

Hebei Yipin Pharmaceutical Co., Ltd

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031231103
Batch No.	C031231103	Batch quantity	3600.0kg
Mfg. date	2023.11.02	Exp. date	2026.10
Specification	USP 46	Report date	2023.12.03

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms	Conforms
Identification	Identification by IR	Conforms	Conforms
Refractive index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Limit of peroxide	NMT 2 µg/mL	0.04 µg/mL	Conforms
Limit of Non-volatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	5 µg/g 20 µg/g 60 µg/g	Conforms
Water	NMT 0.1%	0.1%	Conforms
Assay	C ₄ H ₇ ClO ₂ : 99.97%~100.00%	99.99%	Conforms
End of report			Conforms

Conclusion: It conforms to USP 46.

Reported by: [Signature]

Reviewed by: [Signature]

QC Manager: [Signature]

I/C Number: 0163323000382

Date of Issue: 231205

Address: SANXIAO INDUSTRIAL AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CHINA

Hebei Yipin Pharmaceutical Co., Ltd

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031231201
Batch No.	C031231201	Batch quantity	3600.0kg
Mfg. date	2023.11.14	Exp. date	2026.10
Specification	USP 46	Report date	2023.12.08

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms	Conforms
Identification	Identification by IR	Conforms	Conforms
Refractive Index	1.2745~1.2760 at 30°	1.2757	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Limit of residue	NMT 2 µg/mL	0.04 µg/mL	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.5mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	4 µg/g 11 µg/g 21 µg/g	Conforms
Water	NMT 0.1%	0.1%	Conforms
Assay	C ₄ H ₇ ClO: 99.97%~100.00%	99.9%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 2/6/24

Reviewed by: 2/6/24

QC Manager: 2/6/24

I/C Number: MI62323000382

Date of Issue: 231205

Address: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CHINA

Hebei Yipin Pharmaceutical Co., Ltd
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031240303
Batch No.	C031240303	Batch quantity	3600.0kg
Mfg. date	2023.11.26	Exp. date	2026.10
Specification	USP 46	Report date	2024.04.01

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms	Conforms
Identification	Identification by IR	Conforms	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.1 µg/ml	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.2mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	4 µg/g 13 µg/g 69 µg/g	Conforms
Water	NMT 0.1%	0.1%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 张立叶

Reviewed by: 李荣升

QC Manager: 唐海

L/C Number: ILC0077240001079

Date of Issue: 240307

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CHINA

Hebei Yipin Pharmaceutical Co., Ltd
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031240304
Batch No.	C031240304	Batch quantity	3600.0kg
Mfg. date	2024.03.09	Exp. date	2027.02
Specification	USP 46	Report date	2024.04.04

Test Items	Specification	Results	Conclusion
Description	Clear, colorless, volatile, nonflammable liquid.	Clear, colorless, volatile, nonflammable liquid.	Conforms
Solubility	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms	Conforms
Identification	Identification by IR	Conforms	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.03µg/ml	Conforms
Limit of Nonvolatile Residue	NMT 1.0 mg	0.3mg	Conforms
Organic Impurities	Sevoflurane related compound A NMT 25 µg/g Any other single impurity NMT 100 µg/g Total impurities NMT 300 µg/g	Not detected 72µg/g 91 µg/g	Conforms
Water	NMT 0.1%	0.1%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.99%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 孙少明

Reviewed by: 孙少明

QC Manager: 李静

L/C Number: ILC0077240001079

Date of Issue: 240307

Add: SANXIA ROAD, ECONOMIC AND TECHNOLOGICAL DEVELOPMENT ZONE, SHIJIAZHUANG, HEBEI, CHINA