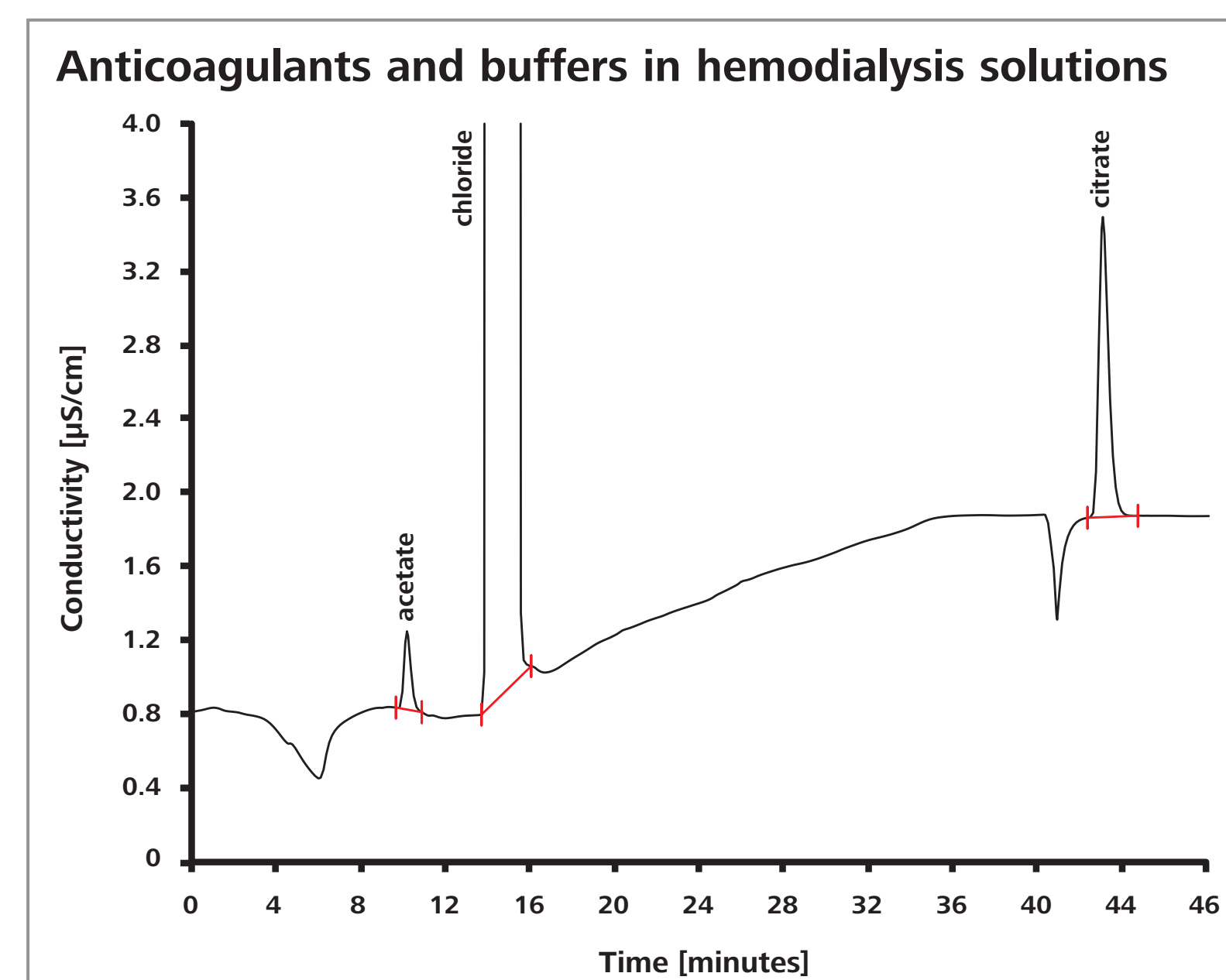


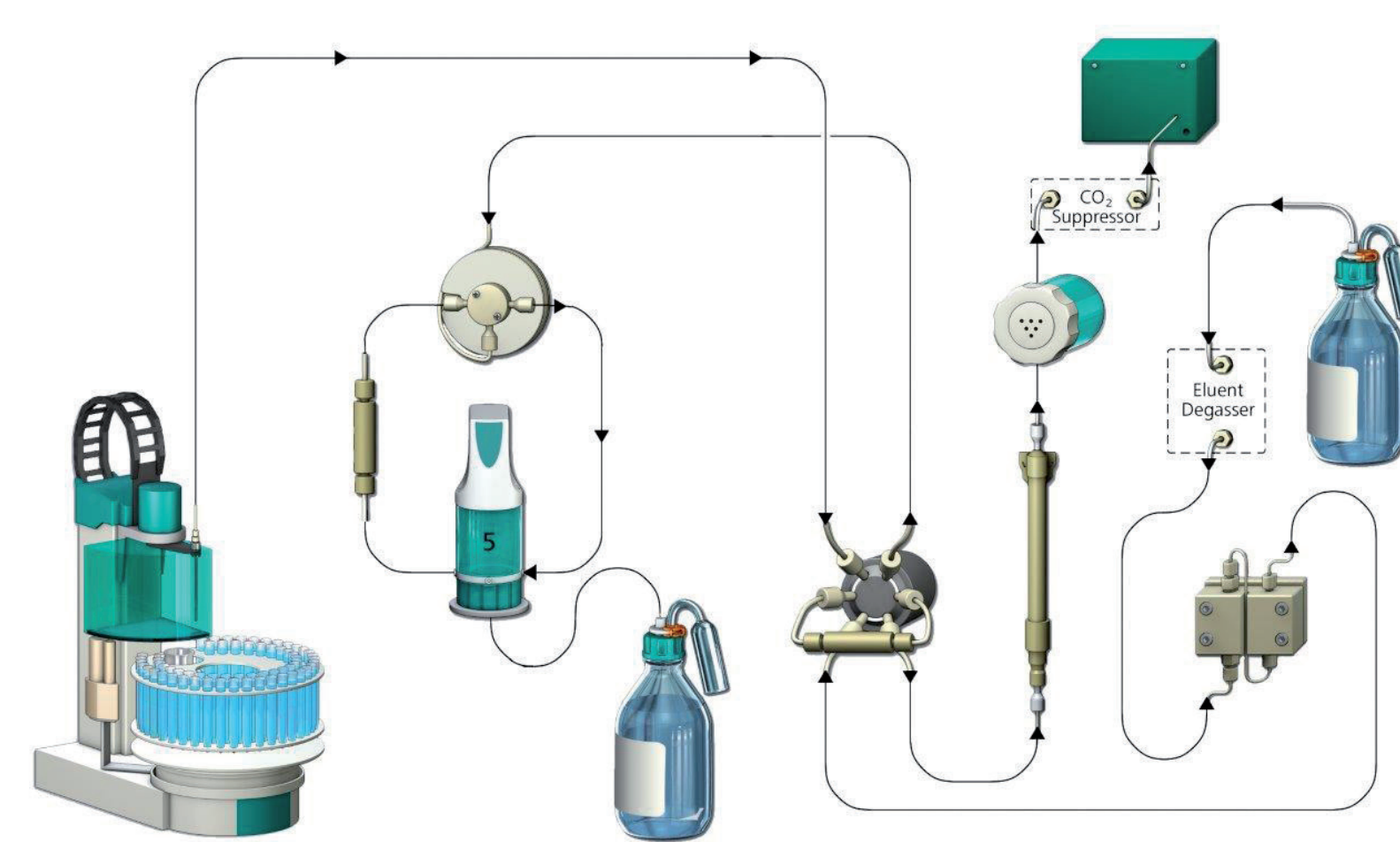
## Pharmaceutical solutions

Pharmaceutical solutions denote isotonic, hemodialysis, or infusion solutions, containing ingredients in concentrations of several orders of magnitude. IC accomplishes their analyses precisely and with short running times. Thereby, intelligent analytical procedures and Inline Sample Preparation (MISP), e.g., Matrix Elimination (ME) or Preconcentration (MiPCT), imply minimal efforts.

