

# 精華製藥集團南通有限公司

## Nantong Jinghua Pharmaceutical Co., Ltd.

No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong, Nantong, Jiangsu, China,226407

Tel: 86 513 85609408/6/5 Fax: 86 513 85609407



### Risk Management Summary acc. to ICH Q3D

Name of API Phenylbutazone

API  
Supplier/Manufacturer: Nantong Jinghua Pharmaceutical Co., Ltd. No.20, 3 Haibin Road,,Yanhai Economic Development Zone,Rudong,Nantong,Jiangsu,China,226407  
Name / full address

Route of Administration Oral/Parenteral  
oral/ parenteral/ inhalation

Element	Class	Intention-ally added? ①	Potential source though not added intentionally?②	Considered in RMS by route of admin.?③	Risk Management Summary, Conclusion ④	Analytical Investigation, Conclusion ⑤
Cd	1	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.1µg/g (ppm).
Pb	1	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.1µg/g (ppm).
As	1	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.1µg/g (ppm)
Hg	1	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is	Three batches are tested by ICP-MS, the test results < LOR LOR=0.1µg/g (ppm)

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Element	Class	Intentionally added? ①	Potential source though not added intentionally? ②	Considered in RMS by route of admin.? ③	Risk Management Summary, Conclusion ④	Analytical Investigation, Conclusion ⑤
					present in our products.	
<b>Co</b>	2A	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.3 µg/g (ppm).
<b>V</b>	2A	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.1µg/g (ppm)
<b>Ni</b>	2A	No	No	Yes	From assessment of raw material, equipment, water, PE bag there is low risk that this element is present in our products.	Three batches are tested by ICP-MS, the test results < LOR LOR=0.3µg/g (ppm).
<b>Tl</b>	2B	No	No	No	N/A	NA
<b>Au</b>	2B	No	No	No	N/A	NA
<b>Pd</b>	2B	No	No	No	N/A	NA
<b>Ir</b>	2B	No	No	No	N/A	NA
<b>Os</b>	2B	No	No	No	N/A	NA
<b>Rh</b>	2B	No	No	No	N/A	NA
<b>Ru</b>	2B	No	No	No	N/A	NA
<b>Se</b>	2B	No	No	No	N/A	NA
<b>Ag</b>	2B	No	No	No	N/A	NA
<b>Pt</b>	2B	No	No	No	N/A	NA

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Element	Class	Intentionally added? ①	Potential source though not added intentionally? ②	Considered in RMS by route of admin.? ③	Risk Management Summary, Conclusion ④	Analytical Investigation, Conclusion ⑤
Li	3	No	No	Yes	N/A	NA
Sb	3	No	No	Yes	N/A	NA
Ba	3	No	No	No	N/A	NA
Mo	3	No	No	No	N/A	NA
Cu	3	No	No	Yes	N/A	NA
Sn	3	No	No	No	N/A	NA
Cr	3	No	No	No	N/A	NA

\*The a. m. table shall function as a cover sheet for the Risk Management Summary (RMS); please fill in steps ① to ⑤; for steps ④ and ⑤, the RMS needs to be written  
Guidance

:

- ① consider (e. g. catalyst with Pd added) and fill in YES or NO
- ② consider (e. g. from starting material [inherent or as impurity], from manufacturing process [equipment, utilities], from packaging) and fill in YES or NO
- ③ refer now to sheet below "route of admin.", select and check which of the class 2B + 3 elements have to be considered for the route of admin. (if two routes are possible, select the one with higher risk, e. g. oral + parenteral, take the requirements for parenteral)
- ④ for all class 1+2A elements + those with YES in column ① + those with YES in column ②+③ → include in Risk Management Report!  
in Risk Management Report discuss potential risk for pre-selected elements based on scientific rationale and/or available published data;  
possible statements: "potential risk excluded by scientific rationale" or "potential remaining risk to be controlled"
- ⑤ ONLY for elements with remaining risk after discussion in ④, do an analytical investigation, and provide control method (type e. g. ICP-MS; LOD, LOQ, etc.)  
possible final statements: "absent" (meaning less than 30 % of ICH Q3D option 1 limit defined under 3.1.1) or "maximum level < X ppm"

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**Evaluation completed by:**

Wu Jihong (QA supervisor)

Name/Function

**Completion date:**

Mar.1, 2018

