

Ethanolamines/Glycol Ethers

In Plant Training (IPT)

Section Number :5A

Issue Number :1.2

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Section Test :8

Loading Familiarization Certificate of Analysis

Answers:

1. **Explain what a certificate of analysis is.**
It is a document generated using analytical data derived from a shipment sample.
2. **State the purpose of the certificate of analysis.**
To confirm or certify the product shipped meets the sales specification or the customer specification.
3. **State where you would find the test items that should appear on the certificate of analysis.**
Tier two and the specification book.
4. **State why certificates of analysis differ.**
Each product has its own specific certificate. Customer specific certificates of analysis are tailored to the customers requests.
5. **State when a certificate of analysis should be generated.**
When all analysis are complete and the data is entered into the computer.
6. **State when you would not generate a certificate of analysis.**
Never, every shipment or lot number will have a certificate of analysis created for that particular analysis. Remember, our products have up to 18 months self life and certificates of analysis can be obtained at anytime during that period. (national formulary retention is 4 years plus current)
7. **State how a certificate of analysis can be obtained 6 months after shipment.**
The computer will search for the certificate of analysis by the lot and Dow order numbers. To search for a certificate of analysis you must have either the lot number or the shipping invoice number.
8. **Explain why a lot number cannot be changed on a certificate of analysis.**
If the lot number is changed and the certificate of analysis is questioned by the customer, the original sample will be difficult to find.

9. **State how you would know if the certificate of analysis is to be customer specific.**
By checking the PI number.
10. **State the first thing to do if the certificate of analysis if to be customer specific.**
First you must look at the customer spec sheet. There may be additional analysis, or additional information concerning the product to appear on the certificate of analysis. Be sure the certificate of analysis reflects the spec sheet!
11. **State what should be done if the customer spec is not built into the lab program.**
You must contact a LIMS system manager to build the customer spec. Once it is built, you no longer have to build or generate the certificate of analysis customer specific, it will be permanently fixed in the computer.
12. **State what should be done if the customer spec is already built into the system.**
Analyze the product and enter the data in the computer under the spec number and the certificate of analysis should automatically print customer specific. Be sure the certificate of analysis matches the customer spec sheet before shipping, mailing or faxing.
13. **State what is to be done if a customer request additional testing but does not have a customer spec.**
Let the production supervisor know about it so he/she may work on a customer spec if this should become a routine purchase. Run the additional test if production supervisor instructs. Input all the data and generate a certificate of analysis for that product. To include the additional test, you have to edit the certificate of analysis and add the test and test results.
14. **State how certificates of analysis are handled for samples at shipping and receiving.**
A certificate of analysis is generated in the same manner as a shipment sample. Each COA is faxed to receiving for any order that calls for a COA.

Revisions:

No. 1	07-08-93	Yearly review
No. 2	12-12-94	Adjusted answer to # 7 as instructed. added "contract a LIMS system manager" in answer to # 11. replaced QAC with production super. & added working "production supervisor instructs" in # 13. added last sentence to # 14. deleted #'s 15, 16 & 17
No. 3	12-12-95	Yearly review, no changes.
No. 4	02-22-96	Yearly review, no changes.