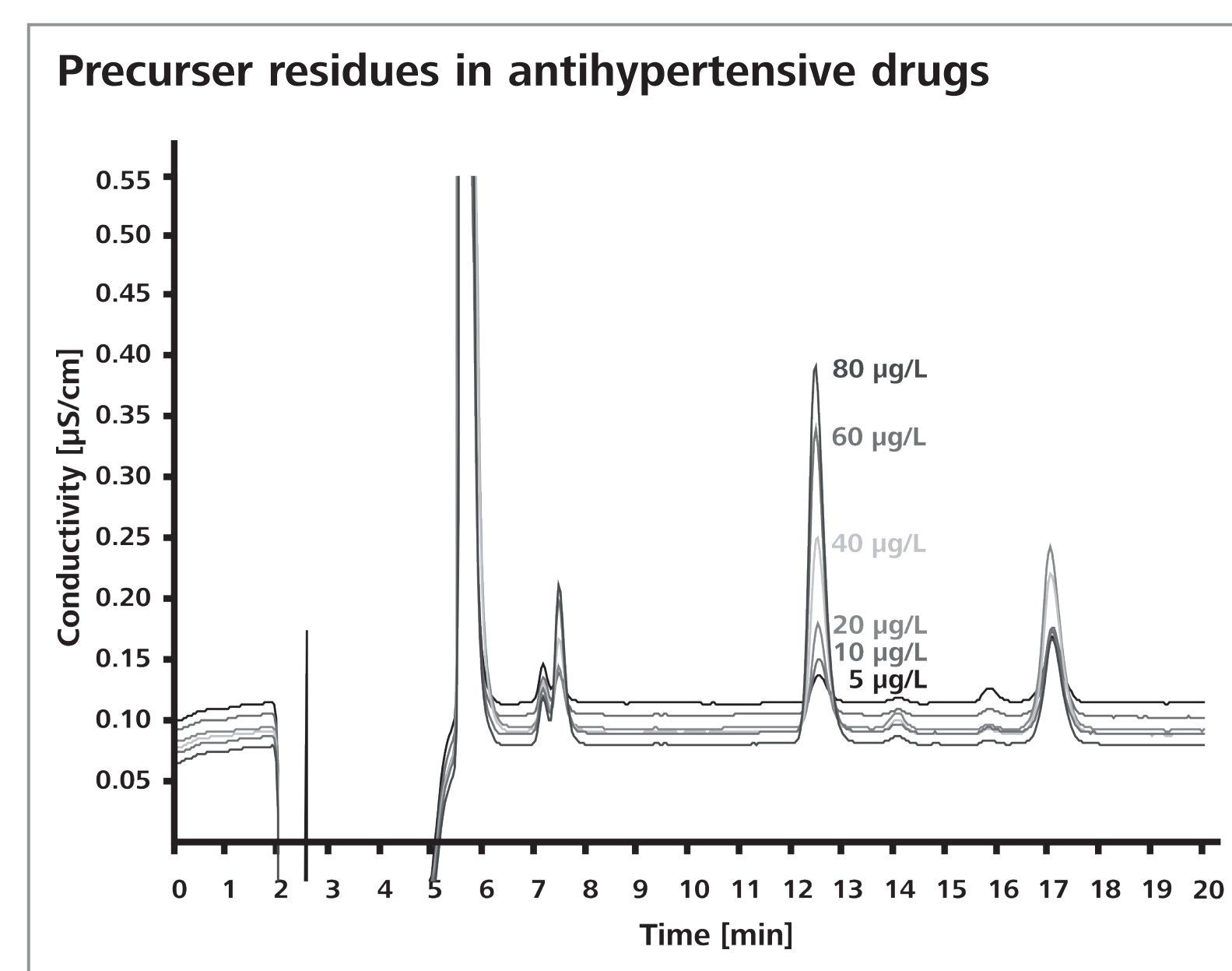


Acetate and citrate in diluted hemodialysis solution measured on a Metrosep A Supp 7 - 250/4.0 using a Na<sub>2</sub>CO<sub>3</sub>-gradient and conductivity detection after sequential suppression.

