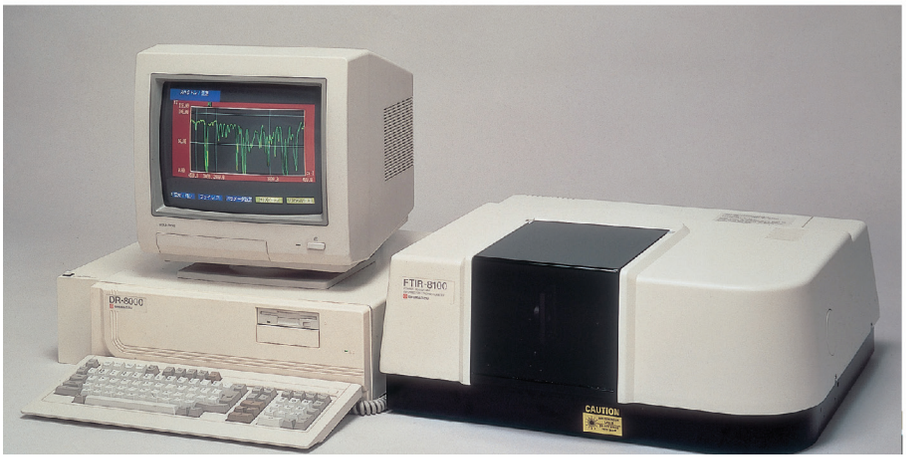
Neutron®
Pharmachemical Co.

ULTRA PURE FOR CHROMATOGRAPHY AND SPECTROSCOPY



Responsible For Quality
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Acetone for GC

Product Code: 1.1030.

Ultra Pure for gas Chromatography

C3H6O

M= 58.08 g/mol

1lit= 0.79 g/cm³

Specification

Assay	≥	99.5	%
Description		Conforms	
Solubility		Conforms	
Identification		Conforms	
Specific gravity		0.789 – 0.791	g/cm³
Evaporation residue	≤	0.004	%
Water	≤	0.3	%

Technical Information

Formula:	C3H6O
Chemical formula:	CH3COCH³
Density:	0.79 g/cm³ (20 °C)
Molar mass:	58.08 g/mol
CAS number:	67-64-1
EC index number:	606-001-00-8
HS code:	29141100
EC number:	200-662-2
Storage (temperature):	Store at +15 °C to +25 °C
MSDS	available
RTECS:	AL3150000
R phrase:	R 11-36-66-67
S phrase:	S 9-16-26
Odour:	fruity
Form:	liquid
Color:	colourless
Explosion limit:	2.6 -12.8 Vol %
Ignition temperature:	465 °C (DIN 51794)
PH value:	5 - 6 (395 g/l 20 °C)
Solubility in water:	(20°C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	< -20 °C (c.c.)
Boiling point:	56.2 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	233 hPa (20 °C)
Viscosity dynamical :	0.32 mPa*s (20 °C)
Saturation concentration (air):	533 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Acetone for HPLC

Product Code: 1.1050.

Ultra Pure for Liquid Chromatography

C3H6O

M= 58.08 g/mol

1lit= 0.79 g/cm³

Specification

Assay	≥	99.8	%
Description		Conforms	
Solubility		Conforms	
Identification		Conforms	
Acidity	≤	0.0002	%
Alkalinity	≤	0.0002	%
Specific gravity		0.789 – 0.791	g/cm³
Residue on evaporation	≤	0.002	%
Readily carbonizable substance		Conforms	
Transmission at 335nm	≥	50.0	%
Transmission at 340nm	≥	80.0	%
Transmission from 350nm	≥	98.0	%
Filtered by 0.2µm suitable filter			
Water	≤	0.05	%

Technical Information

Formula:	C3H6O
Chemical formula:	CH3COCH3
Density:	0.79 g/cm³ (20 °C)
Molar mass:	58.08 g/mol
CAS number:	67-64-1
EC index number:	606-001-00-8
HS code:	29141100
EC number:	200-662-2
Storage (temperature):	Store at +15 °C to +25 °C
MSDS	available
RTECS:	AL3150000
R phrase:	R 11-36-66-67
S phrase:	S 9-16-26
Odour:	fruity
Form:	liquid
Color:	colourless
Explosion limit:	2.6 -12.8 Vol %
Ignition temperature:	465 °C (DIN 51794)
PH value:	5 - 6 (395 g/l 20 °C)
Solubility in water:	(20°C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	< -20 °C (c.c.)
Boiling point:	56.2 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	233 hPa (20 °C)
Viscosity dynamical :	0.32 mPa*s (20 °C)
Saturation concentration (air):	533 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Acetone for UV

Product Code: 1.1780.

