



OPTEL

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FDA Pilot Project Test Report

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**Document Identification:
FDA Pilot Project Test Report (Revision 1)**

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Table of Contents

1. Purpose	4
2. Scope.....	4
2.1 Pilot Project Duration	5
2.2 System Description	5
3. Test Strategy	6
3.1 Assumption	6
3.2 General Procedure	6
4. Prerequisite Steps	6
5. Test Evidences	7
6. Test Phase Observations	22
7. Overall Pilot Project Observations.....	23
8. Review and Approval.....	24

REVISION HISTORY

Rev.	Date	Author	Revision Summary
.1	2020-01-24	Jacinthe Mongrain	Initial Version

APPROVAL

List all personnel reviewing and authorizing this test protocol.

Department	Printed Name	Signature	Initials	Date
		N/A	(1)	
		JM		15 JUN 2020

(1) No approval signature was captured. Test phase approval was provided by email.

JM
15 JUN 2020

IDENTIFICATION RECORD

Document the name, title, signature and initials of all the persons who participate in this test effort. By signing this page, they certify that they have read and understood this protocol.

Name	Title	Signature	Initials / Date
Julien Galibois Sauvageau	Software Deployment Specialist	Julien G. Sauvageau	JGS
Jacinthe Mongrain	Validation Specialist	Jacinthe Mongrain	JM
	N/A		
		JM	15 JUN 2020

1. Purpose

The goal of the Optel Pilot Project with the FDA is to show that it is possible to meet the Drug Supply Chain Security Act (DSCSA) requirements related to interoperable, electronic tracing of products at the package level, specifically the enhanced requirements for package level tracing and verification that will go into effect in 2023.

2. Scope

The purpose of the present document is to provide documented evidences that the transfer of serialization data to and from all the different parties of the pharmaceutical products distribution chain can be done during the processing of the physical serialized products, without any corruption or blocking issue, from the manufacturer to the dispenser.

The test strategy that was determined to demonstrate this interoperability consists mainly in modifying physical EPC dispositions on simulated physical products at each stage of the distribution chain, and to reconcile the simulated physical products dispositions with the EPCIS serialization data after each modification of an aggregation. The intention behind this strategy is to simulate a distribution scenario compliant with the Drug Supply Chain Security Act (DSCSA) requirements which is as close as possible to a real-life compliant pharmaceutical products distribution use case.

The present document is loosely based on validation standards in order to produce relevant technical test evidences, and is to be filled up according to the Good Documentation Practices of the industry. It has previously been agreed with the FDA representative that no formal validation effort will be required in the course of this pilot project, since the simulated products that will be handled to demonstrate technical success of this pilot solution will not be actual pharmaceutical products to be sold on the market.

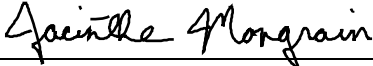
No physical pharmaceutical product will be used for the tests included in the present document. Physical products will be simulated with printed labels. When a reference to a pallet is stated in the test script, it always refers to a simulated pallet that will take the physical form of printed label and the virtual form of aggregated serial numbers.

The following companies are involved in this pilot project:

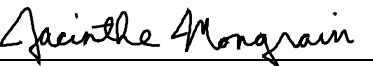
- Solution provider
 - Role: To provide the serialization systems required to transfer serialization data to all the involved parties.
 - Name of company representative: Simon Bastarache
- Manufacturer: ANI Pharmaceuticals
 - Role: To produce the initial serialized and aggregated homogenous pallet simulations on a serialized packaging line. To rework these pallet simulations in the warehouse to make them heterogenous.
 - Name of company representative: Matt Haataja
- Distributor: McKesson
 - Role: To rework the heterogenous pallet simulations at the distribution site.
 - Name of company representative: Khushboo Joshi and Brian Schmidt
- Dispenser: simulated by McKesson and Optel
 - Role: To reconcile the simulated delivered products with the related serialization repository data.
 - Name of company representative: Julien Galibois-Sauvageau

2.1 Pilot Project Duration

Start Date: March 11, 2019

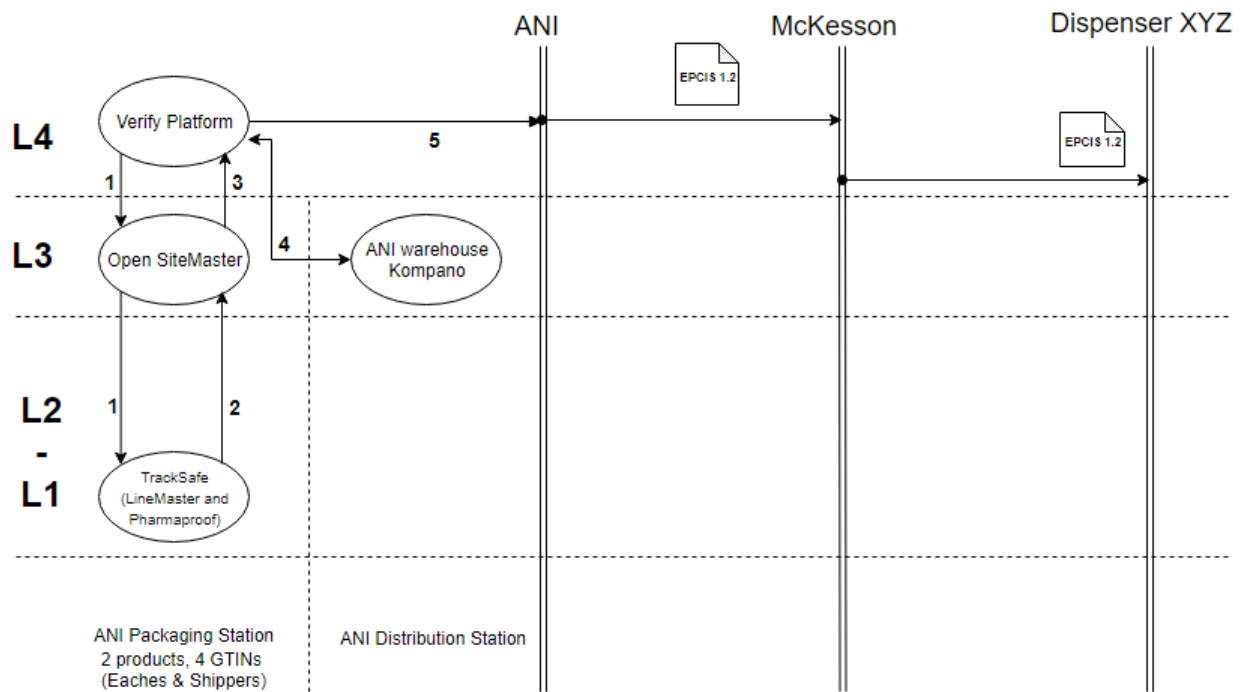
Jacinthe Mongrain		2020-06-15
Printed Name	Signature	Signature Date (YYYY-MM-DD)

