



Jinan Hongfangde Pharmatech Co., Ltd.
Tel:86-531-88870908 Fax:86-531-88870908
sdhfdchem@163.com
www.hfdpharma.com

CERTIFICATE OF ANALYSIS

Product	Gadopentetate Dimeglumine	Mfg.date	2019-03-15
Batch No.	19031501	Exp. date	2021-03-14
Report Date	2019.06.10	Quantity	255kg

Inspection Items	Accepted Standard	Results
Appearance	White to yellowish crystalline powder.	White crystalline powder
Identification	UV $\lambda_{max}275nm$	Complies
Loss on drying	$\leq 6.0\%$ (1g,105°C,4hours)	4.15%
PH	6.5-8.5	7.8
Heavy metals	$\leq 20ppm$	Complies
Content of meglumine	40.5% ~ 42.5%	41.5%
Content of gadolinium	15.1% ~ 18.4%	16.68%
Content of pentetic acid	$\leq 0.04\%$	Complies
Bacterial endotoxins	$< 3.0Eu/mg$	Conforms
Assay	98.0 ~ 102.0%	99.78%
Conclusion : Complies to the enterprise standard		
Storage: Keep tightly closed. Store in a dry place.		

Analyst :liyuling

Checker: wuhao

Supervisor :lichao

