



山东欣宏药业有限公司  
SHANDONG XINHONG PHARMACEUTICAL CO., LTD

**CERTIFICATE OF ANALYSIS**

Product	<b>CALCIUM GLUCONATE for Injection</b>	
Batch No.	20171011	Mfg.Date: Oct. 2017
Quantity :		Exp.Date: Oct. 2020
Specification	<b>EP9.0</b>	Report Date:
<b>Tests</b>	<b>Specifications</b>	<b>Results</b>
	A White,crystalline or granular	
Characters	powder	Meets the requirements
Loss on drying	$\leq 1.0 \%$	0.15%
Identification	Meets the requirements	Meets the requirements
	Sparingly soluble in water,	
Solubility	freely soluble in boiling water.	Meets the requirements
<b>PH</b>	6.4~8.3	6.8
Organic impurities and		
boric acid	Meets the requirements	Meets the requirements
Oxalate	$\leq 100 \text{ ppm}$	$< 50 \text{ ppm}$
Chloride	$\leq 50 \text{ ppm}$	$< 50 \text{ ppm}$
Sulphates	$\leq 50 \text{ ppm}$	$< 50 \text{ ppm}$
Iron	$\leq 5 \text{ ppm}$	$< 5 \text{ ppm}$
Phosphates	$\leq 100 \text{ ppm}$	$< 100 \text{ ppm}$
Magnesium and alkali	$\leq 0.4 \%$	0.30%
metals		
Sucrose and reducing		
sugars	Meets the requirements	Meets the requirements
Bacterial endotoxins	$\leq 167 \text{ I.U./g}$	$< 150 \text{ I.U./g}$
TAMC	$\leq 10^2 \text{ CFU/g}$	20CFU/g
Assay	99.0~101.0 %	99.30%
Conclusion	Complies with the requirements of <b>EP9.0 Ed</b>	

**Analyst:**

**Checker:**

**Approver:**



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