Completion Date:

Jacinthe Mongrain		2020-06-15
Printed Name	Signature	Signature Date (YYYY-MM-DD)

2.2 System Description

FDA Pilot - DSCSA



1. UID Provisioning to the Optel Lines
2. Finished Goods Data
3. Finished Goods Data (EPCIS format, contains COMM and AGG only from OSM)
4. Kompano triggering SHIP event using prototype API on VP
5. Trigger activates Outcomes on VP to send files to McKesson. (All three - COMM, AGG and SHIP)

Figure 1: Distribution Flow Illustration

3. Test Strategy

Step 1

More of a prerequisite:
1- Prepare 2 homogenous pallets (16 eaches, 4 cases).
2- Reserve all labels from these pallets.
3- Open the EPCIS reports and reconcile each label with an EPC in the report.

Step 2

Kompano Rework:
1- Decommission one each
2- Destroy one each
3- Sample one each
4- Switch a case from Pallet 1 to Pallet 2)

Outcome:
-1 partial heterogenous palet
-1 complete heterogenous pallet

Step 3

Ask McKesson to:
- Reconciliate received labels with EPCIS report(s)
- Switch 2 cases on the 2 pallets.
- Update and transfer EPCIS report with the annotated labels.

Outcome:
- 2 partial heterogenous pallets

Step 4

1- Reconciliate the 2 heterogenous pallets with the EPCIS report(s).
2- Confirm destroyed items are not in EPCIS.

3.1 Assumption

The tests are meant to be executed by technical experts familiar with the Optel solutions. The people executing the tests must understand the Optel systems environments.

The tests are to be reviewed by a trained compliance specialist for test results accuracy and tests documentation compliance with the Good Documentation Practices of the pharmaceutical industry.

3.2 General Procedure

Ensure that all information spaces in the test scripts are completed as the testing is performed. If a page is blank or information is not applicable, then cross it out with a single line and write "N/A". Print and sign your name then date the section that has been crossed out.

Verify that all the test actions produce the expected outcome and provide a test evidence for each outcome. If any outstanding item is observed during a test action, document all the related information in the **Comments** section.

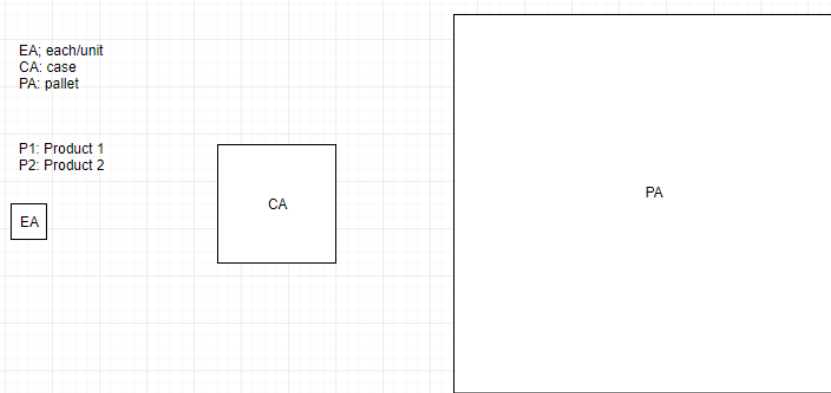
The person filling the test script must sign and date the **Performed by / Date** spaces. The execution should be verified, and then the revision should be signed and dated in the **Reviewed by / Date** boxes at the end of each test section.

Attach all supporting documentation must be attached to the present document.

4. Prerequisite Steps

1. Ensure a demo environment is created for the serialization data management in the course of this pilot project.
2. Ensure the Optel systems installed at ANI Pharmaceuticals are functional and can produce data for at least two (2) simulated pallets with two (2) different types of product. Ensure a label sample is available for each simulated product package.
3. Ensure the Kompano system is functional and communicates with the Verify Platform without any issue.
4. Ensure the Verify Platform is configured to send shipping event to McKesson without any issue.
5. Ensure that a Dispenser is simulated and is ready to receive serialization data.
6. Ensure the McKesson system can send serialization data to the simulated Dispenser.

