Complying points 21 CFR

Test Point	Description/ section	Question	Answer Yes	No	N/A	Comments
Validation						
1	Instrument Verification	Is all validation documents supplied with system? Are those documents in-line with the system.				System is supplied with all the Qualification and validation documents.
Control of Identification						
2	User Policy	How does instrument indentifies the unique USER?				Software requires UserID (Unique for the user) and Password.
3	Password Policy					
	a. Password Length	Minimum password length				
	b. Password Complexity	How does system ensures that the password is complex.				Password complexity is implemented by Password must have 1 Uppercase letter, 1 Number and 1 Special Character.
	c. Account lockout /Unauthorized Access protection	Has it been ensured that the account Lockout (after 3 invalid password entries – Message appears on the display and the account is disabled) is activated				After 3 incorrect attempts a message is displayed , saying that the user is deactivated due to too many failed login attemnpts.
	d. Password Check	Has it ben ensured that two persons will never have the same combination of user ID & Password?				The instrument does not allow the same combination of User ID password Twice.
	e. Password Disabling	Has it been insured that accounts which are disabled still remain in the instrument Without access rights?				The corresponding user can be rmoved from the system by the administrator but remains saved in the system as part without any access rights.
4	Password privacy Password change	Has it been insured that the user must be able to change				The corresponding uesr can change the

		his password					password. After the creating the new user , the password of this new user has to be changed after the first login.

Instrument Access Control

5	Login, Access, Authorization user	Are security mechanisms in place to limit the instrument access to entitled persons?					Software ensures that every identity (User ID/ Password) is used only once. Modification of names can be done by the administrator. The guideline for the whole organisation(creating of user ,using password ,length period of validity)are owner responsibilities.
6	Login, Access, Authorization User	Dose the instrument ensure that only persons, who are authorized, can use the instrument and all function of the instruments (export, print, electronic signature, Audit, trail….?)					The software provides different user levels. The administrator of the instrument must take care that access rights are assigned to authorized persons only. All the changes of access right are recorded in the audit trail.

Audit Trail

7	Generating an Audit Trail	Dose the instrument generate an audit trail. Which records all changes?					The Audit trail document all user entries and action on electronic records with date and time. All modification of security setting, system setting and user setting are recorded in the audit trail.
8	View the Audit Trail	Is the audit trail data available in readable form and position to forwarding to authorities?					The audit trail can be exported as a pdf-file or as an excel file with checksum and forwarded to authorities. Via this checksum, the intigrity of the audit trial can be verified
9	Printout of the Audit Trail	Is it possible to print out the audit trial data in a readable form?					The audit trail can be printed out by the instrument.
10	Export and Archiving the	Is the audit trail data available in readable form					The audit trail can be exported as a PDF file or

	Audit Trail	for export and also available electronically during the archiving period?				as an excel file with a checksum, Via this checksum, the integrity of audit trail can be verified and forwarded. The owner is responsible for archiving the audit trail.
Electronic records						
11	Status	Can the status of record (valid or not valid) be differentiated				Whether the record is valid can be seen on the display of the instrument and in the data memory.
12	Reporting, Print out of electronic record	Can complete and precise copies be provided in a readable form from electronic records?				Configurable reports can be printed out. The automatic print out at the end of an analysis can be define each print out is accompanied by a time stamp.
13	Reporting, printout of electronic record	Can complete and precise copies of the records be forwarded to the authority?				All reports can be provided in the pdf format and can be forwarded to the authorities.
14	Deleting of electronic record	Is it impossible to delete the electronic records at the level "operator" (lowest access right level)?				The software of the instruments does not allow the deletion of electronic records.
15	Change of Electronic Record	Is a change of the records (Measured Data) for any user prohibited?				The software does not allow any changes of measured records.
16	Training maintenance	Are the person who develop, maintain& use the instrument sufficiently qualified are skilled in order to carry out the task assigned?				The owner of the instrument is responsible for the training of the user and administrators. The people who are trained during the installation are listed in qualification instruction
Backup / restore						
17	Backup/Restore	Does the instrument allow the creation of instrument backup and restore?				There is backup function for : Global setting, method settings,user management and Adjustments.