

METAPHARMACEUTICAL

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17/03/2025

Hallochem Group

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Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

-revised

Product name	Colistin Sulfate	Batch No.	CS-20241204
Manuf. Date	2024-12-07	Expiry Date	2027-12-06
Batch Quantity	1600kgs	Test Standard	EP10

TEST	SPECIFICATIONS	RESULTS
Appearance	White or almost white powder	white powder
Visible foreign matter	No visible foreign matter shall be tested	No visible foreign matter
Identification E	Complies with the test	Complies
pH	4.0~6.0	5.3
Sulfate(dried substance)	16.0%~18.0%	17.1%
Loss on drying	≤3.5%	2.3%
Sulfated ash	≤1.0%	0.3%
Identification B	Complies with the test	Complies
Composition		
E4+E2-Val	≤3.0%	1.7%
E6	≤4.5%	1.1%
E2-I	≤2.5%	0.7%
E3	≤5.5%	4.1%
E1-Nva	≤4.5%	0.4%
E1-I	≤8.5%	0.4%
2,3-dehydro E1	≤1.5%	0.4%
E1-7MOA	≤5.0%	4.0%
Sum of polymyxins E1, E2, E3, E4, E6 E1-7MOA, E1-I, E1-Nva, E2-I, E2-Val and 2,3-dehydro E1	≥86.0%	88.9%

Add: No. 138 YuWu Road, XinMin Town, DianJiang 408302, Chongqing, China

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Related substances	HALLOCHEM	
Impurity B	$\leq 4.0\%$	$< 0.35\%$
Total impurities	$\leq 11.0\%$	7.2%
Any other impurity	$\leq 2.5\%$	1.6%
	Not more than 4 such impurities exceed 1.0 per cent	3 (1.1%; 1.1%; 1.6%)
Assay (dried substances)	≥ 19000 IU/mg	23194 IU/mg
Assay	≥ 19000 IU/mg	22661 IU/mg

Conclusion: The product complies with the requirements of EP10 standard

Quality Manager:

吴永章

Rechecker:

易洪成

Analyst:

刘琪

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