5. Test Evidences

Objective	The objective of the present document is to provide evidences that the transfer of serialization data throughout the pharmaceutical distribution chain can technically be successful, and therefore that the whole distribution chain can be compliant with the current and upcoming DSCSA regulations implementation phases.
Test Procedure	Execute the Test Action and document the Observed Results as indicated.
Test Technical Scope	<ul style="list-style-type: none"> - Two (2) different simulated pharmaceutical products will be used for this test. - Four (4) different GTINs will be used, one for each unit of product, and one for each case of products. - SSCCs will be used for pallets. - Two (2) pallets (P1 and P2), each containing four (4) cases (C1, C2, C3 and C4), each containing four (4) units (E1, E2, E3, E4, etc.), will be aggregated and reworked. Therefore, P1 and P2 will both initially contain 16 units. - The EPCs will be reconciliated with the EPCIS messages related to these EPCs after each rework phases and at the simulated final Dispenser site. - All communications will occur in a demo environment, with no impact on ANI Pharmaceuticals and McKesson actual production data. 

Comments / Additional Information

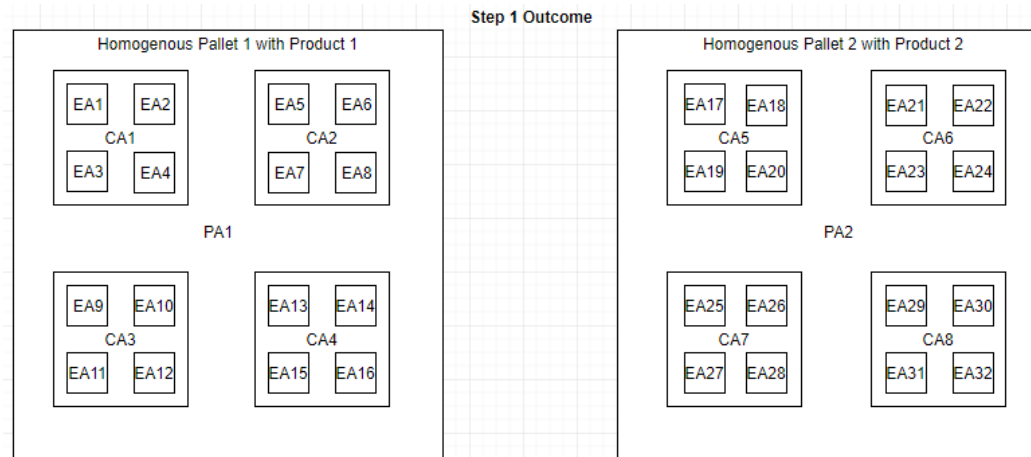
N/A ☒

Performed by:	Julien G. Sauvageau	Date:	22 MAY 2020
Reviewed by:	Jacinthe Monaghan	Date:	15 JUN 2020

Test Start Date and Time (YYYY-MM-DD_HH-MM): 2020-05-22_10:06

#	Test Action	Observed Result	Test Evidence
Step 1: Homogenous Pallets Aggregation with the ANI Pharmaceuticals Optel Systems			
1.	Start a batch on the LineMaster and homogenous aggregated Pallet 1 with 16 units in 4 cases of Product 1.	Pallet 1 is aggregated.	Simulated Products Labels Location: Virtual barcode files
2.	Start a batch on the LineMaster and homogenous aggregated Pallet 1 with 16 units in 4 cases of Product 2.	Pallet 2 is aggregated.	Simulated Products Labels Location: Virtual barcode files

Step 1 Visual Outcome



Comments / Additional Information

N/A ☒

Performed by:	<i>Julien G. Sauvageau</i>	Date:	<i>22MAY2020</i>
Reviewed by:	<i>Jacinthe Mongrain</i>	Date:	<i>15MAY2020</i>

#	Test Action	Observed Result	Test Evidence
Step 1 Reconciliation			
3.	<p>Note the Pallet 1 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet:</p> <p>PA1 SSCC: <u>(00)803625591000001239</u></p> <p>CA1 SGTIN: <u>(01)50362559620371(21)13Z3LK8ZNJ4TXZ</u></p> <p>CA2 SGTIN: <u>(01)50362559620371(21)14TGDZKRWFHNV</u></p> <p>CA3 SGTIN: <u>(01)50362559620371(21)14XG98KXSP89GN</u></p> <p>CA4 SGTIN: <u>(01)50362559620371(21)15QGKS3W8FJFYM</u></p> <p>EA1 SGTIN: <u>(01)00362559620376(21)1558HT89Z9KYXH</u></p> <p>EA2 SGTIN: <u>(01)00362559620376(21)15ZVKNF4TC78JJ</u></p> <p>EA3 SGTIN: <u>(01)00362559620376(21)16WQSQZHR4RPT1</u></p> <p>EA4 SGTIN: <u>(01)00362559620376(21)16ZYCR7HPFSTLX</u></p> <p>EA5 SGTIN: <u>(01)00362559620376(21)179KHJM7DK2R6Y</u></p> <p>EA6 SGTIN: <u>(01)00362559620376(21)17DPCXCH66RL1L</u></p> <p>EA7 SGTIN: <u>(01)00362559620376(21)17GFDYNCKQQWPQ</u></p>	<p>The EPCIS report contains the Pallet 1 EPCs in the "Active" disposition and the pallet aggregation data matches the physical pallet configuration.</p>	<p>EPCIS Serialization Report Identification: <u>Test04_EPCIS_Report.xml</u></p> <hr/> <hr/> <hr/> <p>Simulated Products Labels Location: Virtual barcode files</p> <hr/> <hr/> <hr/>

Comments / Additional Information

N/A ☒

Performed by:	<i>Julien G. Sauvageau</i>	Date:	22MAY2020
Reviewed by:	<i>Jacinte Mongrain</i>	Date:	15JUN2020

