    17.0                    1.0                    16.0		
8                    17.0                    1.0                    16.0		
9                    17.0                    1.0                    16.0		
10                   17.0                   1.0                   16.0		
11                   17.0                   1.0                   16.0		
12                   17.0                   1.0                   16.0		
13                   17.0                   1.0                   16.0		
14                   17.0                   1.0                   16.0		
15                   17.0                   1.0                   16.0		
16                   17.0                   1.0                   16.0		
17                   17.0                   1.0                   16.0		
18                   17.0                   1.0                   16.0		
	<u>MS</u> <u>11/29/23</u>	<u>IR</u> <u>11/28/23</u>

**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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COMPRESSION				Performed By/ Date (MM/DD/YY)	QA Checked By/ Date (MM/DD/YY)
Container #	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)		
19	17.0	1.0	16.0		
20	17.0	1.0	16.0		
21	17.0	1.0	16.0		
22	17.0	1.0	16.0		
23	17.0	1.0	16.0		
24	17.0	1.0	16.0		
25	17.0	1.0	16.0		
26	17.0	1.0	16.0		
27	17.0	1.0	16.0		
28	17.0	1.0	16.0		
29	17.0	1.0	16.0		
30	17.0	1.0	16.0		
31	17.0	1.0	16.0		
32	17.0	1.0	16.0		
33	17.0	1.0	16.0		
34	17.0	1.0	16.0		
35	17.0	1.0	16.0		
36	17.0	1.0	16.0		
37	17.0	1.0	16.0		
38	17.0	1.0	16.0		
39	17.0	1.0	16.0		
40	17.0	1.0	16.0		
41	17.0	1.0	16.0		
42	17.0	1.0	16.0		
43	17.0	1.0	16.0		
Total Net Weight <u>N/A</u> kg				MS <u>11/30/23</u>	IR <u>11/30/23</u>



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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<b>COMPRESSION</b>				<b>Performed By/ Date (MM/DD/YY)</b>	<b>QA Checked By/ Date (MM/DD/YY)</b>
<b>Container #</b>	<b>Gross Weight (Kg)</b>	<b>Tare Weight (Kg)</b>	<b>Net Weight (Kg)</b>		
41	17.0	1.0	16.0		
45	17.0	1.0	16.0		
46	17.0	1.0	16.0		
47	17.0	1.0	16.0		
48	17.0	1.0	16.0		
49	17.0	1.0	16.0		
50	17.0	1.0	16.0		
51	17.0	1.0	16.0		
52	17.0	1.0	16.0		
53	17.0	1.0	16.0		
54	17.0	1.0	16.0		
55	17.0	1.0	16.0		
56	17.0	1.0	16.0		
57	17.0	1.0	16.0		
58	17.0	1.0	16.0		
59	17.0	1.0	16.0		
60	17.0	1.0	16.0		
61	17.0	1.0	16.0		
62	17.0	1.0	16.0		
63	17.0	1.0	16.0		
64	17.0	1.0	16.0		
65	17.0	1.0	16.0		
66	17.0	1.0	16.0		
67	17.0	1.0	16.0		
68	17.0	1.0	16.0		
<b>Total Net Weight</b>			<u>N/A</u>	<b>kg</b>	

MS  
12/05/23

IR  
12/05/23

**S IDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>2312T013</u>
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COMPRESSION				Performed By/ Date (MM/DD/YY)	QA Checked By/ Date (MM/DD/YY)
Container #	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)		
69	17.0	1.0	16.0		
70	17.0	1.0	16.0		
71	17.0	1.0	16.0		
72	17.0	1.0	16.0		
73	17.0	1.0	16.0		
74	17.0	1.0	16.0		
75	17.0	1.0	16.0		
76	17.0	1.0	16.0		
77	17.0	1.0	16.0		
78	17.0	1.0	16.0		
79	17.0	1.0	16.0		
80	17.0	1.0	16.0		
81	17.0	1.0	16.0		
82	17.0	1.0	16.0		
83	17.0	1.0	16.0		
84	17.0	1.0	16.0		
85	17.0	1.0	16.0		
86	17.0	1.0	16.0		
87	17.0	1.0	16.0		
88	17.0	1.0	16.0		
89	17.0	1.0	16.0		
90	17.0	1.0	16.0		
91	17.0	1.0	16.0		
92	17.0	1.0	16.0		
93	12.42	1.0	11.42		
<b>Total Net Weight</b> <u>1,483.42</u> kg				MS <u>12/05/23</u>	JR <u>12/05/23</u>

STANDARD OPERATING INSTRUCTIONS

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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**COMPRESSION YIELD**

Net Weight Received from Blending	(B) <u>1,499.82</u> Kg
Blending Net Weight (B)/ Target material Weight x 1,000,000	(C) <u>2,999,640</u> tablets
# tablets (C) x Average tablets Weight/1,000,000	(D) <u>1,592.80</u> Kg
Waste	(E) <u>3.0</u> Kg
Returned to Stock ( <u>0</u> # of Drums)	(F) <u>0.0</u> Kg
Total tablets Net Weight	(L) <u>1,483.42</u> Kg
Gross Weight (E+F+L)	(G) <u>1,486.42</u> Kg
% Yield [(G/D) x 100]	(H) <u>93</u> %
% Yield Target	<u>95% - 105%</u>
If % Yield is outside of Target, what is/are the possible reason(s):	
Performed By/Date: <u>MS 12/06/23</u>	
Quality Checked By/Date: <u>IR 12/06/23</u>	



**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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**Eagle Labs, Inc. Batch Review**

Area Reviewed	Completed ✓ (please check each item)
<b>Weighing</b>	
RM Receiving # listed for each raw material used	✓
Documentation Complete	✓
Theoretical Batch Size: <u>3000 00</u> Capsules/Tablets/Gummies	
<b>Bottling</b>	
Correct packaging used	✓
Lot Number/ Exp./Best by/Mfg. Date correct	✓
Documentation Complete	✓
Product accounted for Bottling: <u>2750,190</u> Capsules/Tablets/Gummies	
<b>Printed Packaging Component</b>	
Correct printed packaging component used	✓
Approved and Used label/carton affixed in the BPR	✓
Shipping label affixed in the BPR	✓
Documentation Complete	✓
Final Batch Yield = (g) product accounted for / theoretical batch size x 100%	
Final Batch Yield = <u>92</u> %	
% Yield Target <u>90 – 110 %</u>	
If Yield is outside of target, what is/are the possible reason(s):	

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**STANDARD OPERATING INSTRUCTIONS**

<b>PRODUCT CODE #:</b> STB0635	<b>PRODUCT NAME:</b> EL635 Blood Sugar Support Chewable Tablets	<b>Batch #</b> <u>23121013</u>
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<b>Eagle Labs, Inc. Batch Review</b>	
Area Reviewed	Completed ✓ (please check each item)
<b>Quality</b>	
Product Tested and Released	✓
Certificate of Analysis Completed and in BPR	✓
Finished Product Reserve Samples Collected	✓
The total number of units filled, labeled, and packaged has been backflushed.	✓
If an investigation was conducted on this batch at any time, is investigation closed and a copy of the completed form included: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, document the SIR Number: <u>None</u>	
<input checked="" type="checkbox"/> The batch is Released    QA Manager: <u>RG</u> Date: <u>12/14/2023</u>	
<input type="checkbox"/> The batch is REJECTED    QA Manager: <u>NONE</u> Date: <u>NONE</u>	