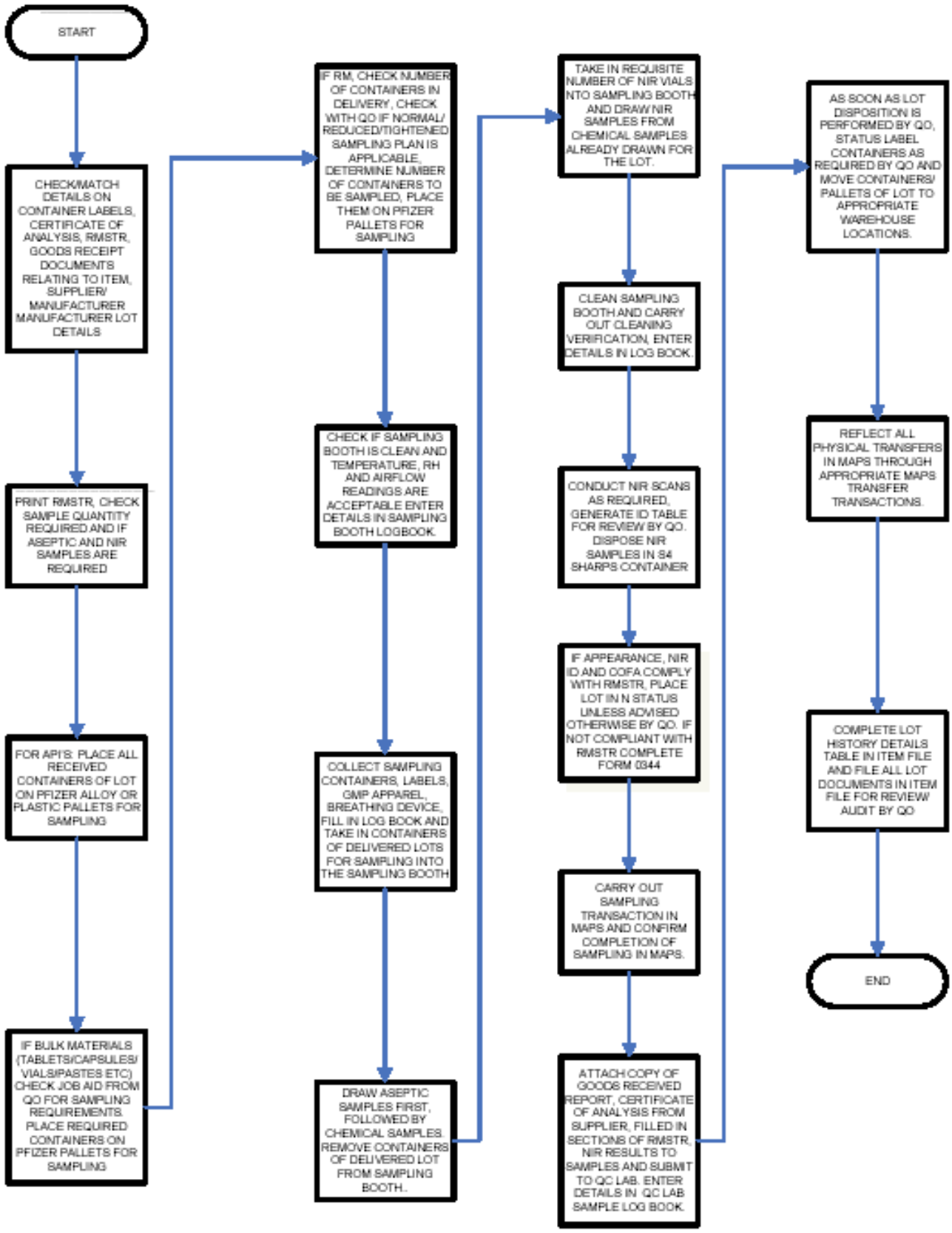
WAR-085

Appendix A: Flowchart for Process

5.5.5 Flowchart for Process



Appendix B: Form: Inspection of Goods on Delivery

Item No: _____ Receiving Date: ___/___/___

Description of Product: _____

_____ Identification Labels Printed _____

Receiving Use Only:

Receiving Statement:
"The description of the goods received matches the **Purchase Order**. The goods are in their original containers and marked with supplier details. There is **NO** physical damage, **NO** contamination evident, and **NO** soiling."