### Metrohm intelligent Preconcentration Technique (MiPCT)

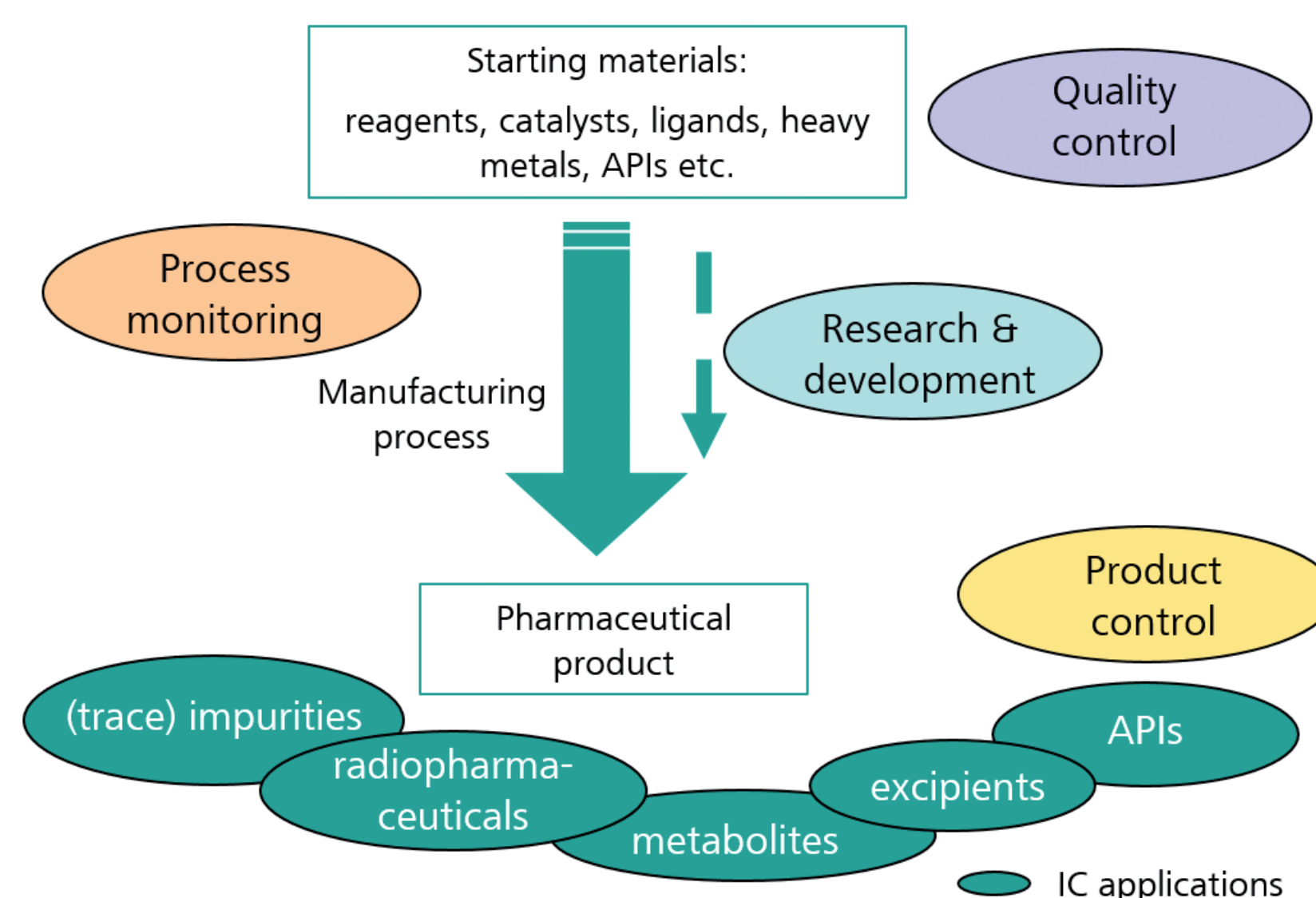


## Impurities



Impurities are mainly introduced from the starting materials used and/or during synthesis of the APIs. They are monitored according to the pharmacopeias. Generally, their concentration is very low, and therefore analysis at trace levels is required, involving Inline Sample Preparation (MISP).