Ultra Pure for Spectroscopy

C3H6O

M=58.08 g/mol

1lit=0.79 g/cm³

Specification

Assay	≥	99.9	%
Description		Conforms	
Solubility		Conforms	
Identification		Conforms	
Specific gravity		0.789 – 0.791	g/cm³
Nonvolatile residue	≤	0.004	%
Acidity	≤	0.0005	meq/g
Alkalinity	≤	0.0002	meq/g
Transmission at 330 nm	≥	10	%
Transmission at 335 nm	≥	50	%
Transmission at 339 nm	≥	80	%
Transmission at 342nm	≥	90	%
Transmission from 350 nm	≥	98	%
Water	≤	0.1	%

Technical Information

Formula:	C3H6O
Chemical formula:	CH3COCH3
Density:	0.79 g/cm³ (20 °C)
Molar mass:	58.08 g/mol
CAS number:	67-64-1
EC index number:	606-001-00-8
HS code:	29141100
EC number:	200-662-2
Storage (temperature):	Store at +15 °C to +25 °C
MSDS	available
RTECS:	AL3150000
R phrase:	R 11-36-66-67
S phrase:	S 9-16-26
Odour:	fruity
Form:	liquid
Color:	colourless
Explosion limit:	2.6 -12.8 Vol %
Ignition temperature:	465 °C (DIN 51794)
PH value:	5 - 6 (395 g/l 20 °C)
Solubility in water:	(20°C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	< -20 °C (c.c.)
Boiling point:	56.2 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	233 hPa (20 °C)
Viscosity dynamical :	0.32 mPa*s (20 °C)
Saturation concentration (air):	533 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Chloroform for GC

Product Code: 1.1880.

Ultra Pure for gas Chromatography

CHCl3

M=119.38 g/mol

1lit= 1.48 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Specific gravity		1.474 – 1.479	g/cm³
Nonvolatile residue	≤	0.001	%
Water	≤	0.1	%

Technical Information

Formula:	CHCl3
Density:	1.48 g/cm³ (20 °C)
Molar mass:	119.38 g/mol
CAS number:	67-66-3
EC index number:	602-006-00-4
HS code:	29031300
EC number:	200-663-8
Storage (temperature):	+15 °C to +25 °C
SDS	available
RTECS:	FS9100000
R phrase:	R 22-38-40-48/20/22
S phrase:	S 36/37
Odour:	sweetish
Form:	liquid
Color:	colourless
Solubility in water:	8 g/l (20 °C)
Boiling point:	61 °C
Melting point:	-63 °C
Vapour pressure:	213 hPa (20 °C)
Viscosity dynamical:	0.56 mPa*s (20 °C)
Saturation concentration (air):	1027 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Chloroform for HPLC

Product Code: 1.2230.

Ultra Pure for Liquid Chromatography

CHCl3
M=119.38 g/mol
1lit= 1.48 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Acidity & Alkalinity	≤	0.0002	meq/g
Residue on evaporation	≤	5.0	mg/l
Transmission at 255 nm	≥	70	%
Transmission at 260 nm	≥	85	%
Transmission from 300 nm	≥	98	%
Water	≤	0.01	%
Filtered by 0.2 µm suitable filter			

Technical Information

Formula:	CHCl3
Density:	1.48 g/cm³ (20 °C)
Molar mass:	119.38 g/mol
CAS number:	67-66-3
EC index number:	602-006-00-4
HS code:	29031300
EC number:	200-663-8
Storage (temperature):	Store at +15 °C to +25 °C
SDS	available
RTECS:	FS9100000
R phrase:	R 22-38-40-48/20/22
S phrase:	S 36/37
Odour:	sweetish
Form:	liquid
Color:	colourless
Solubility in water:	8 g/l (20 °C)
Boiling point:	61 °C
Melting point:	-63 °C
Vapour pressure:	213 hPa (20 °C)
Viscosity dynamical:	0.56 mPa*s (20 °C)
Saturation concentration (air):	1027 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Chloroform for UV

Product Code: 1.2220.

