

CERTIFICATE OF ANALYSIS

MANU.DATE: 2011. APR. 24

RETEST.DATE: 2013. APR. 20

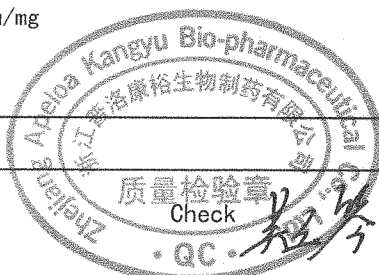
REP.DATE: 2011. APR. 26

Product name	Colistin Sulfate	Packing	20kg/tub
Batch No.	1104044	Report No.	1104239
Quantity	22103BOU	Quality standard	EP7.0

ITEM	CRITERIA	ANALYSIS RESULTS
Description	White or almost white powder	Almost white powder
Identification A	Complies with the test	Complies with the test
Identification B	Complies with the test	Complies with the test
Identification C	Complies with the test	Complies with the test
Identification D	Complies with the test	Complies with the test
Identification E	Complies with the test	Complies with the test
pH	4.0~6.0	4.8
Optical rotation	-63° ~ -73°	-72°
Total impurities	≤23.0%	12.6%
Impurity RRT0.11	≤4.0%	0.7%
Impurity RRT0.25	≤3.0%	1.0%
Impurity RRT0.31	≤4.0%	2.6%
Impurity RRT0.74	≤3.0%	0.7%
Any other detectable impurity than those mentioned in the monograph	≤4.0%	1.7%
Sulfate(dried basis)	16.0%~18.0%	17.3%
Loss on drying	≤3.5%	2.1%
Sulphated ash	≤1.0%	0.2%
Sum of E1 E2 E3 E1-I and E1-7MOA(dried basis)	≥77.0%	84.3%
E1-I (dried basis)	≤10.0%	0.3%
E1-7MOA(dried basis)	≤10.0%	2.6%
E3(dried basis)	≤10.0%	3.1%
Potency		22103u/mg
Potency(dried basis)	≥19000u/mg	22577u/mg

Conclusion	Conform to EP7.0
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QC Minister

Lab. Technician



CERTIFICATE OF ANALYSIS

MANU.DATE: 2011. APR. 24

RETEST.DATE: 2013. APR. 20

REP.DATE: 2011. JUN. 02

Product name	Colistin Sulfate	Packing	20kg/tub
Batch No.	1104044	Report No.	1104239
Quantity	22103B0U	Quality standard	Additional test

ITEM

CRITERIA

ANALYSIS RESULTS

Microbiological quality

according to ph. Eur. 5.1.4 (oral use)

TAMC

not more than 1000 CFU/g

<10CFU/g

TYMC

not more than 100 CFU/g

<10CFU/g

E. coli

absent in 1g

absent in 1g

COS Number

NO. R0-CEP 2004-258-Rev 02

Conclusion	Conform to Additional test
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QC Minister

Check

Lab. Technician

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