#	Test Action	Observed Result	Test Evidence
	EA8 SGTIN: <u>(01)00362559620376(21)17R1M6HY4N2RMN</u> EA9 SGTIN: <u>(01)00362559620376(21)18R87F47Y333D6</u> EA10 SGTIN: <u>(01)00362559620376(21)18SW3YHKLHX2H8</u> EA11 SGTIN: <u>(01)00362559620376(21)18VDC8HN9SXVL7</u> EA12 SGTIN: <u>(01)00362559620376(21)18VNTQPJ1CQW1M</u> EA13 SGTIN: <u>(01)00362559620376(21)1CFX64W86ZC9TH</u> EA14 SGTIN: <u>(01)00362559620376(21)1CY29LW3X1LGL3</u> EA15 SGTIN: <u>(01)00362559620376(21)1D8DXZXXRZKS7W</u> EA16 SGTIN: <u>(01)00362559620376(21)1DZ8KQNSS1KRXZ</u>		
4.	Note the Pallet 2 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet: PA2 SSCC: <u>(00)803625591000001246</u> CA5 SGTIN: <u>(01)50362559160013(21)1142X8W7DG1FRY</u> CA6 SGTIN: <u>(01)50362559160013(21)11CRNCVLVFCQ14</u> CA7 SGTIN: <u>(01)50362559160013(21)11CZN4PYV25QH8</u>	The EPCIS report contains the Pallet 2 EPCs in the "Active" disposition and the pallet aggregation data matches the physical pallet configuration.	EPCIS Serialization Report Identification: <u>Test05_EPCIS_Report.xml</u> Simulated Products Labels Location: <u>Virtual barcode files</u>

Comments / Additional Information

N/A ☒

Performed by:	<i>Julien G. Sauvageau</i>	Date:	22MAY2020
Reviewed by:	<i>Gacinte Mongrain</i>	Date:	15JUN2020

#	Test Action	Observed Result	Test Evidence
	CA8 SGTIN: <u>(01)50362559160013(21)124DP42ZHRHSRN</u>		N/A
	EA17 SGTIN: <u>(01)00362559160018(21)11KND8SZ2STR6Q</u>		
	EA18 SGTIN: <u>(01)00362559160018(21)11NHMWX9Y36PY8</u>		
	EA19 SGTIN: <u>(01)00362559160018(21)11Y74DQ848CPGW</u>		
	EA20 SGTIN: <u>(01)00362559160018(21)125SLNZJHFXD92</u>		
	EA21 SGTIN: <u>(01)00362559160018(21)12HWWYHZFL5D3H</u>		
	EA22 SGTIN: <u>(01)00362559160018(21)135P9LFWRCGPSL</u>		
	EA23 SGTIN: <u>(01)00362559160018(21)14DMWTKGDQ7RMJ</u>		
	EA24 SGTIN: <u>(01)00362559160018(21)14KZHP3HHCML5L</u>		
	EA25 SGTIN: <u>(01)00362559160018(21)14ZCVPWR275VTL</u>		
	EA26 SGTIN: <u>(01)00362559160018(21)15Y5JN18GJLMGH</u>		
	EA27 SGTIN: <u>(01)00362559160018(21)165KX4VQR1TKF3</u>		
	EA28 SGTIN: <u>(01)00362559160018(21)16CDM4ZY93Y8F6</u>		
	EA29 SGTIN: <u>(01)00362559160018(21)17X5NK5ML5FYGJ</u>		
	EA30 SGTIN: <u>(01)00362559160018(21)182SCYZ85WC32M</u>		

Comments / Additional Information

N/A ☒

Performed by:		Date:	
Reviewed by:	<i>Jacinthe Monograin</i>	Date:	15 JUN 2020

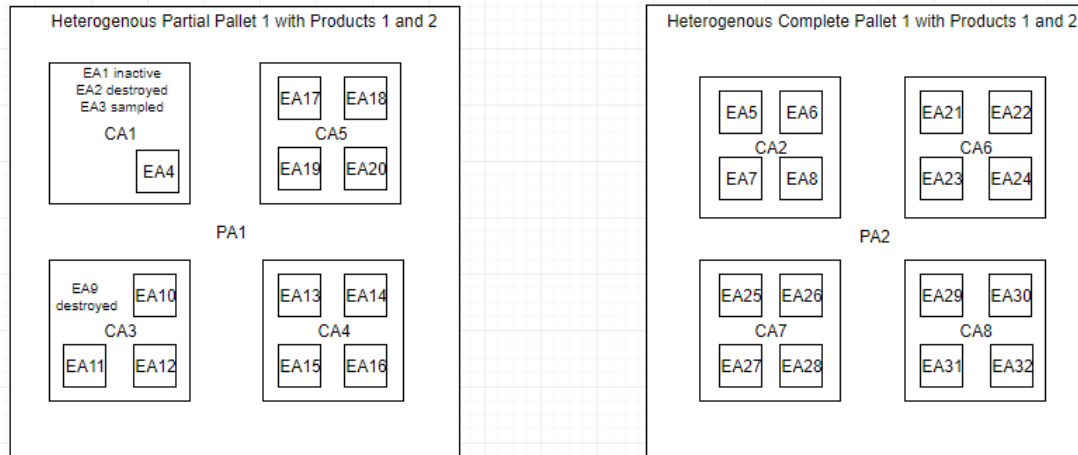
#	Test Action	Observed Result	Test Evidence
	EA31 SGTIN: (01)00362559160018(21)18DVL6657QJ3R2 EA32 SGTIN: (01)00362559160018(21)18H73JZ1RLH5RD		

Step 2: Heterogenous Pallet Rework with Kompano

5.	<p>Kompano Rework:</p> <ol style="list-style-type: none"> 1- Decommission EA1 2- Destroy EA2 and EA9 3- Sample EA3 4- Switch CA2 on PA1 with CA5 on PA2 	<p>Outcome:</p> <ul style="list-style-type: none"> - PA1 is partial and heterogenous - PA2 is complete and heterogenous 	<p>Simulated Products Labels Location:</p> <p>Virtual barcode files</p>
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Step 2 Visual Outcome

Step 2 Outcome



Comments / Additional Information

See comments in Section 6.

