



## Hubei Zhuxi Humanwell Pharmaceutical Co., Ltd.

Address: Industrial park, Zhuxi County, Shiyan city, Hubei province 442300, China

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### Elemental impurities statement of Pregnenolone

We declare here in that in the production process of Pregnenolone manufactured at Industry park, Zhuxi County, Shiyan City, 442300 Hubei, China, Ni is used. According to CHMP Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents in Pharmaceutical Substances, Ni is controlled as follows: Ni ≤ 10ppm.

Furthermore, we confirm that only Ni listed in the “Guideline on the specification limits for residues of metal catalysts or metal reagents” (EMEA/CHMP/SWP/4446/2000, in the Eur. Ph. General Text “5.20. Metal catalyst or metal reagent residues and USP general chapter <232> Elemental impurities – Limits and USP <233> Elemental Impurities - Procedure “is used in the manufacturing process.

### Appendix

#### Risk Assessment Summary

Product name: Pregnenolone				
Element	Class	Intentionally added	Considered in Risk Assessment?	Conclusion
Cd	1	N	Y	Absent
Pb	1	N	Y	Absent
As	1	N	Y	Absent
Hg	1	N	Y	Absent
Co	2A	N	Y	Absent
V	2A	N	Y	Absent
Ni	2A	Y	Y	Confirm
Ti	2B	N	N	Absent
Au	2B	N	N	Absent
Pd	2B	N	N	Absent
Ir	2B	N	N	Absent
Os	2B	N	N	Absent
Rh	2B	N	N	Absent
Ru	2B	N	N	Absent
Se	2B	N	N	Absent
Ag	2B	N	N	Absent
Pt	2B	N	N	Absent
Li	3	N	N	Absent
Sb	3	N	N	Absent
Ba	3	N	N	Absent
Mo	3	N	N	Absent
Cu	3	N	N	Absent
Sn	3	N	N	Absent
Cr	3	N	N	Absent



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Date: 2021.03.08

Li Nian (Name)

Quality department (Designation & Department)