

# WUHAN WUYAO PHARMACEUTICAL CO.,LTD



## CERTIFICATE OF ANALYSIS

REC-QC-00343-06

Report Number: B-210530

Product Name:	<b>Chloramphenicol</b>	Batch No:	C08-211141
Test Standard:	USP-NF 2021, Issue 1	Manufacturing Date:	2021.11.26
Packing:	25kg/drum	Report Date:	2022.01.10
Quantity:	25kg/drum×23drum+7.68kg	Retest Date:	2026.10

Item	Requirements	Result
【Description】	Fine, white to grayish-white or yellowish-white, needle-like crystals or elongated plates	Yellowish-white crystalline powder
Solubility	Freely soluble in alcohol, in propylene glycol, in acetone, and in ethyl acetate; slightly soluble in water	Conforms
【Identification】		
A. IR	The sample spectrum complies with the reference standard spectrum	Conforms
B. HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay	Conforms
【Melting range】	149 ~ 153 °	151-152°C
【Specific rotation】	+17.0° ~ +20.0°	+19.0°
【Crystallinity】	Meets the requirements	Conforms
【Bacterial endotoxins test】	Not more than 0.2 EU/mg	Less than 0.2EU/mg
【pH】	4.5 ~ 7.5	6.0
【Chromatographic purity】		
Any impurity	Not more than 1%	Less than 1%
Total impurities	Not more than 2%	Less than 2%
【Assay】		
(on dried basis)	97.0% to 103.0%	99.5%

Conclusion: The above product complies with the standard USP-NF 2021, Issue 1

Approved by: *王维 2022.01.10*   Checked by: *李伟 2022.01.10*   Prepared by: *王维 2022.01.10*

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<u>Item</u>	<u>Requirements</u>	<u>Result</u>
<b>【Residual solvent】</b>		
Methanol	Not more than 3000ppm	98ppm
Ethanol	Not more than 5000ppm	Not detected
Chlorobenzene	Not more than 360ppm	Not detected

**Conclusion:** The above product complies with the standard      **Customer Standard**

Approved by: 王海 2022.01.10    Checked by: 李伟 2022.01.10    Prepared by: 王海 2022.01.10

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