Ultra Pure for Spectroscopy

CHCl3
M=119.38 g/mol
1lit= 1.48 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Acidity & Alkalinity	≤	0.0002	meq/g
Residue on evaporation	≤	5.0	mg/l
Transmission at 245 nm	≥	10	%
Transmission at 250 nm	≥	50	%
Transmission at 257 nm	≥	80	%
Transmission at 270 nm	≥	90	%
Transmission from 300 nm	≥	98	%
Water	≤	0.01	%
Color	≤	10	Hazen

Technical Information

Formula:	CHCl3
Density:	1.48 g/cm³ (20 °C)
Molar mass:	119.38 g/mol
CAS number:	67-66-3
EC index number:	602-006-00-4
HS code:	29031300
EC number:	200-663-8
Storage (temperature):	Store at +15 °C to +25 °C
SDS	available
RTECS:	FS9100000
R phrase:	R 22-38-40-48/20/22
S phrase:	S 36/37
Odour:	sweetish
Form:	liquid
Color:	colourless
Solubility in water:	8 g/l (20 °C)
Boiling point:	61 °C
Melting point:	-63 °C
Vapour pressure:	213 hPa (20 °C)
Viscosity dynamical:	0.56 mPa*s (20 °C)
Saturation concentration (air):	1027 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Dichloromethane for GC
(Methylene chloride for GC)

Ultra Pure for gas Chromatography

CH2Cl2

M= 84.93 g/mol

1lit= 1.32 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Specific gravity		1.318– 1.322	g/cm³
Free Chlorine		Conforms	
Limit of hydrogen chloride	≤	0.01	%
Residue on evaporation	≤	5.0	mg/l
Heavy metals	≤	1.0	ppm
Water	≤	0.01	%

Product Code: 1.1910.

Technical Information

Formula:	CH2Cl2
Density:	1.33 g/cm³ (20 °C)
Molar mass:	84.93 g/mol
CAS number:	75-09-2
EC index number:	602-004-00-3
HS code:	29031200
EC number:	200-838-9
Storage (temperature):	Store at +15°C to +25 °C
SDS	available
RTECS:	PA8050000
R phrase:	R 40
S phrase:	S 23.2-24/25-36/37
Odour:	seweetish
Form:	liquid
Color:	colourless
Explosion limit:	13 -22 Vol %
Ignition temperature:	605 °C
Solubility in water:	20 g/l (20 °C)
Boiling point:	40 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	475 hPa (20 °C)
Evaporation number:	1.9 °C
Thermal decomposition:	> 120 °C
Viscosity dynamical:	0.43 mPa*s (20 °C)
Saturation concentration (air):	1549 g/m³ (20 °C)

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

Dichloromethane for HPLC
(Methylene chloride for HPLC)

Ultra Pure for Liquid Chromatography

CH2Cl2

M= 84.93 g/mol

1lit= 1.32 g/cm³

Specification

Assay	≥	99.9	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Specific gravity		1.318– 1.322	g/cm³
Residue on evaporation	≤	5.0	mg/l
Acidity & Alkalinity	≤	0.0002	meq/g
Transmission at 240nm	≥	70	%
Transmission at 254nm	≥	90	%
Transmission from 260nm	≥	99	%
Water	≤	0.01	%

Filtered by 0.2 µm suitable filter

Product Code: 1.2250.

Technical Information

Formula:	CH2Cl2
Density:	1.33 g/cm³ (20 °C)
Molar mass:	84.93 g/mol
CAS number:	75-09-2
EC index number:	602-004-00-3
HS code:	29031200
EC number:	200-838-9
Storage (temperature):	+15°C to +25 °C
SDS	available
RTECS:	PA8050000
R phrase:	R 40
S phrase:	S 23.2-24/25-36/37
Odour:	seweetish
Form:	liquid
Color:	colourless
Explosion limit:	13 -22 Vol %
Ignition temperature:	605 °C
Solubility in water:	20 g/l (20 °C)
Boiling point:	40 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	475 hPa (20 °C)
Evaporation number:	1.9 °C
Thermal decomposition:	> 120 °C
Viscosity dynamical:	0.43 mPa*s (20 °C)
Saturation concentration (air):	1549 g/m³ (20 °C)

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

Dichloromethane for UV

(Methylene chloride for UV)

Ultra Pure for Spectroscopy

CH2Cl2
M= 84.93 g/mol
1lit= 1.33 g/cm³

Specification

Assay	≥	99.9	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Specific gravity		1.318– 1.322	g/cm³
Residue on evaporation	≤	5.0	mg/l
Acidity & Alkalinity	≤	0.0002	meq/g
Transmission at 235nm	≥	10	%
Transmission at 240nm	≥	50	%
Transmission at 245nm	≥	80	%
Transmission at 248nm	≥	90	%
Transmission from 255nm	≥	99	%
Water	≤	0.01	%

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Product Code: 1.2240.

