MBR for MO version

5957004 - Obesity SDD 0.25mg/0.5 ml D

Regular production



BRR status Released

MO status Finished
Valid pious ---

MBR ID/Version/Description 5957004/00000032/Obesity SDD 0.25mg/0.5mlD

 Finished
 Order size
 30000 ea

 -- Batch no.
 NHJM068881

 00000001
 MO no.
 NHJM00013246

BRR Approval						
Status	Text	MBR fulfilled				
Batch Record Report NHJM00013246						
Released	Automatically released by system					
		Date - User: 2023-09-14 10:35:22 +0100 - 111111111 /				
MBR fulfilled: yes						

Reviews	Review status							
Review step		Status	Number of elements					
Exception review		Executed	0					
	Batch record report review (Exception)							
			Date - User: 2023-09-14 10:22:47 +0100 - 270 / Nishranth Mahesh (nhjm)					
CPP review		Not needed	0					
CQA rev	iew	Not needed	0					

Basic operations					
Basic operation	SFO ID	Actual start	Current end		
0100 - SDD assembly	806363	2023-09-14 08:18:28 +01	2023-09-14 08:18:28 +0100 2023-09-14 10:20:34 +0100		

Summing bill of input material				
Material no.	Material name	Target quantity	Actual quantity	No. of positions
2700145	FRONT ASSEMBLY_MK2, NN WHITE	20000 ea	20000 ea	1
2701018	REAR ASSEMBLY, NN WHITE, 0.5 20	000 ea	20000 ea	1
5185500	SEMAGLUTIDE D 0.5MG/ML,PFS 0.5	20000 ea	20000 ea	1

Produced batches	3					
Material no. Material name		Batch no.	Expiration date	Actual start	Current end	Actual
						quantity
5957004	Obesity SDD 0.25 mg/	NHJM068881 202	29-09-14 23:59 +0100 20	023-09-14 10:06:30 +0100 2023-09-14 1	0:35:20	19703 etc
	0.5 ml D				+0100	

Batch Record Report

Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D

Regular production

Basic operation: 0100 - SDD assembly
Batch no.: NHJM068881

	ıt material / Takeo	<u>_</u>						
Pos.	Material no.	Material name		Manufacturing date set	Target quanti	ty	Actual quantity	
0001	5185500	SEMAGLUTIDE	D 0.5MG/ML, PFS 0.5	No	20000 ea		20000 ea	
	Action	SU	Batch no.	Scale ID	Scale quantity	Takeout	Effective	
	Take over	123400004868171362	NHJM068882			10000 ea	10000 ea	
				Date - User: 2023-09-14 09	:57:47 +0100 - 121 /	PAS-X Produ	ction Operator	
	Take over	123400004868171386	NHJM068882			10000 ea	10000 ea	
			Date - User: 2023-09-14 09	:58:12 +0100 - 121 /	PAS-X Produ	ction Operator		
Pos.	Material no.	Material name		Manufacturing date set		ty	Actual quantity	
0002	2700145	FRONT ASSEMBLY_MK2, NN WHITE		No 20000 ea 20000 ea		20000 ea		
	Action	SU	Batch no.	Scale ID	Scale quantity	Takeout	Effective	
	Take over	123400004868171461	NHJM068884			quantity 10000 ea	quantity 10000 ea	
	l'ake over	123400004000171401	N11310100004	Date - User: 2023-09-14	00:57:02 :0100 27			
	Take over	123400004868171423	NHJM068884	Date - Oser. 2023-09-14		10000 ea	10000 ea	
				Date - User: 2023-09-14	09:57:15 +0100 - 27	0 / Nishranth	Mahesh (nhjm)	
Pos.	Material no.	Material name		Manufacturing date set	Target quanti	ty	Actual quantity	
0003	2701018	REAR ASSEMI	BLY, NN WHITE, 0.5	No	20000 ea	•	20000 ea	
	Action	SU	Batch no.	Scale ID	Scale quantity	Takeout	Effective	
						guantity	guantity	
	Take over	123400004868171485	NHJM068885			10000 ea	10000 ea	
				Date - User: 2023-09-14 09				
	Take over	123400004868171508	NHJM068885			10000 ea	10000 ea	
				Date - User: 2023-09-14 09	:56:48 +0100 - 121 /	PAS-X Produ	ction Operator	

