What are the requirements for the quality of water used in the last steps of the synthesis and reported on the CEP 2.0?

Answer:

The choice and definition of the grade of water to be used should be based on the EMA "Guideline on the quality of water for pharmaceutical use (EMA /CHMP/CVMP/QWP/496873/2018)" and the relevant Ph. Eur. monographs, namely potable water, purified water, water for injections or water for preparation of extracts. Terms such as deionised water, process water, drinking water, reverse osmosis water, distilled water, etc. should not be used as they are not referenced in the EMA guideline.

For potable water, confirmation should be provided that the quality is equivalent to that defined in Directive (EU) 2020/2184 or in WHO guidelines.

For purified water and water for injections, specifications in line with the corresponding Ph. Eur. monographs *0008* and *0169* are expected. If the specification does not meet these requirements, the quality is reported as potable water on the CEP 2.0.

For water used for the manufacture of extracts, specifications in line with Ph. Eur. monograph *2249* are expected.

The quality of the water used in the last steps of the synthesis is reported on the CEP 2.0 to enable CEP users to confirm the suitability of the substance /product quality for its intended use.