

Statement

Regarding: Nitrosamines in Sepax™ C-Pro and Sefia™ S-2000 single use kits and accessories

Background

According to the World Health Organization (WHO), nitrosamines are any compound containing a nitroso (NO) functional group. These compounds are of concern because they are potential carcinogens. Nitrosamine is formed when secondary or tertiary amines react with a nitrosating agent. The most common source of nitrosating agents is sodium nitrite.


EMA finalized a review under Article 5(3) of Regulation (EC) No 726/2004 in June 2020 to provide guidance to marketing authorization holders on how to avoid presence of nitrosamine impurities in human medicines. Assessment report EMA/369136/2020 "Nitrosamine impurities in human medicinal products" as adopted by the CHMP was published on 25 June 2020.

FDA Guidance for Industry "Control of Nitrosamine Impurities in Human Drugs" published in September 2020 recommends steps manufacturers of APIs and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

Statement

It is hereby stated that nitrosamines are not primary raw materials of wetted components of the products listed below, however assessment currently on-going.

Product/Part name	Product number
CT-49.1 – Sepax cell separation kit - Box of 6 Units	29264738
CT-60.1 – Sepax cell separation kit - Box of 6 Units	29264739
CT-90.1 – Sepax cell separation kit - Box of 6 Units	29264740
CT-300.1 – Sefia cell processing kit - Box of 8 Units	29284866
CT-800.1 – Sefia cell processing kit - Box of 8 Units	20001
CPAK-100 - Box of 60 Units	29275109
CPAK-101 - Box of 60 Units	29275108

Signature: 	Date: 7 February 2023
Name: Henrik Norberg	Title Customer Regulatory Support Leader



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