Pos. Material no.		Material name	Material name Batch no.		Target quantity	Actual quantity
0001	5957004	Obesity SDD 0.25mg/0.5ml D	NHJM068881	Stock	30000 ea	19703 etc
	SU		Action			Actual quantity
	357108691600	055130	Stock creation			10000 ea
				Date - User: 2023-09-14 10:06:30	+0100 - 270 / Nishranth M	Mahesh (nhjm)
	357108691600	055147	Stock creation			9703 ea
				Date - User: 2023-09-14 10:07:18	+0100 - 270 / Nishranth M	Mahesh (nhjm)

Material reconciliation - Input material								
Pos.	Material	Material Accounted S						
0001	5185500 - SEMAGL	UTIDE D 0.5MG/ML, PF	S 0.5	99.425% ()				
	Batch	Take-out	Return	Lose	Produced	Difference		
	Total	20000 ea	0 ea	0 ea	19885 ea	115 ea		
	NHJM068882	20000 ea	0 ea	0 ea				

Material reconciliation - Target material					
Material	Target	Actual	Samples		
5957004 - Obesity SDD 0.25mg/0.5 ml D	30000 ea	19703 etc	182 ea		

Material reconciliation - Confirmation signatures	Date - User
Material reconciliation confirmation	2023-09-14 10:20:23 +0100 - 112 / PAS-X Production Support
Material reconciliation confirmation	2023-09-14 10:19:17 +0100 - 112 / PAS-X Production Support

Production unit	
Basic operation	Production unit
0100 - SDD assembly	DF0601AL

Batch Record Report

Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D

Regular production

Basic operation: 0100 - SDD assembly

Batch no.: NHJM068881

Check lists Check list: ID receipt Number of samples using this list: 1 OK Not OK Check list: IPC receipt Number of samples using this list: 1 OK Check list: OPC receipt Number of samples using this list: 2 Not OK OK 2 Check list: Reference receipt Number of samples using this list: 2 OK Not OK 2

Samples							
ID	Sample type Var	riant	Check list	Product counter	SU	Sample quantity	Critical results
REF1	REF	AUTON	MATIC Reference receipt	10		35 ea	OK
			Date: 2023-09-14 08:47:54 +01			User: 121/PAS-X Pro	duction Operator Verification:
			PCS Date: 2017-06-15 11:33:3				
OPC1 O	PC	AUTON	MATIC OPC receipt	30		40 ea	OK
			Date: 2023-09-14 08:48:25 +01	100		User: 121/PAS-X Pro	duction Operator
			PCS Date: 2017-06-15 11:33:3	2,861			Verification:
ID1	PFS ID	AUTON	MATIC ID receipt	30		10 ea	OK
			Date: 2023-09-14 08:49:00 +01	100		User: 121/PAS-X Pro	duction Operator
4			PCS Date: 2017-06-15 11:33:3	2,861			Verification:
IPC1	IPC	AUTON	MATIC IPC receipt	30		20 ea	OK
			Date: 2023-09-14 08:49:35 +01	100		User: 121/PAS-X Pro	duction Operator
			PCS Date: 2017-06-15 11:33:3	2,861			Verification:
OPC2 O	PC	AUTON	MATIC OPC receipt	30		12 ea	OK
			Date: 2023-09-14 09:19:58 +01	100		User: 121/PAS-X Pro	duction Operator
			PCS Date: 2017-06-15 11:33:3	2,861			Verification:
REF2	REF	AUTON	MATIC Reference receipt	10		65 ea	OK
			Date: 2023-09-14 09:23:41 +01	100		User: 121/PAS-X Pro	duction Operator
			PCS Date: 2017-06-15 11:33:3	2,861			Verification:

Bill of equipment			
Pos. Equipment class	Equipment type	Equipment	Number of items
1 Workroom	ASSEM / Assembly Line	AL0601 / Assembly Line 06.01	1

	led BO				01-1
evel	Step				Status
Ш	1 - 0100STR - Start-up activi	ities	Subtype:	Tabular execution: no NF	
Function handles all startup activities: - Back-to-Back assessment - Back-to-Back confirmation - Batch information (PID Board Information) - Allocation of equipment - Sampling calculations - Batch download and start					
_evel	l Step				Status
2	1 - N0100DEC - Back to bac	ck?	Subtype:		NF
Back to Back is selected if this batch is started immediately after the previous batch. If this order meets the criteria for a back-to-back order, select yes. If not, select no.					
Ш	Decision type: User selection	n	Predecessor: Start	Repetition: 1	
11	Set value	Actual value		User & date / Signature Stat	us
		N0100 Yes			NF