N/A

Performed by:	Julien G. Sauvageau	Date:	10 JUN 2020
Reviewed by:	Jacinte Mongrain	Date:	15 JUN 2020

#	Test Action	Observed Result	Test Evidence
Step 2 Reconciliation			
6.	<p>Note the Pallet 1 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet:</p> <p>Partial PA1 SSCC: <u>(00)803625591000001239</u></p> <p>Partial CA1 SGTIN: <u>(01)50362559620371(21)13Z3LK8ZNJ4TXZ</u></p> <p>CA5 SGTIN: <u>(01)50362559160013(21)1142X8W7DG1FRY</u></p> <p>Partial CA3 SGTIN: <u>(01)50362559620371(21)14XG98KXSP89GN</u></p> <p>CA4 SGTIN: <u>(01)50362559620371(21)15QGKS3W8FJFYM</u></p> <p>Inactive EA1 SGTIN: <u>(01)00362559620376(21)1558HT89Z9KYXH</u></p> <p>Destroyed EA2 SGTIN: <u>(01)00362559620376(21)15ZVKNF4TC78JJ</u></p> <p>Sampled EA3 SGTIN: <u>(01)00362559620376(21)16WQSQZHR4RPT1</u></p> <p>EA4 SGTIN: <u>(01)00362559620376(21)16ZYCR7HPFSTLX</u></p> <p>EA17 SGTIN: <u>(01)00362559160018(21)11KND8SZ2STR6Q</u></p> <p>EA18 SGTIN: <u>(01)00362559160018(21)11NHMWX9Y36PY8</u></p> <p>EA19 SGTIN: <u>(01)00362559160018(21)11Y74DQ848CPGW</u></p>	<p>The EPCIS report contains the Pallet 1 EPCs and the pallet aggregation data matches the physical pallet configuration.</p> <ul style="list-style-type: none"> - EA1 is inactive - EA2 is destroyed - EA3 is sampled - EA9 is destroyed - CA5 is aggregated to PA1 - CA2 is not aggregated to PA1 anymore 	<p>EPCIS Serialization Report Identification:</p> <p><u>(00)803625591000001239</u> <u>after_Kompano_rework.xlsx</u></p> <p>Simulated Products Labels Location: Virtual barcode files</p>

Comments / Additional Information

See comments in Section 6.

JGS
10 JUN 2020

N/A

Performed by:	<i>Julien G. Sauvageau</i>	Date:	10 JUN 2020
Reviewed by:	<i>Jacinte Mongrain</i>	Date:	15 JUN 2020

#	Test Action	Observed Result	Test Evidence
	EA20 SGTIN: <u>(01)00362559160018(21)125SLNZJHFXD92</u> Destroyed EA9 SGTIN: <u>(01)00362559620376(21)18R87F47Y333D6</u> EA10 SGTIN: <u>(01)00362559620376(21)18SW3YHKLHX2H8</u> EA11 SGTIN: <u>(01)00362559620376(21)18VDC8HN9SXVL7</u> EA12 SGTIN: <u>(01)00362559620376(21)18VNTQPJ1CQW1M</u> EA13 SGTIN: <u>(01)00362559620376(21)1CFX64W86ZC9TH</u> EA14 SGTIN: <u>(01)00362559620376(21)1CY29LW3X1LGL3</u> EA15 SGTIN: <u>(01)00362559620376(21)1D8DXZXXRZKS7W</u> EA16 SGTIN: <u>(01)00362559620376(21)1DZ8KQNSS1KRXZ</u>		
7.	Note the Pallet 2 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet: PA2 SSCC: <u>(00)803625591000001246</u> CA2 SGTIN: <u>(01)50362559620371(21)14TGDZKRWYFHNV</u> CA6 SGTIN: <u>(01)50362559160013(21)11CRNCVLVFCQ14</u> CA7 SGTIN: <u>(01)50362559160013(21)11CZN4PYV25QH8</u>	The EPCIS report contains the Pallet 2 EPCs in the "Active" disposition and the pallet aggregation data matches the physical pallet configuration. <ul style="list-style-type: none"> - CA2 is aggregated to PA2 - CA5 is not aggregated to PA2 anymore 	EPCIS Serialization Report Identification: <u>(00)803625591000001246_</u> <u>after_Kompano_rework.xlsx</u> Simulated Products Labels Location: Virtual barcode files

Comments / Additional Information

N/A ☒

Performed by:	<i>Julien G. Sauvageau</i>	Date:	10 JUN 2020
Reviewed by:	<i>Gacinte Mongrain</i>	Date:	15 JUN 2020

#	Test Action	Observed Result	Test Evidence
	CA8 SGTIN: (01)50362559160013(21)124DP42ZHRHSRN		N/A
	EA5 SGTIN: (01)00362559620376(21)179KHJM7DK2R6Y		
	EA6 SGTIN: (01)00362559620376(21)17DPCXCH66RL1L		
	EA7 SGTIN: (01)00362559620376(21)17GFDYNCKQQWPQ		
	EA8 SGTIN: (01)00362559620376(21)17R1M6HY4N2RMN		
	EA21 SGTIN: (01)00362559160018(21)12HWWYHZFL5D3H		
	EA22 SGTIN: (01)00362559160018(21)135P9LFWRCGPSL		
	EA23 SGTIN: (01)00362559160018(21)14DMWTKGDQ7RMJ		
	EA24 SGTIN: (01)00362559160018(21)14KZHP3HHCML5L		
	EA25 SGTIN: (01)00362559160018(21)14ZCVPWR275VTL		
	EA26 SGTIN: (01)00362559160018(21)15Y5JN18GJLMGH		
	EA27 SGTIN: (01)00362559160018(21)165KX4VQR1TKF3		
	EA28 SGTIN: (01)00362559160018(21)16CDM4ZY93Y8F6		
	EA29 SGTIN: (01)00362559160018(21)17X5NK5ML5FYGJ		
	EA30 SGTIN: (01)00362559160018(21)182SCYZ85WC32M		

