



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

CERTIFICATE OF ANALYSIS

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

Analyst:

Checker:

Approver:



Tel: 0086-531-84779777 84779123

Fax: 0086-531-84779888 P.C.: 251601

地址:中国山东省济南市商河县经济开发区

<http://www.xhpharm.cn> Email:mandy@xhpharm.cn

Address: ShangHe Economic Development Zone Jinan Shandong China