

SHAANXI THE RIVER PHARMACEUTICAL CO., LTD.

Certificate of Analysis

PRODUCT NO.	20230103	COA No.	JC <sub>004</sub> -202302-002
PRODUCT NAME	CYTISINE	PACKAGE	PLASTIC BAG
BATCH NO.	JQ-W-20230103	SAMPLE DATE	18.02.2023
REPORT DATE	25.02.2023	BATCH SIZE	52.91Kg
PRODUCTION DATE	10.01.2023	EXPIRY DATE	09.01.2025
INSPECTION BASIS	JB-ZL-05005-05		

NO	Indices	Specification and standard	Result
1.	Appearance	Crystalline powder	Crystalline powder
2.	Colour	White or pale yellowish	Pale yellowish
3.	Odour	Odourless	Odourless
4.	Identity		
	- IR spectrum	To comply with the test	Complies
	- UV spectrum	To comply with the test	Complies
	- Colour reaction	To comply with the test	Complies
5.	Type of solution		
	- clarity	Not more intensely opalescent than reference suspension II	Complies
	- colour	Not more intensely coloured than reference solution Y <sub>1</sub>	Complies
6.	Solubility		
	- in water	Freely soluble	Freely soluble
	- in ethanol (96 per cent)	Freely soluble	Freely soluble
	- in chloroform	Soluble	Soluble
	- in acetonitrile	Soluble	Soluble
7	Chloride	≤0.02%	0.01%
8	Sulphates	≤0.03%	0.01%
9	Related substances, per cent, not more than		

	- any impurity	<0.10%	0
	- Total impurities	<0.50%	0
10.	Heavy metals, ppm, not more than	≤20	Complies
11.	Loss on drying, per cent, not more than	≤0.5	0.26
12.	Specific optical rotation [α] <sub>20</sub> , °	From -120.0 to -125.0	-122.96
13.	Melting range, °C	From 154.0 to 157.0	154.3-156.6
14.	Sulphated ash, per cent, not more than	≤0.10	0.07
15.	- acetone (ppm)	≤5000	542
	- ethanol (ppm)	≤5000	7
	- ethyl acetate (ppm)	≤5000	2
	- chloroform (ppm)	≤60	1
16.	Assay of cytosine(C <sub>11</sub> H <sub>14</sub> N <sub>2</sub> O),per cent, calculated as dry substance	From 99.0 to 101.0	99.84
17.	Microbiological quality		
	Total viable aerobic count:		
	- TAMC, CFU/g, not more than	≤10 <sup>3</sup>	Complies
	- TYMC, CFU/g, not more than	≤10 <sup>2</sup>	Complies
	Salmonella, CFU/10g	Inadmissible	Inadmissible
	E.coli, CFU/g	Inadmissible	Inadmissible
	Ps.aeruginosa, CFU/g	Inadmissible	Inadmissible
	S. aureus, CFU/g	Inadmissible	Inadmissible

Conclusion: Pass through test.

QC:

1. 雷晓婷
2. 吴爱倩
3. 邓艳

QA:

张亚明