

STATEMENT ON THE POTENTIAL PRESENCE OF NITROSAMINES

3402 *POTASSIUM DIHYDROGEN PHOSPHATE parenteral GMP

Based on our current knowledge of the raw materials and our processes regarding the potential presence of nitrosamines in the product referenced above, we hereby confirm the following:

- The manufacture process does not include nitrite salts, alkyl nitrites or any other nitrosating agent.
- Neither the manufacture process nor the raw materials do not include secondary amines, tertiary amines, quaternary alkyl ammonium salts or alkyl amides e.g. DMF, DMAc, NMP, TEA, DIPEA, NMM, TBA, etc.
- Nitrites (NO₂-) or nitrates (NO₃-) are not potentially present in any raw materials used, including water.
- No potential presence of nitrosamines in any of the materials used in the manufacturing process (raw materials, reagents, solvents...) is identified.
- Neither catalysts nor solvents other than water, including amide solvents, are involved in the manufacturing process.
- Neither solvents nor organic products are used the equipment cleaning.
- No amines or ammonium salts can be formed during the manufacturing process of the product.
- No nitrosamines are handled in the facilities (including manufacturing plant and equipment)

Nitrosamines are not expected to be formed during the manufacturing process of the product referenced above.

Esparreguera, January 20th 2025

Laia Galitó
Regulatory Affairs Specialist