Comments / Additional Information

N/A ☒

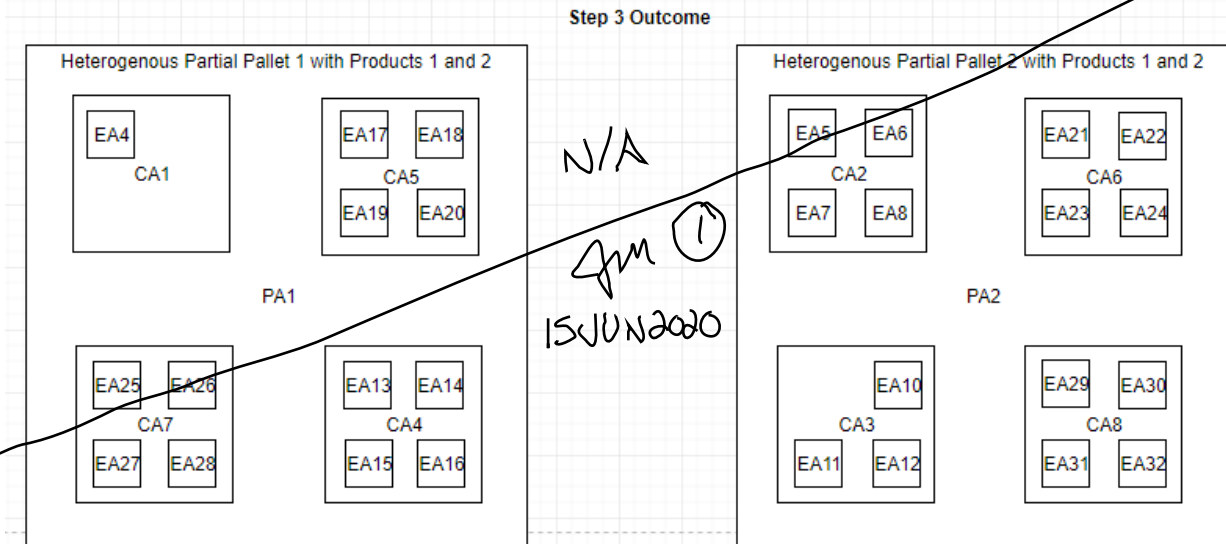
Performed by:		Date:	
Reviewed by:	<i>Jacinthe Mongrain</i>	Date:	15 JUN 2020

#	Test Action	Observed Result	Test Evidence
	EA31 SGTIN: <u>(01)00362559160018(21)18DVL6657QJ3R2</u> EA32 SGTIN: <u>(01)00362559160018(21)18H73JZ1RLH5RD</u>		

Step 3: Heterogenous Pallet Rework at McKesson

8.	McKesson Rework: - Switch CA3 on PA1 with CA7 on PA2	Outcome: - PA1 is partial and heterogenous - PA2 is partial and heterogenous	Simulated Products Labels Location: _____
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Step 3 Visual Outcome



Comments / Additional Information

① EPCIS files were received by McKesson but the subsequent test steps were not executed due to lack of time.

N/A

Jm 15 JUN 2020

Performed by:	N/A	Date:	
Reviewed by:	Jm 15 JUN 2020	Date:	

#	Test Action	Observed Result	Test Evidence
Step 3 Reconciliation			
9.	<p>Note the Pallet 1 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet:</p> <p>Partial PA1 SSCC: _____</p> <p>Partial CA1 SGTIN: _____</p> <p>CA5 SGTIN: _____</p> <p>CA7 SGTIN: _____</p> <p>CA4 SGTIN: _____</p> <p>EA4 SGTIN: _____</p> <p>EA13 SGTIN: _____</p> <p>EA14 SGTIN: _____</p> <p>EA15 SGTIN: _____</p> <p>EA16 SGTIN: _____</p> <p>EA17 SGTIN: _____</p> <p>EA18 SGTIN: _____</p>	<p>The EPCIS report contains the Pallet 1 EPCs and the pallet aggregation data matches the physical pallet configuration.</p> <ul style="list-style-type: none"> - CA7 is aggregated to PA1 - CA3 is not aggregated to PA1 anymore <p>N/A</p> <p><i>QJM 15 JUN 2020</i></p>	<p>EPCIS Serialization Report Identification:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Simulated Products Labels Location:</p> <p>_____</p> <p>_____</p> <p>_____</p>

Comments / Additional Information

N/A

Performed by:		Date:	
Reviewed by:		Date:	

#	Test Action	Observed Result	Test Evidence
	EA19 SGTIN: _____ EA20 SGTIN: _____ EA25 SGTIN: _____ EA26 SGTIN: _____ EA27 SGTIN: _____ EA28 SGTIN: _____		
10.	Note the Pallet 2 contents labels EPCs and reconcile the printed EPCs with the EPCIS report aggregation information for this pallet: Partial PA2 SSCC: _____ CA2 SGTIN: _____ Partial CA3 SGTIN: _____ CA6 SGTIN: _____ CA8 SGTIN: _____ EA5 SGTIN: _____ EA6 SGTIN: _____	N/A The EPCIS report contains the Pallet 2EPCs and the pallet aggregation data matches the physical pallet configuration. - CA3 is aggregated to PA2 CA7 is not aggregated to PA2 anymore. Jm 15JUN2020	EPCIS Serialization Report Identification: _____ _____ _____ Simulated Products Labels Location: _____ _____ _____