## Production of pharmaceuticals



## IC – a pharmaceutical standard method

Pharmaceutical analysis guarantees drug safety by providing information on the identity, content, quality, purity, and stability of pharmaceutical products using analytical chemistry. Ion chromatography (IC) offers a broad range of pharmacopeia-compliant applications for quality control, monitoring, and improving drug manufacturing.

As a very accurate and versatile technique, IC meets the requirements of many pharmaceutical applications. IC is a USP-accepted standard method for the determination of active pharmaceutical ingredients (APIs), excipients, impurities, pharmaceutical solutions as well as pharmaceutical starting materials, finished pharmaceutical products (FPPs) and even body fluids.

IC supports the analysis of several substances within a very short time and in a single analysis distinguishing chemically similar analytes in mg/L to even µg/L levels. Thereby, interferences caused by the sample matrix can be efficiently eliminated by specific Inline Sample Preparation (MISP) tools and the use of appropriate detection methods (see table below).

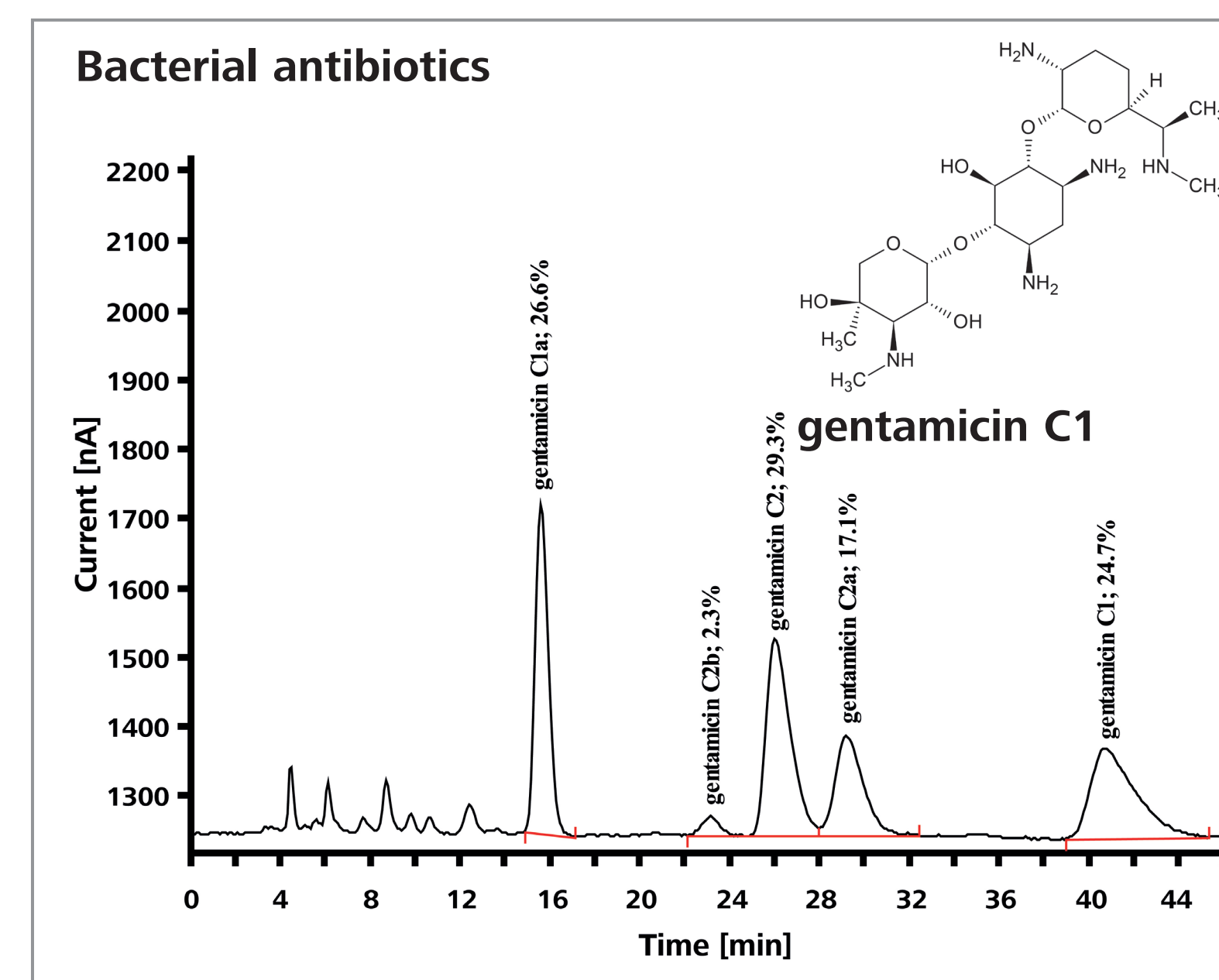
Irbesartan sample spiked with 5–80 µg/L azide; column: Metrosep A Supp 10 - 250/4.0; eluent: 5 mmol/L Na<sub>2</sub>CO<sub>3</sub> and 5 mmol/L NaHCO<sub>3</sub>; Inline Matrix Elimination (ME) with 70:30 (v/v) methanol/water and followed by suppressed conductivity detection.

