Optical Appearance of EDTA in VACUETTE® Tubes

Additives are present in different forms; powder, granulate or solution. They all should meet the requirements of international societies and/or standards.

EDTA SPECIFICATION

GBO uses potassium EDTA (purity >99%) which conforms to the requirements of the international standard ISO 6710:

"Blood concentrations of ethylenediaminetetra-acetic acid (EDTA) shall be within the range of 0,004 11 mol/l to 0,006 84 mol/l. That means, for the free acid (M = 292,24 g/mol), there should be 1,2 mg to 2 mg EDTA per mllilitre of blood.

Current EDTA compounds for application in blood collection tubes are, for example, ethylenediaminetetraacetic acid dipotassium salt dihydrate, K2-EDTA (CAS: 25102-12-9, M = 404,45 g/mol), ethylenediaminetetraacetic acid tripotassium salt dihydrate, K3-EDTA (CAS: 65501-24-8, M = 442,54 g/mol) […]"[1]

EDTA is a chelating agent of ions, thus inhibiting the coagulation process by binding Calcium upon mixing with blood.[2] The powder form is usually white to lightly yellow[3], and the stock solution is prepared with H_2O at room temperature. Because the solubility is low in water, the pH is adjusted with chemicals (including potassium) to improve solubility and accelerate dissolving.[4] This can lead to a slight yellow colouring of the primary chemical; the more potassium that is present, the more yellow discoloration of the solution.

For correct functioning of the product, the final solution must however have the properties as described in the ISO 6710, as stated before.

Quality Control

Potassium is measured during quality control and must be within a certain range. An additional test was carried out for EDTA tubes by complexometric titration with zinc sulfate to evaluate the actual concentration of EDTA in mg/ml by the end of the shelf-life. All parameters where within defined tolerances.[5]

PRODUCTION

The solution is dosed by nozzles which spray the additive into the tubes at the right amount depending on the actual tube size i.e. desired fill volume. A drying process leaves the dehydrated salts on the tube walls.

The droplet size is an effect that increases with draw volume. The more additive spray-dried into the tubes, the better the visibility of the crystallization of the additive. Occasionally these crystals can even reach a size that is visible as yellow dots.

FINDING

The detailed information leads to the statement that the discolouration is an optical phenomenon caused by ions which enhance the solubility leading to an optimum dosing of the potassium EDTA. It does not influence the function of the additive nor performance of the tube in any way.

PERFORMANCE STUDIES

See studies on https://www.gbo.com/de_AT/know-how-services/download-center.html

(See also the official instructions for use: 980200)

- Comparison of VACUETTE® K2EDTA and VACUETTE® K3EDTA Tubes
- Evaluation of VACUETTE® K2EDTA Evacuated Blood Collection Tube for Immunohematology
- Evaluation of VACUETTE® K2EDTA Evacuated Blood Collection Tubes Using the Immucor® ABS2000
- Evaluation of VACUETTE® K2EDTA Gel Tubes for Molecular Diagnostics
- Evaluation of VACUETTE® K3EDTA and K2EDTA Evacuated Blood Collection Tubes for Viral Marker Testing
- Evaluation of VACUETTE® K3EDTA and K2EDTA Evacuated Blood Collection Tubes Using the ID-Micro Typing System(TM) (ID-MTS) Gel Test(TM)
- Evaluation of VACUETTE® K3EDTA and K2EDTA Evacuated Blood Collection Tubes using the Olympus® PK 7200(TM)
- Evaluation of VACUETTE® K3EDTA Evacuated Blood Collection Tube Using the Immucor® ABS 2000
- Evaluation of VACUETTE® K3EDTA Evacuated Blood Collection Tubes for Immunohematology

REFERENCE LIST

This information will not be passed on because it also contains proprietary information such as internal testing and supplier information.

1. International Organization for Standardization ISO. ISO 6710:2017 Single-use containers for human venous blood specimen collection. *Norm*. 2017;2Second Ed:23.
2. Banfi G, Salvagno GL, Lippi G. The role of ethylenediamine tetraacetic acid (EDTA) as in vitro anticoagulant for diagnostic purposes. *Clin Chem Lab Med*. 2007;45(5):565-576. doi:10.1515/CCLM.2007.110
3. Zertifikat_HC2131_5D372F38.pdf.
4. EDTA dipotassium salt dihydrate BioChemica. *ITW Reagents*. 2011;A4220:20110208.
5. STA-14GBO49_Test report.