

Date: Dec 03, 2020

To whom it may concern,

**Elemental impurities statement –Dehydroepiandrosterone (DHEA)**

Hereby we declare that the levels of elemental impurities in Dehydroepiandrosterone (DHEA) manufactured at [Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd], are within the limits of the following guidelines:

- EMA/CHMP/ICH/353369/2013: ICH Q3D Elemental impurities
- Ph. Eur. General Text 5.20. "Elemental Impurities"
- USP general chapter <232>"Elemental impurities - Limits"

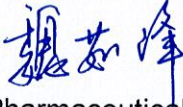
We confirm that metal catalyst containing Cr is used in the manufacturing process of the starting material 16-DPA. No unintentionally added metal residues (e.g., through interactions with processing equipment or container/closure systems or by being present in components of the drug product) are likely to be present in Dehydroepiandrosterone (DHEA). For elemental impurities that are likely to be present, a risk assessment is performed (see appendix).

**Appendix**  
**Risk Assessment Summary**

Product name: Dehydroepiandrosterone (DHEA)				
Intended Route of Administration: —				
Element	Class	Likely to be present?	Risk Assessment performed?	Conclusion
Cd	1	N	Y	additional controls are not required
Pb	1	N	Y	additional controls are not required
As	1	N	Y	additional controls are not required
Hg	1	N	Y	additional controls are not required
Co	2A	N	N	—
V	2A	N	N	—
Ni	2A	N	N	—
Ti	2B	N	N	—
Au	2B	N	N	—
Pd	2B	N	N	—
Ir	2B	N	N	—
Os	2B	N	N	—
Rh	2B	N	N	—



Ru	2B	N	N	—
Se	2B	N	N	—
Ag	2B	N	N	—
Pt	2B	N	N	—
Li	3	N	N	—
Sb	3	N	N	—
Ba	3	N	N	—
Mo	3	N	N	—
Cu	3	N	N	—
Sn	3	N	N	—
Cr	3	Y	Y	Three batches are tested quarterly

Mr. Wei Rufeng  
Quality Director   
Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.