Chromatogram with peaks of the radio-tracer [<sup>18</sup>F]FDG and the impurity chlorodeoxyglucose analyzed on a Metrosep Carb 2 - 150/4.0 using 0.1 mol/L NaOH and pulsed amperometric detection (PAD).

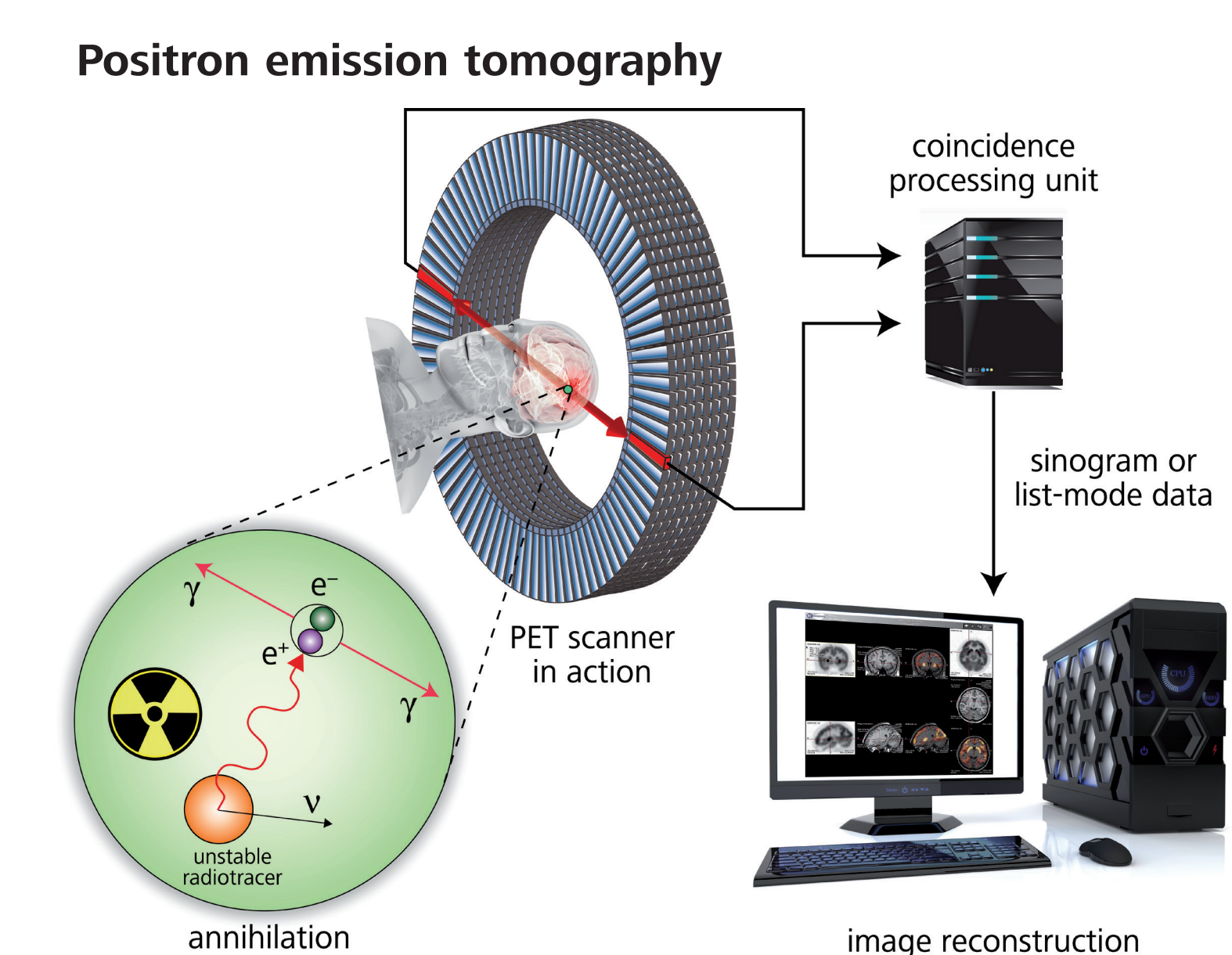
Radiopharmaceuticals are radioactive substances used for 3D-imaging in nuclear medicine to study biochemical and physiological processes. [<sup>18</sup>F]Fluorodeoxyglucose ([<sup>18</sup>F]FDG) is commonly used as radiopharmaceutical in positron emission tomography (PET), e.g., to explore cancer metastasis or brain mapping. Radio IC is a flexible and safe high-performance method to control the purity of radiochemicals.