Technical Information

Formula:	CH2Cl2
Density:	1.33 g/cm³ (20 °C)
Molar mass:	84.93 g/mol
CAS number:	75-09-2
EC index number:	602-004-00-3
HS code:	29031200
EC number:	200-838-9
Storage (temperature):	Store at +15°C to +25 °C
SDS	available
RTECS:	PA8050000
R phrase:	R 40
S phrase:	S 23.2-24/25-36/37
Odour:	seweetish
Form:	liquid
Color:	colourless
Explosion limit:	13 -22 Vol %
Ignition temperature:	605 °C
Solubility in water:	20 g/l (20 °C)
Boiling point:	40 °C (1013 hPa)
Melting point:	-95 °C
Vapour pressure:	475 hPa (20 °C)
Evaporation number:	1.9 °C
Thermal decomposition:	> 120 °C
Viscosity dynamical:	0.43 mPa*s (20 °C)
Saturation concentration (air):	1549 g/m³ (20 °C)

Methanol for GC

Ultra Pure for gas Chromatography

CH3OH
M= 32.04 g/mol
1 lit= 0.79 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Color & Description		Conforms	
Identification		Conforms	
Alkalinity	≤	3.0	ppm
Acidity	≤	0.45	ml
Readily carbonizable substances		Conforms	
Acetone & aldehyde		Conforms	
Nonvolatile residue		Conforms	
Evaporation residue	≤	0.001	%
Carbonyl compounds (as acetone)	≤	0.003	%
Substances reducing		Conforms	
Boiling Point		64.0 – 65.0	°C
Water	≤	0.1	%

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Product Code: 1.1230.

Technical Information

Formula:	CH4O
Chemical formula:	CH3OH
Density:	0.79 g/cm³ (20 °C)
Molar mass:	32.04 g/mol
CAS number:	67-56-1
EC index number:	603-001-00-X
HS code:	29051100
EC number:	200-659-6
Storage (temperature):	Without limitation
SDS	available
RTECS:	PC1400000
R phrase:	R 11-23/24/25-39/23/24/25
S phrase:	S 7-16-36/37-45
Odour:	characteristic
Form:	liquid
Color:	colourless
Explosion limit:	5.5 -36.5 Vol %
Ignition temperature:	455 °C (DIN 51794)
Solubility in water:	(20°C) soluble
Flash point:	11 °C (c.c.)
Boiling point:	64.5 °C (1013 hPa)
Melting point:	-98 °C
Vapour pressure:	128 hPa (20 °C)
Viscosity dynamical :	0.597 mPa*s (20 °C)
Saturation concentration (air):	166 g/m³ (20 °C)

Methanol for isocratic HPLC

Product Code: 1.1240.

Ultra Pure for Liquid Chromatography

CH3OH

M= 32.04 g/mol

1 lit= 0.79 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Color & Description		Conforms	
Identification		Conforms	
Alkalinity	≤	3.0	ppm
Acidity	≤	0.45	ml
Acetone & aldehyde		Conforms	
Residue on evaporation	≤	3.0	mg/l
Transmission at 225nm	≥	50	%
Transmission at 240nm	≥	80	%
Transmission from 265nm	≥	98	%
Absorbance at 235nm	≤	2.0	mAU
Absorbance at 254nm	≤	1.0	mAU
Boiling Point		64.0 – 65.0	°C
Filtered by 0.2 µm suitable filter			
Water	≤	0.03	%

Technical Information

Formula:	CH4O
Chemical formula:	CH3OH
Density:	0.79 g/cm³ (20 °C)
Molar mass:	32.04 g/mol
CAS number:	67-56-1
EC index number:	603-001-00-X
HS code:	29051100
EC number:	200-659-6
Storage (temperature):	Without limitation
SDS	available
RTECS:	PC1400000
R phrase:	R 11-23/24/25-39/23/24/25
S phrase:	S 7-16-36/37-45
Odour:	characteristic
Form:	liquid
Color:	colourless
Explosion limit:	5.5 -36.5 Vol %
Ignition temperature:	455 °C (DIN 51794)
Solubility in water:	(20°C) soluble
Flash point:	11 °C (c.c.)
Boiling point:	64.5 °C (1013 hPa)
Melting point:	-98 °C
Vapour pressure:	128 hPa (20 °C)
Viscosity dynamical :	0.597 mPa*s (20 °C)
Saturation concentration (air):	166 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Methanol for UV

Product Code: 1.1980.

