



OOS Verification for Raw Material ID Using NIR

(Ref. SOP WAR-085)

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 <input type="checkbox"/>	No <input type="checkbox"/> if "No", comment and contact QO Lab
2a	How many samples in the set vary unexpectedly?	All <input type="checkbox"/>	>95% <input type="checkbox"/> >75% <input type="checkbox"/> >50% <input type="checkbox"/> >25% <input type="checkbox"/> <25% <input type="checkbox"/>
3a	Is the NIR within daily (PQ) and 6 monthly (OQ) diagnostics?	PQ: Yes <input type="checkbox"/> No <input type="checkbox"/> OQ: Yes <input type="checkbox"/> No <input type="checkbox"/>	Date of last OQ diagnostics: _____
4a	Is workspace clean and the NIR window free from contamination?	Workspace clean? Yes <input type="checkbox"/> No <input type="checkbox"/>	NIR window clean? Yes <input type="checkbox"/> No <input type="checkbox"/>
5a	Is the operator trained?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6a	Is the sample labelled the same as the original material?	Yes <input type="checkbox"/>	No <input type="checkbox"/> if "No", comment
7a	Check the sample and the sample vial.	Surface of vial free from contamination? Yes <input type="checkbox"/> No <input type="checkbox"/> Is sample free from air gaps? Yes <input type="checkbox"/> No <input type="checkbox"/> Is the scanning surface free from large particles? Yes <input type="checkbox"/> No <input type="checkbox"/> Appropriate volume of material? Yes <input type="checkbox"/> No <input type="checkbox"/>	
8a	Was there an assignable cause (was No ticked anywhere in Sections 3a-7a)?	Yes <input type="checkbox"/>	No <input type="checkbox"/> 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 <input type="checkbox"/> Go to Step 2B.	No <input type="checkbox"/> Go to Step 4B.
2b	Were all original results confirmed after Confirmation Step 2?	Yes <input type="checkbox"/> Notify QO Lab N/A <input type="checkbox"/>	No <input type="checkbox"/> Go to Step 3B.
3b	Was an assignable cause identified and rectified in Section A?	Yes <input type="checkbox"/> Go to Step 5B. N/A <input type="checkbox"/>	No <input type="checkbox"/> Notify QO Lab
4b	Was an assignable cause identified and rectified in Section A?	Yes <input type="checkbox"/> Go to Step 2B. N/A <input type="checkbox"/>	No <input type="checkbox"/> Notify QO Lab
5b	Was the assignable cause system related?	Yes <input type="checkbox"/> Rescan original samples No <input type="checkbox"/> 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 <input type="checkbox"/>	

Operator / Inspector

Date