Regular production

Basic operation: 0100 - SDD assembly
Batch no.: NHJM068881

Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D Status 1 - N0110B2B - Confirm back to back Tabular execution: no NF This function confirms the selection of Back-to-Back 2.0 010 - Confirm back to back Subtype: ---Actual value Status Set value User & date / Signature Confirm that back to back NF Confirm that the back to back conditions are met the conditions are met User & date: 2023-09-14 08:33:28 +0100 - 270 / Nishranth Mahesh (nhjm) Block signature: 2023-09-14 08:33:42 +0100 - 121 / PAS-X Production Operator Verification signature: 2023-09-14 08:33:56 +0100 - 114 / PAS-X Production Operator 2 Status Level Step Tabular execution: no NF 1 - N0140AL - [A] Allocate line The Subtype: -function allocates a line to the order. If "ERROR", the line is allocated to another order. Status **|•|** 3 1 - M0130AL - [A] Line allocation Allocates Subtype: --line to current order. The line cannot be allocated if the status is not OK. Set value Actual value User & date / Signature Status NF ASSEM:Assembly Line / ASSEM: Assembly Line / Workroom: AL0601 (Assembly Line 06.01) User & date: 2023-09-14 08:33:57 +0100 - 111111111 / ---Workroom:AL0601 (Assembly Line 06.01) Attributes Identification type: Scan Reuse equipment: no Equipment items: 1: Workroom AL0601 Assembly Line 06.01 Status Tabular execution: no NF 1 - N0230CAL - [A] Subtype: ---Sampling calculations Calculates sample withdrawal based on selected order ---2.0 010 - Batch Size in Pens Subtype: Set value Actual value Status User & date / Signature 30000 ea User & date: 2023-09-14 08:33:58 +0100 - 111111111 / ---2.1 020 - IPC Subtype: ---1. Withdrawal amount Set value Actual value Status User & date / Signature 20 ea User & date: 2023-09-14 08:33:59 +0100 - 111111111 / ---2.2 030 - OPC Subtype: ---1. Withdrawal amount Actual value Status Set value User & date / Signature 52 ea NF User & date: 2023-09-14 08:33:59 +0100 - 111111111 / ------040 - Reference Subtype: ---1. Withdrawal amount Set value Actual value Status User & date / Signature 100 ea NF User & date: 2023-09-14 08:33:59 +0100 - 111111111 / ---2.4 050 - ID Subtype: -1. Withdrawal quantity Set value Actual value Status User & date / Signature 2 ea NF User & date: 2023-09-14 08:33:59 +0100 - 111111111 / ---Status Level Step Tabular execution: no NF 1 - N0250MBA - [A] Batch start Performs Subtype: --batch start between PAS-X and the line.