Ultra Pure for Spectroscopy

CH3OH

M= 32.04 g/mol

1 lit= 0.79 g/cm³

Specification

Assay	≥	99.9	%
Solubility		Conforms	
Color & Description		Conforms	
Identification		Conforms	
Alkalinity	≤	0.0002	meq/g
Acidity	≤	0.0005	meq/g
Residue on carbonizable substances		Conforms	
Evaporation residue	≤	0.001	%
Transmission at 207	≥	10	%
Transmission at 220	≥	50	%
Transmission from 232	≥	80	%
Absorbance at 242	≥	90	%
Absorbance at 260	≥	98	%
Water	≤	0.02	%

Technical Information

Formula:	CH4O
Chemical formula:	CH3OH
Density:	0.79 g/cm³ (20 °C)
Molar mass:	32.04 g/mol
CAS number:	67-56-1
EC index number:	603-001-00-X
HS code:	29051100
EC number:	200-659-6
Storage (temperature):	Without limitation
SDS	available
RTECS:	PC1400000
R phrase:	R 11-23/24/25-39/23/24/25
S phrase:	S 7-16-36/37-45
Odour:	characteristic
Form:	liquid
Color:	colourless
Explosion limit:	5.5 -36.5 Vol %
Ignition temperature:	455 °C (DIN 51794)
Solubility in water:	(20°C) soluble
Flash point:	11 °C (c.c.)
Boiling point:	64.5 °C (1013 hPa)
Melting point:	-98 °C
Vapour pressure:	128 hPa (20 °C)
Viscosity dynamical :	0.597 mPa*s (20 °C)
Saturation concentration (air):	166 g/m³ (20 °C)

Glass Bottles			Plastic Bottles			Plastic Gallon		
1	Liter	●	1	Liter		5	Liter	
2.5	Liter	●	2.5	Liter		10	Liter	
						20	Liter	

Methanol for Gradient HPLC

Product Code: 1.2180.

Ultra Pure for Liquid Chromatography

CH3OH

M= 32.04 g/mol

1 lit= 0.79 g/cm³

Specification

Assay	≥	99.9	%
Solubility		Conforms	
Color & Description		Conforms	
Identification		Conforms	
Alkalinity	≤	3.0	ppm
Acidity	≤	0.45	ml
Acetone & aldehyde		Conforms	
Residue on evaporation	≤	3.0	mg/l
Transmission at 220nm	≥	55	%
Transmission at 235nm	≥	83	%
Transmission from 260nm	≥	98	%
Absorbance at 235nm	≤	2.0	mAU
Absorbance at 254nm	≤	1.0	mAU
Absorbance at 225nm	≤	0.17	mAU
Water	≤	0.03	%

Filtered by 0.2 µm suitable filter

Technical Information

Formula:	CH4O
Chemical formula:	CH3OH
Density:	0.79 g/cm³ (20 °C)
Molar mass:	32.04 g/mol
CAS number:	67-56-1
EC index number:	603-001-00-X
HS code:	29051100
EC number:	200-659-6
Storage (temperature):	Without limitation
SDS	available
RTECS:	PC1400000
R phrase:	R 11-23/24/25-39/23/24/25
S phrase:	S 7-16-36/37-45
Odour:	characteristic
Form:	liquid
Color:	colourless
Explosion limit:	5.5 -36.5 Vol %
Ignition temperature:	455 °C (DIN 51794)
Solubility in water:	(20°C) soluble
Flash point:	11 °C (c.c.)
Boiling point:	64.5 °C (1013 hPa)
Melting point:	-98 °C
Vapour pressure:	128 hPa (20 °C)
Viscosity dynamical :	0.597 mPa*s (20 °C)
Saturation concentration (air):	166 g/m³ (20 °C)

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

Potassium bromide for IR

Product Code: 1.3130.

Ultra Pure for Spectroscopy

KBr

M=119.01 g/mol

Specification

Description		Conforms
Identification		Conforms
Application test	≤	Conforms
Absorbance water	≤	0.15
Absorbance CH Compounds	≤	0.004
Absorbance Other 420 - 4000 cm-1	≤	0.015

Technical Information

Formula	BrK
Chemical formula	KBr
Density	2.75 g/cm³ (20°C)
Molar mass	119.01 g/mol
Bulk density	~ 900 -1000 kg/m³
CAS number	7758- 02- 3
HS Code	28275100
EC number	231- 830-3
Storage	Without limitation
SDS	available
RTECS	TS7650000
Odour	oderless
Form	solid
Color	colorless to white
p H	5.5 - 8.5 (50g/l 20 °C)
Solubility in water	650 g/l (20°C)
Solubility in ethanol	4 g/l (20°C)
Boiling point	1435 °C
Melting point	730 °C
Vapour pressure	~ 1.3 hpa

