



Certificate of Analysis

Product name	Gadobutrol Monohydrate	Manufacture date	Mar.07.2024
Batch number	SW240307	Analysis date	Mar.08.2024
Batch Size	300kg	Expiry date	Mar.07.2026

Items	Standards	Results
Appearance	White Powder	Conform
Odor	Characteristic	Conform
Assay	≥98.0%	98.62%
Particle Size	100% pass 80mesh	Conform
Moisture	<5.0%	Conform
Ash Content	<4.0%	Conform
Solvent Residue	Eur.Pharm	Conform
Total Heavy Metals	<10 ppm	Conform
Arsenic	<1.0 ppm	Conform
Lead	<1.0 ppm	Conform
Mercury	<0.5 ppm	Conform
DDT	<0.2ppm	Conform
E. Coli	Negative	Negative
GMO Status	Complies	GMO Free
Irradiation	Complies	Irradiation Free

Packing description:	Sealed export grade drum & double of sealed plastic bag
Storage:	Store in cool & dry place not freeze., keep away from strong light and heat
Shelf life:	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方琼

