



Sodium ascorbate

The stabilizer of choice for radiopharmaceuticals

Sodium ascorbate is a highly effective antioxidant that acts as a free radical scavenger, neutralizing reactive species, and protecting radiopharmaceuticals against degradation.

Radiopharmaceuticals are specialized pharmaceutical preparations that contain radioactive isotopes for use in both diagnostic imaging and targeted therapies. Their ability to deliver ionizing radiation directly to diseased tissues – particularly in oncology – enables precise treatment of diseased cells, while minimizing collateral damage to surrounding healthy tissue. Radiopharmaceuticals are increasingly central to innovation in precision medicine. However, their development faces a unique set of challenges related to their logistics, including difficult supply chains, due to the short half-lives and instability of many radioisotopes, cost, and complexity in administration. Stability is the most critical challenge, as products break down over time due to radiolysis, creating free radicals that can degrade the pharmaceutical, compromising its purity, efficacy, and safety.

Enhance stability with sodium ascorbate

Addressing these challenges requires thoughtful formulation strategies, including the addition of stabilizers, such as antioxidants, to improve product stability. Sodium ascorbate is a highly effective antioxidant that acts as a free radical scavenger, neutralizing reactive species, and protecting radiopharmaceuticals against degradation. This not only preserves the product's integrity but also extends its shelf life.^{1,2}

What does sodium ascorbate bring to your formulation:

- Protects the compound from radiolysis, helping to maintain radiochemical purity more effectively than other stabilizers³
- Demonstrates efficacy across a wide range of radioisotopes, making it broadly applicable in various radiopharmaceutical formulations
- Easy to integrate into manufacturing processes due to its high water solubility, near-neutral pH, and robust chemical stability – advantages over less soluble or more pH-sensitive alternatives
- Compatible with other stabilizers, allowing for synergistic effects that further enhance overall formulation stability
- Offers a well-established safety profile and broad regulatory acceptance, reducing risk compared to less-studied alternatives.

Quality is key

The use of high-quality sodium ascorbate in radiopharmaceuticals is vital, as it directly impacts the end product's safety, efficacy, and regulatory approval. As radiopharmaceuticals are administered directly into the body, any impurities or degradation byproducts – such as those formed through radiolysis – can pose serious health risks, including allergic reactions, toxicity, infections or unintended damage to healthy tissues. In diagnostic applications, poor-quality ingredients may lead to unclear or low-resolution imaging, which can compromise clinical decision-making. In therapeutic settings, suboptimal ingredient quality can reduce the ability of the radiopharmaceutical to deliver an effective radiation dose to the target tissue, and potentially increase exposure to the surrounding healthy tissue. Using high-purity sodium ascorbate helps minimize these risks by stabilizing the formulation and preventing the formation of harmful byproducts.

Excipients used in radiopharmaceutical formulations may contain trace metal impurities, which are particularly concerning because they may interfere with radiolabeling process. These metals can directly compete with the desired radioisotope for binding sites on the chelating agent or carrier molecule, potentially reducing labelling efficiency and product effectiveness. Additionally, many biologically active molecules in these formulations are sensitive to oxidation, and the presence of metal contaminants can catalyze oxidation reactions. Even at very low concentrations, trace metals can promote the formation of free radicals, which in turn can also cause oxidative damage to key formulation components, ultimately impacting the stability, safety, and performance of the radiopharmaceutical.

The dsm-firmenich difference

Our sodium ascorbate is a high-quality antioxidant manufactured in Europe to Pharma GMP standards according to ICH Q7 guidelines and supported by a robust quality and regulatory documentation package, compliant with both the European (Ph.Eur.) and the United States (USP) pharmacopeias.

We also offer a worldwide team of quality and regulatory experts dedicated to pharma, and formulation specialists to help our customers realize the full potential of our sodium ascorbate.

Beyond pharma compliance, we help drive sustainable progress through sustainability expert services that can include Life Cycle Assessment (LCA) expertise, transparent data sharing, and tailored support for sustainability targets, certifications, emission calculations, and co-developing sustainable solutions.

Our offering is backed by a robust and resilient supply chain, to help our customers maintain not only operational stability, but ensure that radiopharmaceuticals can reliably reach patients who depend on them.

From solving tough formulation issues to unlocking new possibilities, we're ready to elevate your drug product's potential. Partner with dsm-firmenich to find a solution.



Contact us now to see how we can help you achieve your radiopharmaceutical formulation goals.

1. Smith et al, J Transl Med 2017, 15, 232; 2. Bioconjugate Chem 2003, 14, 5, 1052–1056; 3. Manabe et al, ACS Omega 2021, 6, 14887–14895.

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