## Active pharmaceutical ingredients (APIs)

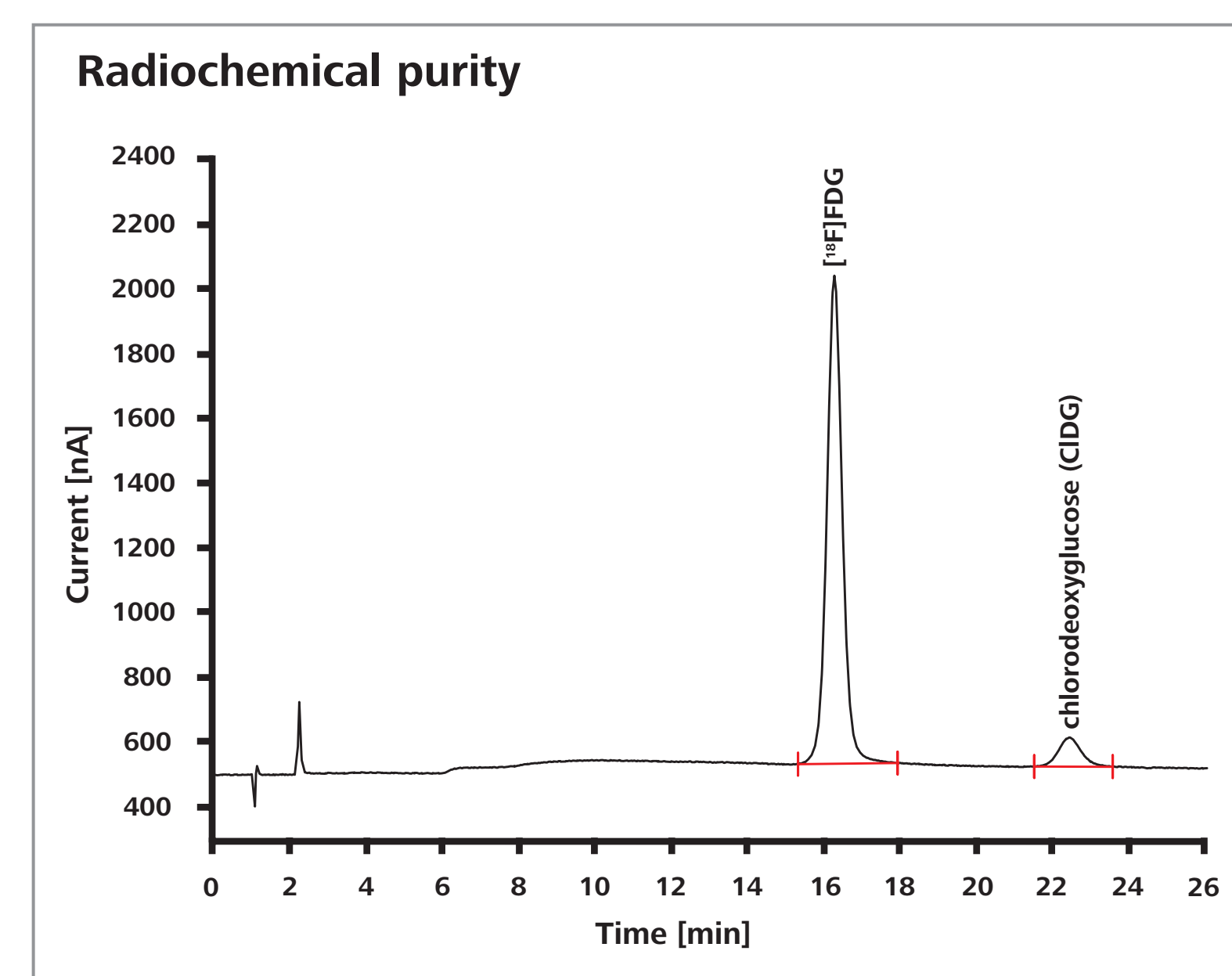
APIs are used to cure, alleviate, prevent, or identify illnesses and diseases. They are present in small quantities and aim at restoring physiological functions in human beings. Prominent examples are gentamicin, neomycin, and cefadroxil. With IC, these ingredients can be accurately determined in accordance with the US Pharmacopeia (USP) and the European Pharmacopoeia (Ph. Eur.).



Separation of gentamicin analogs on a RP-S column (Polymer Laboratories) applying post-column addition of 300 mmol/L NaOH with pulsed amperometric detection (PAD).



## Radio IC



## Further applications for pharmaceutical use of IC

	Pharmaceutical solutions	APIs/antibiotics	Impurities