Regular phono:: NHJM00013246

Basic operation: 0100 - SDD assembly Batch no.: NHJM068881 Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D Status • 3 1 - M0150DEC - [A] Start MOT done? NF Predecessor: M0140MOT Decision type: Formula Repetition: 1 Set value Actual value User & date / Signature Status M0150 Yes NF User & date: 2023-09-14 08:37:05 +0100 - 111111111 / ---Status Level Step • 3 1 - M0160DEC - [A] Start FA done? Subtype: --Predecessor: M0161FA Repetition: 1 Decision type: Formula Set Actual value value User & date / Signature Status M0160Yes NF User & date: 2023-09-14 08:36:53 +0100 - 111111111 / ---Status Level Step • 3 1 - M0170DEC - [A] Start PFS Done? NF Subtype: ---Predecessor: M0171PFS Repetition: 1 Decision type: Formula Set value Actual value User & date / Signature Status M0170 Yes User & date: 2023-09-14 08:37:14 +0100 - 111111111 / ---Status Level Step 1 • 3 - M0180DEC - [A] Start RA Done? NF Subtype: Predecessor: M0181RA Decision type: Formula Repetition: 1 Set value Actual value User & date / Signature Status M0180 Yes NF User & date: 2023-09-14 08:37:24 +0100 - 111111111 / ---Status Level Step Tabular execution: no NF 1 - 0110MAN - [A] Redownload Subtype: ---Steps to redownload Status 1 - N0100DEC - [A] Redownload • Subtype: --This feature is 'No' by default. Change to 'Yes' if redownload is required. Predecessor: Start Repetition: 1 Decision type: Formula Set value Actual value User & date / Signature Status N0100No User & date: 2023-09-14 08:37:26 +0100 - 111111111 / ---Status Tabular execution: no NF 1 - 0150MAT - [A] Material registration Subtype: --- Scan components in for use on the line Status Tabular execution: no NF 2 - N0170LEM - Confirm line is empty Subtype: ---Confirm line is empty. ---1.0 010 - Perform Line Empty 1. Subtype: --Before batch stop -Stop the equipment -Empty the line -Acknowledge any watchdogs and critical alarms. Confirm that the line is empty. Set value Actual value Status User & date / Signature OΚ OK NF User & date: 2023-09-14 10:08:32 +0100 - 270 / Nishranth Mahesh (nhjm) Status Tabular execution: no NF 1 - N0180MBI - Batch stop Subtype: -Steps in connection with ending the batch. Status 1 - LNCLR - Line Clearance Tabular execution: no NF Subtype: ---Status Tabular execution: no NF • 3 1 - CBF5 - Line Clearance Zone 1

Subtype: ---

Regular production Basic operation: 0100 - SDD assembly **Batch Record Report** Batch no.: NHJM068881 Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D Status 4 1 - NO161ALC - Zone 1 Tabular execution: no NF Subtype: 4.0 10 - LC1 ---Subtype: ---1. Perform line clearance and acknowledge Set value Actual value User & date / Signature Status NF User & date: 2023-09-14 10:11:07 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:11:21 +0100 - 121 / PAS-X Production Operator Status Level Step 4 1 - NO162ALC - Zone 1 Tabular execution: no NF Subtype: ---4.0 10 - LC2 Subtype: ---1. Perform line clearance and acknowledge Actual value Status Set value User & date / Signature NF User & date: 2023-09-14 10:11:27 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:11:36 +0100 - 114 / PAS-X Production Operator 2 Status • 3 1 - CBF3 - Line Clearance Zone 2 Tabular execution: no NF Subtype: ---Status 4 1 - NO161ALC - Zone 2 Tabular execution: no NF Subtype: ---4.0 10 - LC1 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value User & date / Signature Status NF User & date: 2023-09-14 10:11:44 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:11:54 +0100 - 121 / PAS-X Production Operator _evel Step Status 4 1 - NO162ALC - Zone 2 Tabular execution: no NF Subtype: ---4.0 10 - LC2 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value User & date / Signature Status NF User & date: 2023-09-14 10:12:00 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:12:09 +0100 - 114 / PAS-X Production Operator 2 Status • 3 1 - CBF2 - Line Clearance Zone 3 Tabular execution: no NF Subtype: ---Status Level Step 4 1 - NO161ALC - Zone 3 Tabular execution: no NF Subtype: ---4.0 10 - LC1 Subtype: ---1. Perform line clearance and acknowledge Actual value Set value Status User & date / Signature NF User & date: 2023-09-14 10:12:18 +0100 - 270 / Nishranth Mahesh (nhim) User identification signature: 2023-09-14 10:12:27 +0100 - 121 / PAS-X Production Operator Status 4 1 - NO162ALC - Zone 3 Tabular execution: no NF Subtype: ------4.0 10 - LC2 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value User & date / Signature Status NF User & date: 2023-09-14 10:12:32 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:12:42 +0100 - 114 / PAS-X Production Operator 2 Status Level Step