Comments / Additional Information


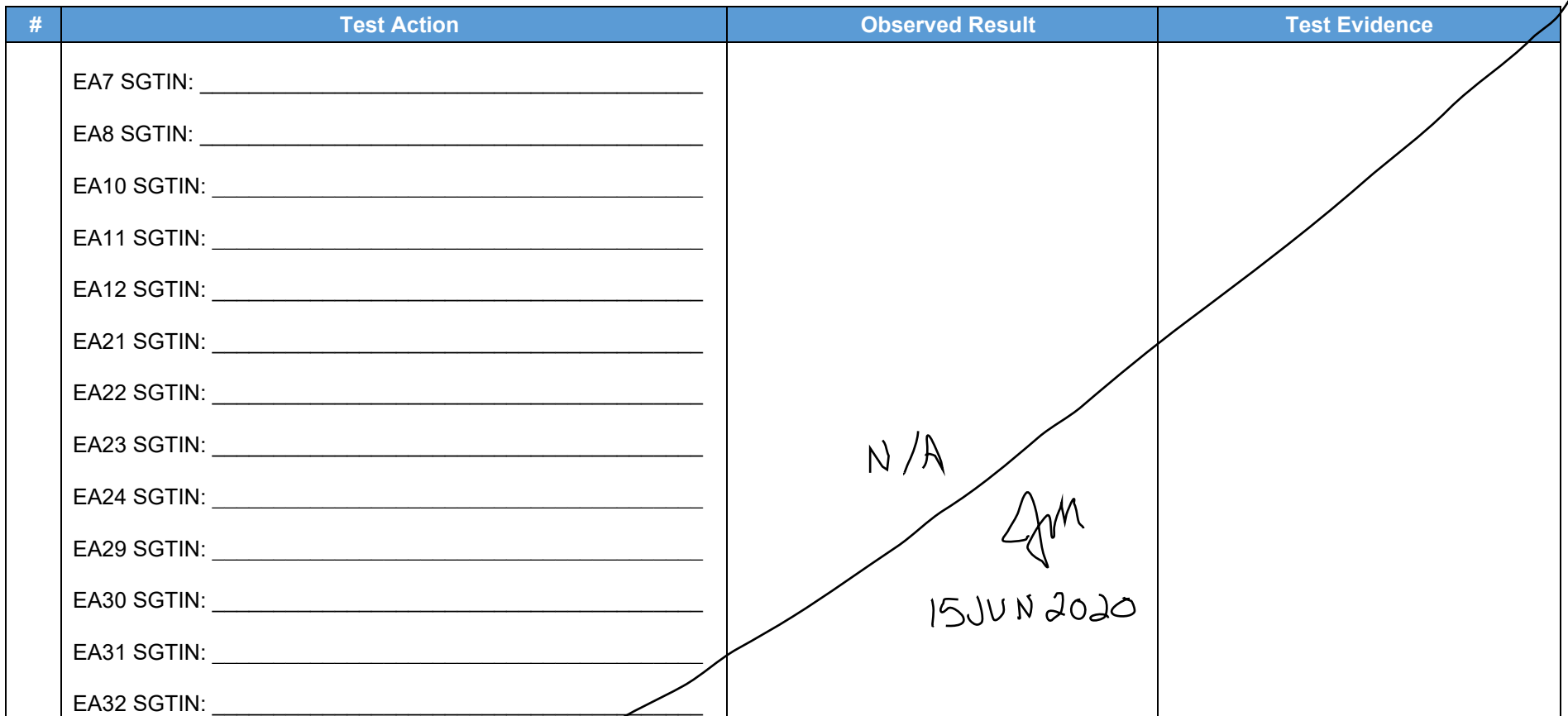
N/A

Performed by:

Date:

Reviewed by:

Date:

#	Test Action	Observed Result	Test Evidence
	EA7 SGTIN: _____	<p>N/A</p>  <p>15 JUN 2020</p>	
	EA8 SGTIN: _____		
	EA10 SGTIN: _____		
	EA11 SGTIN: _____		
	EA12 SGTIN: _____		
	EA21 SGTIN: _____		
	EA22 SGTIN: _____		
	EA23 SGTIN: _____		
	EA24 SGTIN: _____		
	EA29 SGTIN: _____		
	EA30 SGTIN: _____		
	EA31 SGTIN: _____		
	EA32 SGTIN: _____		

Comments / Additional Information			
			N/A <input type="checkbox"/>
Performed by:		Date:	
Reviewed by:		Date:	

#	Test Action	Observed Result	Test Evidence
Step 4: Final Reconciliation at Simulated Dispenser			
11.	Reconciliate the Pallet PA1 contents with the related EPCIS report.	The whole Pallet PA1 contents is logged in the related EPCIS report.	EPCIS Serialization Report Identification: _____ _____ _____ _____ Simulated Products Labels Location: _____ _____ _____
12.	Reconciliate the Pallet PA2 contents with the related EPCIS report.	N/A The whole Pallet PA2 contents is logged in the related EPCIS report. <i>Jm 15 JUN 2020</i>	EPCIS Serialization Report Identification: _____ _____ _____ _____ Simulated Products Labels Location: _____ _____ _____
Comments / Additional Information			
N/A <input type="checkbox"/>			
Performed by:		Date:	
Reviewed by:		Date:	