<b>Conductivity detection</b>	Ca <sup>2+</sup> , citrate, Gd <sup>3+</sup> , K <sup>+</sup> , Na <sup>+</sup> , Mg <sup>2+</sup> , phosphate	Bethanechol, binding capacity of phosphate, camphorsulfonic acid, dicyclopropylmethylamine, ibandronate, K <sup>+</sup> , N-methyl-D-glucamine (meglumine), piperazine, Zn <sup>2+</sup>	Amines, azide, bromide, Ca <sup>2+</sup> , diethyl sulfate, dimethyl sulfate, EDTA, hydrazine, K <sup>+</sup> , Li <sup>+</sup> , Mg <sup>2+</sup> , monomethyl-/dimethylamine, Na <sup>+</sup> , N-methylpyrrolidine, Rb <sup>+</sup> , tetrabutylammonium
<b>Pulsed amperometric detection (PAD)</b>	Amikacin sulfate, streptomycin sulfate	Adrenaline, β-cyclodextrin, ephedrine, gentamicin, kanamycin sulfate, neomycin, norephedrine, pseudoephedrine, ribitol	Cyanide, propargyl alcohol, propylene glycol
<b>UV-VIS</b>	Zinc oxide	Amoxicillin, cefadroxil, ibuprofen, paracetamol, ranitidine hydrochloride, theophylline, thiamine hydrochloride, valerophenone, vitamin C	EDTA, salicylic acid, valerophenone