

Hebei Yipin Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS



Product name	Isoflurane	Report No.	CP087-C087210602
Batch No.	C087210602	Batch quantity	1802.60kg
Mfg. date	2021.06.06	Exp. date	2026.05
Specification	USP41	Report date	2021.06.23

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%	0.04%	Conforms
Organic Impurities	Dichloroisoflurane NMT 0.003%,	Not detected,	Conforms
	Isoflurane isomer NMT 0.003%,	0.002%,	
	Isoflurane related compound A NMT 0.01%,	0.002%,	
	Isoflurane related compound B NMT 0.007%,	0.001%	
	Chloroisoflurane NMT 0.003%,	Not detected,	
	Acetone NMT 0.008%,	0.0005%,	
	Any individual unspecified impurity NMT 0.003%,	0.0005%,	
Residual solvent	Total impurities NMT 0.1%	0.01%	Conforms
	N,N-dimethylformamide NMT 0.088%,	Not detected,	
Assay	N-Methylpyrrolidone NMT 0.053%	Not detected,	Conforms
	C ₃ H ₂ ClF ₅ O: 99.9%~100.0%	99.99%	
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张明

L/C Number: MI62321000498

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

Reviewed by: 高彩

Date of Issue: 211214

QC Manager: 李海

Hebei Yipin Pharmaceutical Co., Ltd.
CERTIFICATE OF ANALYSIS

Product name	Isoflurane	Report No.	CP087-C087210603
Batch No.	C087210603	Batch quantity	1802.60kg
Mfg. date	2021.06.16	Exp. date	2026.05
Specification	USP41	Report date	2021.07.16

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	0.8 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20℃)	1.2995	Conforms
Water	Not more than 0.10%	0.06%	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, 0.004%, 0.0003%, 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: 张研
L/C Number: MI62321000498

Reviewed by: 高巧丽
Date of Issue: 211214

QC Manager: 李康

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

Hebei Yipin Pharmaceutical Co., Ltd.
CERTIFICATE OF ANALYSIS

Product name	Isoflurane	Report No.	CP087-C087210604
Batch No.	C087210604	Batch quantity	1802.60kg
Mfg. date	2021.06.22	Exp. date	2026.05
Specification	USP41	Report date	2021.07.25

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	0.2 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20℃)	1.2995	Conforms
Water	Not more than 0.10%	0.03%	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, 0.004%, 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 ₅ O: 99.9%~100.0%	99.99%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张研

Reviewed by: 高巧彤

QC Manager: 唐海

L/C Number: MI62321000498

Date of Issue: 211214

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

Hebei Yipin Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name	Isoflurane	Report No.	CP087-C087210605
Batch No.	C087210605	Batch quantity	1802.60kg
Mfg. date	2021.06.29	Exp. date	2026.05
Specification	USP41	Report date	2021.07.25

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	0.7 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20°C)	1.2995	Conforms
Water	Not more than 0.10%	0.03%	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%, 0.002%, 0.001%, Not detected, 0.001%, 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 ₅ O:99.9%~100.0%	99.99%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张研

Reviewed by: 高巧彩

QC Manager: 李谦

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-C087210701
Batch No.	C087210701	Batch quantity	1802.60kg
Mfg. date	2021.07.05	Exp. date	2026.06
Specification	USP41	Report date	2021.07.25

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	0.4 mg	Conforms
Refractive Index	1.2990-1.3005 (at 20°C)	1.2995	Conforms
Water	Not more than 0.10%	0.03%	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%, 0.0002%, Not detected, 0.001%, 0.0004%, 0.004%	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 ₅ O:99.9%~100.0%	99.996%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张珊

Reviewed by: 高巧影

QC Manager: 李谦

L/C Number: MI62321000498

Date of Issue: 211214

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

Hebei Yipin Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS



Product name	Isoflurane	Report No.	CP087-C087210702
Batch No.	C087210702	Batch quantity	1802.60kg
Mfg. date	2021.07.10	Exp. date	2026.06
Specification	USP41	Report date	2021.07.25

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%	0.03%	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%, 0.0002%, Not detected, 0.001%, 0.0004%, 0.003%	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 ₅ O: 99.9%~100.0%	99.997%	Conforms
End of Report			

Conclusion: It conforms to USP 41.

Reported by: 张明

Reviewed by: 高彩

QC Manager: 李海

L/C Number: M162321000498

Date of Issue: 211214

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