

HEBEI YIPIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031240801
Batch No.	C031240801	Batch Quantity	3600.0kg
Mfg. Date	2024.07.14	Exp. Date	2027.06
Specification	USP 47	Report Date	2024.08.15

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.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.02mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.02µg/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	Not detected 4µg/g 14µg/g	Conforms
Water	NMT 0.1%	0.06%	Conforms
Assay	C ₄ H ₅ F ₇ O: 99.97%~100.00%	99.999%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 孙小华

Reviewed by: 刘雅

QC Manager: 李强

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-C031241103
Batch No.	C031241103	Batch Quantity	3615.0kg
Mfg. Date	2024.09.11	Exp. Date	2027.08
Specification	USP 47	Report Date	2024.11.30

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.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2754	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.05mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.03µg/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	Not detected 5µg/g 20µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.998%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 刘子叶

Reviewed by: 刘雅

QC Manager: 李强

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-C031240605
Batch No.	C031240605	Batch Quantity	3600.0kg
Mfg. Date	2024.06.10	Exp. Date	2027.05
Specification	USP 47	Report Date	2025.07.21

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.	Slightly soluble in water. Miscible with alcohol, with chloroform, and with ether.	Conforms
Identification	Identification by IR	Meet the requirement	Conforms
Refractive Index	1.2745~1.2760 at 20°	1.2753	Conforms
Acidity or Alkalinity	The aqueous layer requires NMT 0.10 mL of 0.010 N sodium hydroxide or NMT 0.60 mL of 0.010 N hydrochloric acid for neutralization.	0.04mL of 0.010 N hydrochloric acid for neutralization.	Conforms
Limit of Fluoride	NMT 2 µg/mL	0.02µg/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	Not detected 18µg/g 50µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.9995%	Conforms
End Of Report			

Conclusion: It conforms to USP 47.

Reported by: 牛海阳

Reviewed by: 郭小华

QC Manager: 王峰

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-C031240801
Batch No.	C031240801	Batch quantity	3600.0kg
Mfg. date	2024.07.14	Exp. date	2027.06
Specification	USP 46	Report date	2024.08.15

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	0.02µg/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	Not detected 4µg/g 14µg/g	Conforms
Water	NMT 0.1%	0.06%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.999%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 王立华

Reviewed by: 王立华

QC Manager: 王立华

L/C Number: MI62324000297

Date of Issue: 240823

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-C031240704
Batch No.	C031240704	Batch quantity	3600.0kg
Mfg. date	2024.07.07	Exp. date	2027.06
Specification	USP 46	Report date	2024.07.29

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°	1.2753	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	0.2mg	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	Not detected 5µg/g 14µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₃ F ₇ O: 99.97%~100.00%	99.999%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 孙计叶

Reviewed by: 牛明明

QC Manager: 李强

L/C Number: MI62324000297

Date of Issue: 240823

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

Hebei Yipin Pharmaceutical Co., Ltd
CERTIFICATE OF ANALYSIS

Product Name	Sevoflurane	Report Number	CP031-C031240705
Batch No.	C031240705	Batch quantity	3600.0kg
Mfg. date	2024.07.11	Exp. date	2027.06
Specification	USP 46	Report date	2024.08.07

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 9µg/g 28µg/g	Conforms
Water	NMT 0.1%	0.05%	Conforms
Assay	C ₄ H ₇ F ₇ O: 99.97%~100.00%	99.997%	Conforms
End of report			

Conclusion: It conforms to USP 46.

Reported by: 孙小华

Reviewed by: 牛明刚

QC Manager: 李海

L/C Number: MI62324000297

Date of Issue: 240823

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

Hebei Yipin Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name	Isoflurane	Report No.	CP087-C087210704
Batch No.	C087210704	Batch quantity	1802.60kg
Mfg. date	2021.07.20	Exp. date	2026.06
Specification	USP41	Report date	2021.08.10

Test Items	Specification	Results	Conclusion
Identification	Identification by IR	Conforms	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Chloride	Not more than 10ppm	Conforms	Conforms
Limit of Fluoride	Not more than 5 µg/ml	0.01 µg/ml	Conforms
Limit of Nonvolatile Residue	Not more than 2.0 mg	0.6 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20°C)	1.2995	Conforms
Water	Not more than 0.10%	0.02%	Conforms
Organic Impurities	Dichloroisoflurane NMT 0.003%, Isoflurane isomer NMT 0.003%, Isoflurane related compound A NMT 0.01%, Isoflurane related compound B NMT 0.007%, Chloroisoflurane NMT 0.003%, Acetone NMT 0.008%, Any individual unspecified impurity NMT 0.003%, Total impurities NMT 0.1%	Not detected, 0.002%, 0.001%, 0.001%, Not detected, 0.003%, 0.0005%, 0.01%	Conforms
Residual solvent	N,N-dimethylformamide NMT 0.088%, N-Methylpyrrolidone NMT 0.053%	Not detected, Not detected,	Conforms
Assay	C ₃ H ₂ ClF ₃ O: 99.9%~100.0%	99.99%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张明

Reviewed by: 高巧来

QC Manager: 李静

L/C Number: MI62321000498

Date of Issue: 211214

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

Hebei Yipin Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name	Isoflurane	Report No.	CP087-C087210705
Batch No.	C087210705	Batch quantity	1802.60kg
Mfg. date	2021.07.27	Exp. date	2026.06
Specification	USP41	Report date	2021.08.21

Test Items	Specification	Results	Conclusion
Identification	Identification by IR	Conforms	Conforms
Acidity or Alkalinity	Meet the requirement	Conforms	Conforms
Chloride	Not more than 10ppm	Conforms	Conforms
Limit of Fluoride	Not more than 5 µg/ml	0.01 µg/ml	Conforms
Limit of Nonvolatile Residue	Not more than 2.0 mg	0.9 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20°C)	1.2995	Conforms
Water	Not more than 0.10%	0.07%	Conforms
Organic Impurities	Dichloroisoflurane NMT 0.003%, Isoflurane isomer NMT 0.003%, Isoflurane related compound A NMT 0.01%, Isoflurane related compound B NMT 0.007%, Chloroisoflurane NMT 0.003%, Acetone NMT 0.008%, Any individual unspecified impurity NMT 0.003%, Total impurities NMT 0.1%	Not detected, 0.001%, 0.001%, 0.0003%, Not detected, 0.002%, 0.0004%, 0.01%	Conforms
Residual solvent	N,N-dimethylformamide NMT 0.088%, N-Methylpyrrolidone NMT 0.053%	Not detected, Not detected,	Conforms
Assay	C ₃ H ₂ ClF ₃ O: 99.9%~100.0%	99.99%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张博

Reviewed by: 高巧彤

QC Manager: 李峰

L/C Number: M162321000498

Date of Issue: 211214

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