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CERTIFICATE OF ANALYSIS

Product	Gadopentetate Dimeglumine	Batch No.	18120101
Mfg.date	2018.12.01	Exp. date	2020.12
Report Date	2018.12.12	Quantity	323kg

Inspection Items	Accepted Standard	Results
Appearance	White to light yellow crystalline powder.	White crystalline powder
Identification	UV $\lambda_{max}275nm$	Complies
Loss on drying	$\leq 6.0\%$ (1g,105°C,4hours)	3.95%
Analogous substance	$\leq 0.5\%$	0.29%
Heavy metals	$\leq 20ppm$	Complies
Content of meglumine	40.5%~42.5%	41.6%
Content of gadolinium	15.1% ~ 18.4%	16.7%
Content of DTPA	$\leq 0.04\%$	Complies
Microbial limits	500cfu/g	Conforms
Bacterial endotoxins	$< 3.0Eu/mg$	Conforms
Assay	98.0~102.0%	99.85%
Conclusion : Complies to the enterprise standard		

Analyst :liyuling

Checker: wuhao

Supervisor :lichao