Glass Bottles		
5	gr	
10	gr	
25	gr	●

Plastic Bottles		
100	gr	●
500	gr	
800	gr	

Plastic Gallon		
1	kg	
5	kg	
10	kg	

2-Propanol for GC
(Iso Propanol for GC)

Ultra Pure for gas Chromatography

C3H8O

M= 60.10 g/mol

1 lit= 0.786 g/cm³

Specification

Assay	≥	99.5	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Evaporation residue	≤	0.002	%
Acidity	≤	0.7	ml
Specification gravity		0.784 – 0.785	g/cm³
Water	≤	0.1	%

Product Code: 1.1410.

Technical Information

Formula:	C3H8O
Chemical formula:	CH3CH(OH)CH3
Density:	0.786 g/cm³ (20 °C)
Molar mass:	60.10 g/mol
CAS number:	67-63-0
EC index number:	603-117-00-0
HS code:	29051200
EC number:	200-661-7
Storage (temperature):	Store at +5 °C to +30 °C
SDS	available
RTECS:	NT8050000
R phrase:	R 11-36-67
S phrase:	S 7-16-24/25-26
Odour:	alcohol-like
Form:	liquid
Color:	colourless
Explosion limit:	2 - 12.7 Vol %
Ignition temperature:	425 °C (DIN 51794)
Solubility in water:	(20 °C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	12 °C (c.c.)
Boiling point:	82.4 °C (1013 hPa)
Melting point:	-89.5 °C
Vapour pressure:	43 hPa (20 °C)
Viscosity dynamical:	2.2 mPa*s (20 °C)
Saturation concentration (air):	105 g/m³ (20 °C)

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

2-Propanol for UV
(Iso Propanol for UV)

Ultra Pure for Spectroscopy

C3H8O

M= 60.10 g/mol

1 lit= 0.786 g/cm³

Specification

Assay	≥	99.5	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Evaporation residue	≤	0.002	%
Acidity	≤	0.7	ml
Specification gravity		0.784 – 0.785	g/cm³
Transmission at 207	≥	10	%
Transmission at 217	≥	50	%
Transmission at 232	≥	80	%
Transmission at 242	≥	90	%
Transmission from 260	≥	98	%
Water	≤	0.1	%

Product Code: 1.2140.

Technical Information

Formula:	C3H8O
Chemical formula:	CH3CH(OH)CH3
Density:	0.786 g/cm³ (20 °C)
Molar mass:	60.10 g/mol
CAS number:	67-63-0
EC index number:	603-117-00-0
HS code:	29051200
EC number:	200-661-7
Storage (temperature):	Store at +5 °C to +30 °C
SDS	available
RTECS:	NT8050000
R phrase:	R 11-36-67
S phrase:	S 7-16-24/25-26
Odour:	alcohol-like
Form:	liquid
Color:	colourless
Explosion limit:	2 - 12.7 Vol %
Ignition temperature:	425 °C (DIN 51794)
Solubility in water:	(20 °C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	12 °C (c.c.)
Boiling point:	82.4 °C (1013 hPa)
Melting point:	-89.5 °C
Vapour pressure:	43 hPa (20 °C)
Viscosity dynamical:	2.2 mPa*s (20 °C)
Saturation concentration (air):	105 g/m³ (20 °C)

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

2-Propanol for HPLC

(Iso Propanol for HPLC)

Ultra Pure for Liquid Chromatography

C3H8O

M= 60.10 g/mol

1 lit= 0.786 g/cm³

Specification

Assay	≥	99.8	%
Solubility		Conforms	
Description		Conforms	
Identification		Conforms	
Evaporation residue	≤	0.002	%
Acidity	≤	0.7	ml
Specification gravity		0.784 – 0.785	g/cm³
Absorbance at 235		1.0	mAU
Absorbance at 254		1.0	mAU
Transmission at 210	≥	30	%
Transmission at 230	≥	80	%
Transmission from 270	≥	99	%
Water	≤	0.1	%

Glass Bottles		
1	Liter	●
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

Product Code: 1.2150.