Subtype: --

• 3 1 - CBF4 - Line Clearance Zone 4

Tabular execution: no NF

MO no.: NHJM00013246 Batch Record Report Basic operation: 0100 - SDD assembly Regular production Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D Batch no.: NHJM068881 Status Level Step 4 1 - NO161ALC - Zone 4 Tabular execution: no NF Subtype: --4.0 10 - LC1 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value User & date / Signature Status Okay User & date: 2023-09-14 10:12:50 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:12:59 +0100 - 121 / PAS-X Production Operator Status Level Step 1 - NO162ALC - Zone 4 Tabular execution: no NF Subtype: ---10 - LC2 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value Status User & date / Signature NF User & date: 2023-09-14 10:13:05 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:13:21 +0100 - 114 / PAS-X Production Operator 2 Status Level Step 3 1 - CBF1 - Line Clearance Zone 5 Tabular execution: no NF Subtype: ---Status Level Step 4 1 - NO161ALC - Zone 5 Tabular execution: no NF Subtype: ---4.0 10 - LC1 Subtype: ---1. Perform line clearance and acknowledge Actual value Set value Status User & date / Signature NF User & date: 2023-09-14 10:13:31 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:13:40 +0100 - 121 / PAS-X Production Operator Status Level Step 4 1 - NO162ALC - Zone 5 Tabular execution: no NF Subtype: ---4.0 10 - I C2 Subtype: ---1. Perform line clearance and acknowledge Set value Actual value Status User & date / Signature NF User & date: 2023-09-14 10:13:46 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 10:13:57 +0100 - 114 / PAS-X Production Operator 2 Status Level Step Tabular execution: no 1 - 0140MANU - Manual samples NF Subtype: ---Registration of manual samples Level Step Status 1 - N0100DEC - Manual samples Subtype: ---Predecessor: Start Decision type: Formula Repetition: 1 Set value Actual value User & date / Signature Status N0100No User & date: 2023-09-14 08:37:26 +0100 - 111111111 / ---Status Level Step 1 - N0210ERL - Cassation Tabular execution: no NF Subtype: ---Discard material and receipt Status Level Step 1 - N0220ERL - Cassation 1st check Tabular execution: no NF Subtype: ---010 - Cassation 1st check Subtype: ---1. Throw away the PFS/Pen and acknowledge Set value Actual value Status User & date / Signature

User & date: 2023-09-14 09:36:16 +0100 - 270 / Nishranth Mahesh (nhjm)

User identification signature: 2023-09-14 09:36:28 +0100 - 121 / PAS-X Production Operator

NF

Regular production Basic operation: 0100 - SDD assembly **Batch Record Report** Batch no.: NHJM068881 Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D Status 1 - N0230ERL - Cassation 2nd check Tabular execution: no NF Subtype: ---2.0 010 - Cassation 2nd check Subtype: --- Throw away the PFS/Pen and acknowledge Set value Actual value User & date / Signature Status 10 NF User & date: 2023-09-14 09:36:43 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 09:37:36 +0100 - 114 / PAS-X Production Operator 2 Status 2 - N0220ERL - Cassation 1st check Tabular execution: no NF Subtype: ---2.0 010 - Cassation 1st check Subtype: ---1. Throw away the PFS/Pen and acknowledge Actual value Status Set value User & date / Signature NF User & date: 2023-09-14 09:42:45 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 09:42:55 +0100 - 121 / PAS-X Production Operator Status 2 - N0230ERL - Cassation 2nd check Tabular execution: no NF Subtype: ------2.0 010 - Cassation 2nd check Subtype: ---1. Throw away the PFS/Pen and acknowledge Set value Actual value Status User & date / Signature NF User & date: 2023-09-14 09:43:00 +0100 - 270 / Nishranth Mahesh (nhim) User identification signature: 2023-09-14 09:43:10 +0100 - 121 / PAS-X Production Operator Status Level Step 3 - N0220ERL - Cassation 1st check Tabular execution: no NF Subtype: ---2.0 010 - Cassation 1st check Subtype: ---. Throw away the PFS/Pen and acknowledge Set value Actual value Status 5 NF User & date: 2023-09-14 09:43:40 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 09:43:57 +0100 - 121 / PAS-X Production Operator Status 3 - N0230ERL - Cassation 2nd check Tabular execution: no Subtype: ---2.0 010 - Cassation 2nd check Subtype: ---1. Throw away the PFS/Pen and acknowledge Set value Actual value User & date / Signature Status NF User & date: 2023-09-14 09:44:03 +0100 - 270 / Nishranth Mahesh (nhim) User identification signature: 2023-09-14 09:44:14 +0100 - 114 / PAS-X Production Operator 2 Status Level Step 4 - N0220ERL - Cassation 1st check Tabular execution: no NF Subtype: ---2.0 010 - Cassation 1st check Subtype: ---. Throw away the PFS/Pen and acknowledge Actual value Status Set value User & date / Signature User & date: 2023-09-14 09:44:27 +0100 - 270 / Nishranth Mahesh (nhjm) User identification signature: 2023-09-14 09:44:35 +0100 - 114 / PAS-X Production Operator 2 Status <u>_evel Step</u> 4 - N0230ERL - Cassation 2nd check Tabular execution: no NF Subtype: ---2.0 010 - Cassation 2nd check Subtype: ---1. Throw away the PFS/Pen and acknowledge Set value Actual value Status User & date / Signature NF