#	Test Action	Observed Result	Test Evidence
13.	Verify that there is no EPC in the Pallet PA1 EPCIS report that is not part of Pallet PA1. N/A	There is no EPC in the Pallet PA1 EPCIS report that is not part of Pallet PA1.	EPCIS Serialization Report Identification: _____ _____
14.	Verify that there is no EPC in the Pallet PA2 EPCIS report that is not part of Pallet PA2.	<i>JM</i> 15 JUN 2020 There is no EPC in the Pallet PA2 EPCIS report that is not part of Pallet PA2.	EPCIS Serialization Report Identification: _____ _____
Test End Date and Time (YYYY-MM-DD_HH-MM): 2020-06-15_16-29			

Comments / Additional Information

Tests could not be executed in whole due to lack of time. *JM* 15 JUN 2020

N/A

Performed by:

N/A

Date:

Reviewed by:

JM 15 JUN 2020

Date:

6. Test Phase Observations

Steps 5 & 6: At the end of each step, the items were verified. However, from the parents, changing UID statuses to "Destroyed" and "Sampled" via Kompano, or through the web interface. However, it was possible to change them to "Inactive". As a result, EA2 and EA9 were not destroyed but instead decommissioned, and EA3 was not sampled but also decommissioned.

15 JUN 2020

The tests from the present document could not be completed due to lack of time. The last executed action was the transfer of the EPCIS files to McKesson, which confirmed they were received correctly.

JM 15 JUN 2020

N/A

JM 15 JUN 2020

Documented by:

Julien G. Sauvageau

Date:

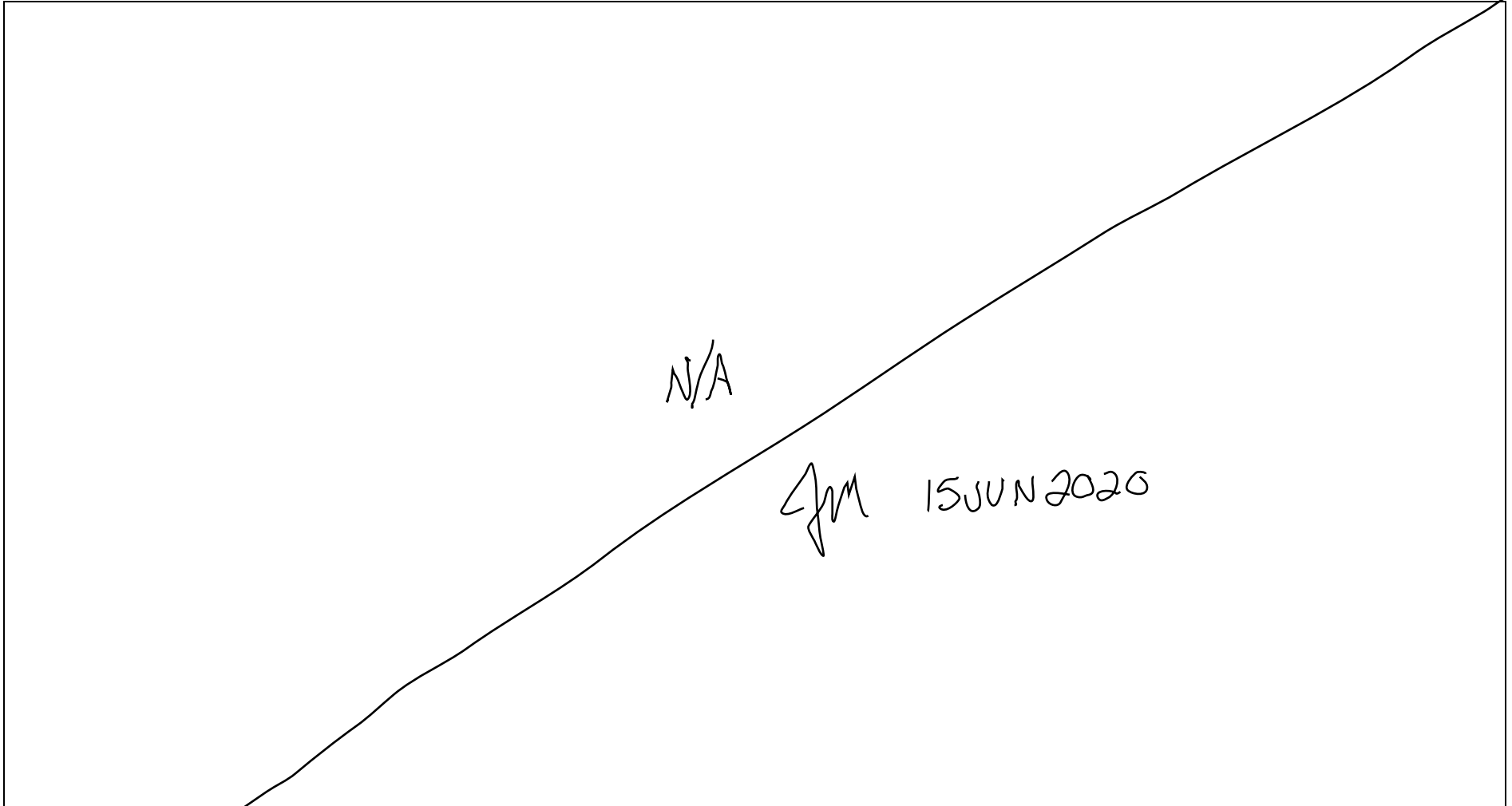
Reviewed by:

Gacinte Mongram

Date:

15 JUN 2020

7. Overall Pilot Project Observations



Documented by:

Date:

Reviewed by:

Date:

8. Review and Approval

The following signatures indicate that the persons have entirely reviewed these tests evidences and all supporting documents and agree that it is complete and correct.

Department	Printed Name	Signature	Date
Validation	Jacinthe Mongrain	<i>Jacinthe Mongrain</i>	15JUN 2020
		N/A	
		<i>JM 15JUN 2020</i>	