Technical Information

Formula:	C3H8O
Chemical formula:	CH3CH(OH)CH3
Density:	0.786 g/cm³ (20 °C)
Molar mass:	60.10 g/mol
CAS number:	67-63-0
EC index number:	603-117-00-0
HS code:	29051200
EC number:	200-661-7
Storage (temperature):	Store at +5 °C to +30 °C
SDS	available
RTECS:	NT8050000
R phrase:	R 11-36-67
S phrase:	S 7-16-24/25-26
Odour:	alcohol-like
Form:	liquid
Color:	colourless
Explosion limit:	2 - 12.7 Vol %
Ignition temperature:	425 °C (DIN 51794)
Solubility in water:	(20 °C) soluble
Solubility in ethanol:	soluble
Solubility in chloroform:	soluble
Flash point:	12 °C (c.c.)
Boiling point:	82.4 °C (1013 hPa)
Melting point:	-89.5 °C
Vapour pressure:	43 hPa (20 °C)
Viscosity dynamical:	2.2 mPa*s (20 °C)
Saturation concentration (air):	105 g/m³ (20 °C)

Water for HPLC

Ultra Pure for Liquid Chromatography

H2O

M= 18.02 g/mol

1lit= 1.0 g/cm³

Specification

Description		Conforms	
Appearance		Conforms	
Abs@200nm	≤	20.0	mAU
Abs@210nm	≤	5.0	mAU
Abs@254nm	≤	0.5	mAU
Abs@300nm		0.005	
Ammonia		Conforms	
Chloride		Conforms	
Calcium		Conforms	
Sulfate		Conforms	
Oxidizable substances		Conforms	
Magnesium		Conforms	
Nitrate		Conforms	
Evaporation residue	≤	5.0	mg/l
Gradient@210nm	≤	5.0	mAU
Gradient@254nm	≤	0.5	mAU
Spec Conductance@25	≤	1.0	µS/cm
p H@25		5.0 - 7.0	

Glass Bottles		
1	Liter	
2.5	Liter	●

Plastic Bottles		
1	Liter	
2.5	Liter	

Plastic Gallon		
5	Liter	
10	Liter	
20	Liter	

Product Code: 1.1720.

Technical Information

Formula (Hill):	H2O
Density:	1.00g/cm3 (20 °C)
Molar mass:	18.02 g/mol
CAS number:	7732-18-5
HS code:	28510010
EC number:	231-791-2
Storage (temperature):	Store at +5 to +30 °C
SDS	Available
RTECS:	ZC0110000
Odour:	Odourless
Form:	Liquid
Color:	Colourless
Boiling point:	100 °C
Melting point:	0 °C
Vapour pressure:	23hpa (20 °C)
Viscosity dynamical:	0.952 mPa*s (20 °C)

CHROMATOGRAPHIC COLUMNS

A complete list of packings (L), phases (G), and supports (S) used in USP-NF tests and assays is located in USP-NF and PF, Reagents, Indicators, and Solutions-Chromatographic Columns. This list is intended to be a convenient reference for the chromatographer in identifying the pertinent chromatographic column specified in the individual monograph.

DEFINITIONS AND INTERPRETATION OF CHROMATOGRAMS

Chromatogram: A chromatogram is a graphical representation of the detector response, concentration of analyte in the effluent, or other quantity used as a measure of effluent concentration versus effluent volume or time. In planar chromatography, chromatogram may refer to the paper or layer with the separated zones. *Figure 1* represents a typical chromatographic separation of two substances, 1 and 2. t_{R1} and t_{R2} are the respective retention times; h is the height, *h/2* is the half-height, and $W_{h/2}$ is the width at half-height, for peak 1. W_1 and W_2 are the respective widths of peaks 1 and 2 at the baseline. Air peaks are a feature of gas chromatograms and correspond to the solvent front in LC. The retention time of these air peaks, or unretained components, is designated as t_M.

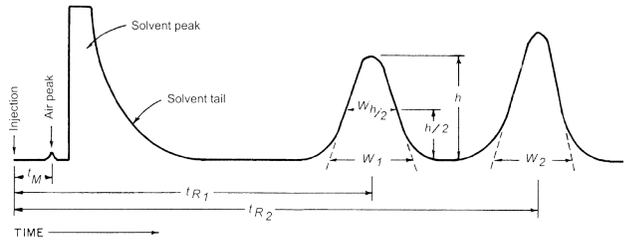

Figure 1. Chromatographic separation of two substances.

Dwell Volume (D): The dwell volume, also known as gradient delay volume, is the volume between the point at which the eluents meet and the top of the column.

Hold-UpTime (t_M): The hold-up time is the time required for elutionof an unretained component (see Figure 1, shown as an airor unretained solvent peak, with the baseline scale in min).