☐ Yes, I agree

Purchase Order No: _____

Supplier Name: _____

Receiving Report No: _____

Manufacturing Lot No: _____

MAPS Lot No: _____

Expiry Date: _____

Quantity Received: _____

No. of Pallets: _____

No. of Containers: _____

_____

Location: _____

Accept: ☐ Reject ☐ (Tick the appropriate box)

Comments: _____

_____

Signature: _____ Date: ___/___/___

Attach Identification Label Here

Sampling Use Only:

Laboratory Samples (if applicable): _____

_____

Revised Quantity: _____

Comments: _____

_____

Signature: _____ Date: ___/___/___

CHECKLIST

- **GO TO** S:\Document Control\RAW MATERIAL SPECIFICATION TEST REPORTS
- **PRINT** relevant RMSTR
- **READ** RMSTR

Legend: Y = Yes / N = No / NS = Not Shown	(Check) Delivery Docket	(Check) Container Labels	(Check) C of A	Comments
Description Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....
Grade Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....
Supplier Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....
Manufacturer Name Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....
Manufacturing Plant Correct?	Y / N / NS	Y / N / NS	Y / N / NS	.....
READ Lot Number on Containers. Does Lot Number Match?	Y / N / NS	Y / N / NS	Y / N / NS	.....
READ Manufacturing and Expiry Dates on Containers. Do they Match?	Y / N / NS	Y / N / NS	Y / N / NS	.....

Signature: _____ Date: ___/___/___

Appendix C: Form: OOS Verification for Raw Material ID Using NIR

This checklist is to be completed whenever sample verification for OOS / confirmation activities are required according to Section 5.5

Product/Item No: _____ Delivery Number: _____ OOS Report No.: _____

Sample Name(s): _____ Operator / Inspector: _____ Date: _____

Section A - Preliminary Results Assessment, see section 5.5.1 of SOP (To be completed by Sampling Operator/Inspector)		
1a	Is the Bruker System in working order and have the required samples been scanned?	Yes ☐ No ☐ if "No", comment and contact QO Lab
2a	How many samples in the set vary unexpectedly?	All ☐ >95% ☐ >75% ☐ >50% ☐ >25% ☐ <25% ☐
3a	Is the NIR within daily (PQ) and 6 monthly (OQ) diagnostics?	PQ: Yes ☐ No ☐ Date of OQ: Yes ☐ No ☐ last OQ diagnostics: _____
4a	Is workspace clean and the NIR window free from contamination?	Workspace clean? Yes ☐ No ☐ NIR window clean? Yes ☐ No ☐
5a	Is the operator trained?	Yes ☐ No ☐
6a	Is the sample labelled the same as the original material?	Yes ☐ No ☐ if "No", comment
7a	Check the sample and the sample vial.	Surface of vial free from contamination? Yes ☐ No ☐ Is sample free from air gaps? Yes ☐ No ☐ Is the scanning surface free from large particles? Yes ☐ No ☐ Appropriate volume of material? Yes ☐ No ☐
8a	Was there an assignable cause (was No ticked anywhere is Sections 3a-7a)?	Yes ☐ No ☐ if "Yes", comment

If "No" is ticked for any of the boxes, rectify the error before continuing to Section B.

Section B - Results Verification (To be completed by Sampling Operator/Inspector)		
1b	Were all original results confirmed after Confirmation Step 1?	Yes ☐ Go to Step 2B. No ☐ Go to Step 4B.
2b	Were all original results confirmed after Confirmation Step 2?	Yes ☐ Notify QO Lab No ☐ Go to Step 3B. N/A ☐
3b	Was an assignable cause identified and rectified in Section A?	Yes ☐ Go to Step 5B. No ☐ Notify QO Lab N/A ☐
4b	Was an assignable cause identified and rectified in Section A?	Yes ☐ Go to Step 2B. No ☐ Notify QO Lab N/A ☐
5b	Was the assignable cause system related?	Yes ☐ Rescan original samples No ☐ Resample all samples and scan If the rescanning above passes ID, have this form reviewed and approved before proceeding approval under 'N' status N/A ☐

_____ _____

Operator / Inspector Date