



Certificate of Analysis

Product name	ISOFLURANUM MIRAL EK	Batch No.	213230701
Specification	250ml	Package	250ml*30bottles/carton
Test according to	USP	Manufacturer	No. 21 workshop
Batch size	2521bottles	Date of manufacture	July. 30, 2023
Shelf life	36 months	Date of expiry	June., 2026
Test items	Acceptance criteria	Test results	
Appearance:	Should be a colorless clear liquid, volatile, with a slight odor	Clear, colorless, volatile, with a slight odor	
Identification:	The IR absorption spectrum of the substance to be examined should be consistent with the reference spectrum.	Conforms	
Refractive index:	Between 1.2990 and 1.3005	1.2995	
Chloride	Not more than 2.11ml silver nitrate titrant to be consumed (0.002mol/L)	0.36ml	
Fluoride:	NMT 5µg/ml	0.02µg/ml	
Nonvolatile residue:	NMT 2.0mg	0.4mg	
Fill:	Average quantity: Not less than the labelled quantity Quantity in each glass bottle: Not less than 97% of the labeled quantity	Conforms Conforms	
Water:	NMT 0.10%	0.066%	
Acidity or alkalinity:	It should conform to the requirements.	Conforms	
Organic impurities:	Related compound A: NMT 0.01% Related compound B: NMT 0.007% Any other single impurity: NMT 0.003% Total impurities: NMT 0.1%	Undetected Undetected 0.000128% 0.000128%	
Microbial limit:	Total Aerobic Microbial Count: NMT 100cfu/g Total Combined Yeasts/Molds Count: NMT 10cfu/g Staphylococcus aureus: Absence Pseudomonas aeruginosa: Absence Escherichia coli: Absence Bile-Tolerant Gram-Negative Bacteria: Absence	NMT 1cfu/g NMT 1cfu/g Absent Absent Absent Absent	
Assay:	C ₃ H ₂ ClF ₅ O: 99.9% ~100.00%	99.99987%	



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Shipped Quantity in the Container	2500 bottles	2500 bottles
Container Number:	TGBU2742956	TGBU2742956
Conclusion	After analysis, it conforms to the requirements of USP.	



Apporved by: Wang Junfeng 230807

王俊峰

Reporter: Li Yuanvue 230807

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