

CERTIFICATE OF ANALYSIS (Bulk Drug Substance)

For Regulatory Submission

Sevoflurane Bulk Drug Substance

Bulk Drug No.: SC1502-22-123-6-2

Manufacturing Date 06-Oct-2022

Source SV-1514

<u>Test</u>	<u>Limits</u>	<u>Results</u>
Appearance	Clear, colourless liquid	Conforms
Identification	Infrared spectra of sample and standard exhibit maxima at the same wavelengths	Conforms
Assay	NLT 99.97% & NMT 100.00%	100.00%
Impurity Profile		
Chlorosevo Ether	NMT 0.0100%	None Detected
Sevo methyl ether	NMT 0.0100%	0.0013%
Hexafluoroisopropanol (HFIP)	NMT 0.0100%	None Detected
Compound A	NMT 0.0025%	None Detected
Dichloromethane	NMT 0.0100%	None Detected
HFIP Formate	NMT 0.0100%	None Detected
2-Chloropropane	NMT 0.0100%	None Detected
Other individual impurities	NMT 0.0100% each	None Detected
Total Impurities	NMT 0.0300%	0.0013%
Acidity or alkalinity	NMT 0.10 mL of 0.010 M NaOH or NMT 0.30 mL of 0.010 M HCl	Conforms
Fluoride Ion	NMT 2 ug/mL (NMT 0.0002%)	LT 0.0000%
Chloride Ion	NMT 10 ppm (0.001%)	LT 10ppm
Refractive Index @ 20°C	1.2745 - 1.2760	1.2756
Nonvolatile Residue	NMT 0.002% w/v (NMT 1 mg/50 mL)	0.000%
Water	NMT 0.0500 % (NMT 500 ppm)	0.0016%

Baxter Healthcare Corporation certifies this material conforms to the above standards.

COA Issued By:



Dennisse Ortiz

Date: 27-Oct-2022

Approved By:



Ivonne Castro

Date: 27-Oct-2022

Baxter Healthcare Corporation
Route 3 Km 144.2
Guayama, Puerto Rico, 00784, USA.