User & date: 2023-09-14 09:44:40 +0100 - 270 / Nishranth Mahesh (nhjm)

User identification signature: 2023-09-14 09:44:50 +0100 - 121 / PAS-X Production Operator

Regular production

Basic operation: 0100 - SDD assembly
Batch no.: NHJM068881

el S	itep				Status
	1 - N0200FC - Count		Subtype:	Tabular execution: no NF	
	Control of the number of samples or	ompared to the sam			
l St	tep 2				Statu
	1 - N230CAL - [A] Consumption		Subtype: •	Tabular execution: no NF	
	Control of the number of samples co	ompared to the sam	pling plan		
2.0	010 - OPC		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	>=52 ea	52 ea			NF
				User & date: 2023-09-14 10:16:02 +0100 - 111111111 /	
2.1	020 - IPC		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	>=20 ea	20 ea			NF
	<u> </u>			User & date: 2023-09-14 10:16:02 +0100 - 111111111 /	
2.2	030 - REF		Subtype:		
	Set value	Actual value	Custypo.	User & date / Signature	Statu
	>=100 each	100 ea		OSCI & date / Oldinature	NF
				User & date: 2023-09-14 10:16:02 +0100 - 111111111 /	
2 3	040 - ID		Culatura		
د.ع		Actual	Subtype:		
	Set value	Actual value		User & date / Signature	Status
	>=2 ea	10 ea		Hear & data: 2022-00-44-40:46:02-10400-44444444-/	NF
				User & date: 2023-09-14 10:16:03 +0100 - 111111111 /	
2.4	050 - PFS/Pen manual checkout		Subtype:		
	Set value	Actual value		User & date / Signature	Status
	l	15			NF
				User & date: 2023-09-14 10:16:03 +0100 - 111111111 /	
2.5	060 - PFS automatic discarded		Subtype:		
	Set value	Actual value		User & date / Signature	Status
		100			NF
				User & date: 2023-09-14 10:16:03 +0100 - 111111111 /	
	070 - PFS, scanned 2.6		Subtype:		
	Set value	Actual value	Cubity bo.	User & date / Signature	Status
	ea	20000 ea		Soor a date / Signaturo	NF
		20000 00		User & date: 2023-09-14 10:16:04 +0100 - 111111111 /	
2 9	100 - Stock Creation		Subtyne:		
	Set value	Actual value	Subtype	11 0 14 /0:	Status
		19703		User & date / Signature	NF
		19703		User & date: 2023-09-14 10:16:04 +0100 - 111111111 /	INI
				Oser & date: 2023-09-14 10:10:04 +0100 - 111111111 /	
2.1	110 - Dividend		Subtype:		
U	Sot value	Actual			Ctatu
	Set value	Actual value		User & date / Signature	Status
	80 - 120%	99.425%		Hear & data: 2022-00-44-40:46:05-10400-44444444-/	NF
				User & date: 2023-09-14 10:16:05 +0100 - 111111111 /	
2.1	120 - Allowed deviation		Subtype:		
1	October	A.z. t. i			0
	Set value	Actual value		User & date / Signature	Status
		200		Here 0, date: 0000, 00, 44,40,40,07, 0400,	NF
				User & date: 2023-09-14 10:16:05 +0100 - 111111111 /	
2.1	130 - Deviation		Subtype:		
2					
	Set value	Actual value		User & date / Signature	Status
	-200 - 200	0			NF
				User & date: 2023-09-14 10:16:05 +0100 - 111111111 /	
					C/ - t
el S	tep T				Statu
	1 - N240REP - Repeat recon calcula	ation Subtype:			NF
	Decision type: User selection		Predecessor: N230CAL	Repetition: 1	
				·	
	Set value	Actual value		User & date / Signature Status	5

