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CVR Number 13246149

To Whom It May Concern

ELEMENTAL IMPURITIES

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This statement is covering the following cGMP manufactured FeF Benzalkonium Chloride products:

FeF Benzalkonium Chloride Ph. Eur., USP/NF
FeF Benzalkonium Chloride Ph. Eur., USP/NF, JP

FeF Benzalkonium Chloride Solution 50% Ph. Eur., USP/NF
FeF Benzalkonium Chloride Solution 50% Ph. Eur., USP/NF, JP
FeF Benzalkonium Chloride Solution 50% (45/55) Ph. Eur., USP/NF
FeF Benzalkonium Chloride Solution 50% (53/30/15/2) Ph. Eur., USP/NF

FeF Benzalkonium Chloride Solution 17% USP/NF

Novo Nordisk Pharmatech A/S are pleased to inform of the steps we have taken in order to assist end users of our products to assess the elemental impurity content in their final medicinal drug products. The following guidelines and regulations have been taken into consideration by Novo Nordisk Pharmatech A/S when evaluating elemental impurities in the above products:

ICH Q3D – Guideline for Elemental Impurities
USP chapter ⟨232⟩ Elemental Impurities - Limits

The aim of ICHQ3D and USP ⟨232⟩ is to control the level of elemental impurities in final medicinal drug products. It is not a direct requirement for APIs.

Although not being a direct requirement for APIs, we are pleased to inform that we have accomplished the following steps to assess the level of elemental impurities in the above mentioned products:

1) Determination of the current level called "Base line test" of elemental impurities for Class 1, 2A and 3 elements and for more than half of Class 2B elements as listed in ICHQ3D. One batch of each FeF Benzalkonium Chloride products was tested.

2) Performed Risk Assessment for Class 1, 2A, 2B and 3 according to ICHQ3D in order to identify if any of these elements could potentially be present.

Please find in the table below a summary of our risk evaluation as a support for the Risk assessment of the elemental impurity content in the final medicinal drug product.

Risk assessment summary					
Element		**Class**	**Intentionally added?**	**Base line test result** *(µg/g)* [1)]	**Potential presence**
Cadmium	Cd	1	No	≤ 0.02 [2)]	4)
Lead	Pb	1	No	≤ 0.04 [2)]	4)
Arsenic (inorganic)	As	1	No	≤ 0.03 [2)]	4)
Mercury (inorganic)	Hg	1	No	≤ 0.4 [2)]	4)
Cobalt	Co	2A	No	≤ 0.02 [2)]	4)
Vanadium	V	2A	No	≤ 0.20 [2)]	4)
Nickel	Ni	2A	No	0.10	4)
Thallium	Tl	2B	No	-	4)
Gold	Au	2B	No	-	4)
Palladium	Pd	2B	No	(2.9 / 4.2 / ≤1.2[2)]) [3)]	4)
Iridium	Ir	2B	No	≤ 1.0 [2)]	4)
Osmium	Os	2B	No	-	4)
Rhodium	Rh	2B	No	≤ 0.09 [2)]	4)
Ruthenium	Ru	2B	No	≤ 0.03 [2)]	4)
Selenium	Se	2B	No	≤ 1.2 [2)]	4)
Silver	Ag	2B	No	-	4)
Platinum	Pt	2B	No	≤ 0.02 [2)]	4)
Lithium	Li	3	No	≤ 0.05 [2)]	4)
Antimony	Sb	3	No	≤ 0.03 [2)]	4)
Barium	Ba	3	No	≤ 0.02 [2)]	4)
Molybdenum	Mo	3	No	≤ 0.11 [2)]	4)
Copper	Cu	3	No	≤ 0.08 [2)]	4)
Tin	Sn	3	No	≤ 0.04 [2)]	4)
Chromium	Cr	3	No	≤ 0.10 [2)]	4)

[1)] Analysed by ICP-MS.
[2)] Content acc. to LOQ.
[3)] FeF BKC / FeF BKC Solution 50% / FeF BKC Solution 17% respectively.
[4)] Has not been identified as potential present in the performed Risk assessment.

Yours faithfully,

J.G. Westergaard

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