

NITROSAMINE STATEMENT

Background:

Nitrosamines or N-nitrosamines refer to any molecule containing the nitroso functional group according to the World Health Organization (WHO). These compounds are of concern because they are potential human carcinogens. It was unexpected that these compounds were found in approved drugs like angiotensin II receptor blockers (ARBs) and Melfomin. Due to this, the European Medicines Agency (EMA) finalized a review of Regulation (EC) No. 726/2004 in June of 2020 providing guidance to marketing authorization holders (MAH) on how to prevent and detect nitrosamine impurities in human drug products. The Assessment Report EMA/369136/36/2020 was published in June 2020 and adopted by the Committee for Medicinal Products for Human Use (CHMP).

The Food and Drug Administration (FDA) put out the position guidance; *Guidance for Industry: Control of Nitrosamine impurities in Human Drugs* published in February 2021. This document recommends steps that manufacturers of active pharmaceutical ingredients (API) or final drug products should take to prevent and detect unacceptable levels of these compounds being present in final drug products.

GeminiBio Statement

GeminiBio does not manufacture API or final drug products but does serve the pharmaceutical market with ancillary reagents used in the manufacture of drug products and takes seriously the health risk that nitrosamines can cause. GeminiBio can state that nitrosamines are not primary raw materials of product contact surfaces nor are they introduced into the manufacturing process of the products listed above. To the best of our knowledge, nitrosamines are not a component in the raw materials that GeminiBio purchases from our suppliers.

Signed by:

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Signing Reason: I approve this document
Signing Time: 13 June 2025 | 10:55 PDT
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