Regular production

Basic operation: 0100 - SDD assembly
Batch no.: NHJM068881

el S	Step				Statu
	2 - N230CAL - [A] Consumption		Subtype:	Tabular execution: no NF	
	Control of the number of samples of	ompared to the sam	pling plan		
2.0	010 - OPC	•	Subtype:		
П	Set value	Actual value		User & date / Signature	Statu
	>=52 ea	52 ea		Cool a date / Digitataro	NF
	02.00	02 00		User & date: 2023-09-14 10:17:54 +0100 - 111111111 /	
2 1	020 - IPC		0.14	0001 ta dation 2020 00 11101110 1110100 1111111117	
۷.۱		A - t 1 1	Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	>=20 ea	20 ea			NF
				User & date: 2023-09-14 10:17:55 +0100 - 111111111 /	
2.2	030 - REF		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	>=100 each	100 ea			NF
				User & date: 2023-09-14 10:17:55 +0100 - 111111111 /	
2.3	040 - ID		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	>=2 ea	10 ea			NF
	n			User & date: 2023-09-14 10:17:55 +0100 - 111111111 /	
2.4	050 - PFS/Pen manual checkout		Subtype:		
	Set value	Actual value	Oubtypo.	User & date / Signature	Statu
		15		Osci & date / Oighatare	NF
		10		User & date: 2023-09-14 10:17:55 +0100 - 111111111 /	
2.5	060 - PFS automatic discarded			5501 ta dato. 2020 60 11 10:17:50 10100 111111117	
2.5		A storal coalica	Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	ļ	100			NF
				User & date: 2023-09-14 10:17:56 +0100 - 111111111 /	
2.6	070 - PFS, scanned		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
	ea	20000 ea			NF
				User & date: 2023-09-14 10:17:56 +0100 - 111111111 /	
2.9	100 - Stock Creation		Subtype:		
	Set value	Actual value		User & date / Signature	Statu
		19703			NF
				User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	
2.1	110 - Dividend		Subtype:		
0	The Bividena		очьтурс.		
	Set value	Actual value		User & date / Signature	Statu
				OCO G GALO / OIGHICIGHO	_
	80 - 120%				NF
	80 - 120%	99.425%		User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	NF
2 1			Subtuno	User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	NF
2.1	80 - 120% 120 - Allowed deviation		Subtype:	User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	
2.1	120 - Allowed deviation	99.425%	Subtype:		-
2.1		99.425% Actual value	Subtype:	User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature	 Statu:
2.1	120 - Allowed deviation	99.425%	Subtype:	User & date / Signature	-
1	120 - Allowed deviation Set value	99.425% Actual value			Statu:
2.1	120 - Allowed deviation	99.425% Actual value	Subtype: Subtype:	User & date / Signature	 Statu:
1	120 - Allowed deviation Set value 130 - Deviation	99.425% Actual value 200		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	Statu:
2.1	120 - Allowed deviation Set value 130 - Deviation Set value	99.425% Actual value 200 Actual value		User & date / Signature	Statu:
2.1	120 - Allowed deviation Set value 130 - Deviation	99.425% Actual value 200		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature	Statu:
2.1	120 - Allowed deviation Set value 130 - Deviation Set value	99.425% Actual value 200 Actual value		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	Statu:
2.1 2	120 - Allowed deviation Set value 130 - Deviation Set value -200 - 200	99.425% Actual value 200 Actual value		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature	Statu: NF
2.1 2	120 - Allowed deviation Set value 130 - Deviation Set value -200 - 200	Actual value 200 Actual value 0		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature	Statu: Statu: Statu: Statu: Statu:
2.1 2	120 - Allowed deviation Set value 130 - Deviation Set value -200 - 200 Step 2 - N240REP - Repeat recon calculates	Actual value 200 Actual value 0	Subtype:	User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	Statu: NF
2.1 2	120 - Allowed deviation Set value 130 - Deviation Set value -200 - 200 Step 2 - N240REP - Repeat recon calculation	Actual value 200 Actual value 0		User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature	Statu: Statu: Statu: Statu: Statu:
2.1 2	120 - Allowed deviation Set value 130 - Deviation Set value -200 - 200 Step 2 - N240REP - Repeat recon calculates	Actual value 200 Actual value 0	Subtype:	User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 / User & date / Signature User & date: 2023-09-14 10:17:57 +0100 - 111111111 /	Statu: Statu: Statu: NF

