

**杭州东瑞医药科技有限公司**  
**HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.**

**CERTIFICATE OF ANALYSIS**

**Meropenem pure**

<b>Batch No.:</b> DR20130330	<b>Quantity:</b> 11632kg
<b>Manufacture Date:</b> 2013.03.30	<b>Expiry Date:</b> 2017.02

**TESTS:**

<b>Items</b>	<b>Specification</b>	<b>Results</b>
Appearance	White to slight yellow crystalline powder	White crystalline powder
Solubility	Soluble in DMF; sparingly soluble in water and in 5% monobasic potassium phosphate solution; practically insoluble in acetone and in ether and in alcohol.	Conforms
Clarity and color of solution	The solution is clear and not more than GY3.	Conforms
Specific optical rotation	-17.0° ~ -21.0°	-18.0°
Identification	UV: Conforms IR: Conforms	Conforms
Particular matter	Great than 10 $\mu$ m: $\leq$ 3000/g Great than 25 $\mu$ m: $\leq$ 300/g	298/g 2/g
PH(Acidity)	4.0~6.0	5.1
Residual solvents	Acetone $\leq$ 500ppm	25ppm
Related substance(on anhydrous basis):		
Impurity RRT 0.45	$\leq$ 0.3%	0.07%
Impurity RRT 1.9	$\leq$ 0.3%	0.07%
Any unspecified impurity	$\leq$ 0.1%	0.03%
Sum of unspecified impurities	$\leq$ 0.3%	0.11%
Total impurity	$\leq$ 0.8%	0.25%
Water	11.4%~13.4%	12.4%
Residue on ignition	$\leq$ 0.1%	0.06%
Heavy metals	$\leq$ 10ppm	< 10ppm
Bacterial endotoxin	< 0.125EU/mg	Conforms
Sterility	Meets the requirements	Conforms
Bulk density	0.25g/ml~0.45g/ml	0.30g/ml
Tapped density	0.25g/ml~0.75g/ml	0.58g/ml

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Assay(on the anhydrous basis)

98.0%~101.0%

99.9%

Conclusion: The results conform with USP35.

Analyst: \_\_\_\_\_

Checker: \_\_\_\_\_

QA.Manager: \_\_\_\_\_



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