Material: 5957004 - Obesity SDD 0.25mg/0.5 ml D

Regular production

PAS-X-triggered exceptions Caused that **Deviation number** Criticality Type 2023-09-14 09:51:46 +0100 Actual value correction Noncritical

Related object: SDD assembly(1)->[A] Material registration(1)->[A] Manual take out(1)

Exception text (system): Correcting actual value for decision 'N0140DEC: [A] Manual take out' (old value: 'No', new value: 'Yes').

Status	Priority	Criticality	Deviation number
Generated	1 / Major	Noncritical	
		User & date: 2023-09-14 09:	51:56 +0100 - 270 / Nishranth Mahesh (nhjm)
Correct decision			
		Signature: 2023-09-14 09:	51:51 +0100 - 270 / Nishranth Mahesh (nhjm)
Cluster Operation 1 / Maj	jor Comment: Exception		
added to cluster C00001	345.		
test			
		User & date: 2023-09-14 10:	21:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Exception added to clust	er		
		Signature: 2023-09-14 10:	21:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledged	1 / Major	Noncritical	
Comment: test			
		User & date: 2023-09-14 10:	22:20 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledge an exception	on		
		Signature: 2023-09-14 10:22:1	6 +0100 - 113 / PAS-X Production Operator 3

2023-09-14 10:05:59 +0100

Actual value correction

Noncritical

Related object: SDD assembly(1)->[A] Material registration(1)->[A] Manual stock creation(1)

Exception text (system): Correcting actual value for decision 'N0100DEC: [A] Manual stock creation' (old value: 'No', new value: 'Yes').

Exception text (user): test

Status	Priority	Criticality	Deviation number
Generated	1 / Major	Noncritical	
		User & date: 2023-09-14 10:00	6:18 +0100 - 270 / Nishranth Mahesh (nhjm)
Correct decision			
		Signature: 2023-09-14 10:06:1	5 +0100 - 121 / PAS-X Production Operator
Cluster Operation 1 / Majo	or Comment: Exception		
added to cluster C0000134	45.		
test			
		User & date: 2023-09-14 10:2	1:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Exception added to cluster	r		
		Signature: 2023-09-14 10:2	1:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledged	1 / Major	Noncritical	
Comment: test			
		User & date: 2023-09-14 10:23	2:20 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledge an exception	า		
		Signature: 2023-09-14 10:22:16	+0100 - 113 / PAS-X Production Operator 3

2023-09-14 10:20:34 +0100

Integrity check warning

Noncritical

Related object: 806363 (NHJM00013246)

Exception text (system): NNCORDERCONTROL0002: Incomplete system configuration for final alarm from PCS. Check for final alarm cannot be executed.

Status	Priority	Criticality	Deviation number
Generated	1 / Major	Noncritical	
Comment: test	•		
		User & date: 2023-09-14 10:2	20:34 +0100 - 270 / Nishranth Mahesh (nhjm)
NNEndShopFloorOrderV	VithWarning		
		Control Signature: 2023-09-14 10:2	0:33 +0100 - 270 / Nishranth Mahesh (nhjm)
Cluster Operation 1 / Ma	jor Comment: Exception		
added to cluster C00001 test	345.		
		User & date: 2023-09-14 10:2	21:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Exception added to clust	er		
		Signature: 2023-09-14 10:2	21:38 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledged	1 / Major	Noncritical	
Comment: test			
		User & date: 2023-09-14 10:2	22:20 +0100 - 270 / Nishranth Mahesh (nhjm)
Acknowledge an exception	on		
		Signature: 2023-09-14 10:22:16	6 +0100 - 113 / PAS-X Production Operator 3

Batch no.: NHJM068881