Hold-Up Volume (V_M): The hold-up volume is the volume of mobile phase required for elution of an unretained component It may be calculated from the hold-up time and the flow rate F, in mL/min:

$$V_M = t_M \times F$$

In size exclusion chromatography, the symbol V_O is used.

Number of Theoretical Plates (N): N is a measure of column efficiency. For Gaussian peaks, it is calculated by:

$$N = 16(t_R/W)^2$$

where t_R is the retention time of the substance, and W is the peak width at its base, obtained by extrapolating the relatively straight sides of the peak to the baseline. The value of N depends upon the substance being chromatographed as well as the operating conditions, such as the flow rate and temperature of the mobile phase or carrier gas, the quality of the packing, the uniformity of the packing within the column, and, for capillary columns, the thickness of the stationary phase film and the internal diameter and length of the column. Where electronic integrators are used, it may be convenient to determine the number of theorical plates, by the equation:

$$N = 5.54\left(\frac{t_R}{W_{h/2}}\right)^2$$

where $W_{h/2}$ is the peak width at half-height. However, in the event of dispute, only equations based on peak width at baseline are to be used. Peak: The peak is the portion of the chromatographic recording of the detector response when a single component is eluted from the column. If separation is incomplete, two or more components may be eluted as one unresolved peak. Peak-to-Valley Ratio (p/v): The p/v may be employed as a system suitability criterion in a test for related substances when baseline separation between two peaks is not achieved. Figure 2 represents a partial separation of two substances, where Hp is the height above the extrapolated baseline of the minor peak and Hv is the height above the extrapolated baseline at the lowest point of the curve separating the minor and major peaks:

$$p/v = H_p/H_v$$

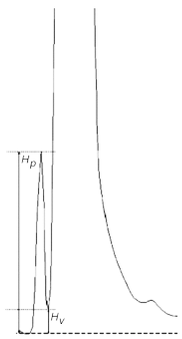

Figure 2. Peak-to-valley ratio determination.

Relative Retardation (R_{ret}): The relative retardation is the ratio of the distance traveled by the analyte to the distance simultaneously traveled by a reference compound (see Figure 3) and is used in planar chromatography.

$$R_{ret} = b/c$$

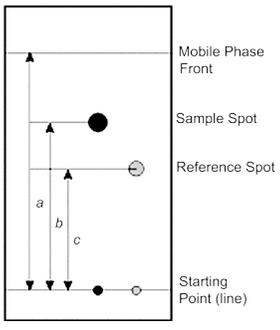

Figure 3. Typical planar chromatography.

Relative Retention (r) : The ratio of the adjusted retention time of a component relative to that of another used as a reference obtained under identical conditions:

$$r = t_{R2} - t_M / t_{R1} - t_M$$

where tR2 is the retention time measured from the point of injection of the compound of interest; tR1 is the retention time measured from the point of injection of the compound used as reference; and tM is the retention time of a nonretained marker defined in the procedure, all determined under identical experimental conditions on the same column.

Relative Retention Time (RRT): Also known as unadjusted relative retention. Comparisons in USP are normally made in terms of unadjusted relative retention, unless otherwise indica

$$RRT = t_{R2}/t_{R1}$$

The symbol r_G is also used to designate unadjusted relative retention values.

Relative Standard Deviation in Percentage

$$\%RSD = \frac{100}{\bar{x}} \left(\frac{\sum_{i=1}^{N} \left(x_i - \bar{x} \right)^2}{N-1} \right)^1$$

Retardation Factor (R_F): The retardation factor is the ratio of the distance traveled by the center of the spot to the distance simultaneously traveled by the mobile phase and is used in planar chromatography. Using the symbols in Figure 3:

$$R_F = b/a$$

Retention Factor (k)[1]: The retention factor is also known as the capacity factor (k^1). Defined as

$$K = \frac{\text{amount of substance in stationary phase}}{\text{amount of substance in mobile phase}}$$

$$K = \frac{\text{time spent by substance in stationary phase}}{\text{time spent by substance in mobile phase}}$$

:

The retention factor of a component may be determined from the chromatogram:

$$k = (t_R - t_M)/t_M$$

Retention Time (t_R): In liquid chromatography and gas chromatography, the retention time, t_R, is defined as the time elapsed between the injection of the sample and the appearance of the maximum peak response of the eluted sample zone. t_R may be used as a parameter for identification. Chromatographic retention times are characteristic of the compounds they represent but are not unique. Coincidence of retention times of a sample and a reference substance can be used as a partial criterion in construction of an identity profile but may not be sufficient on its own to establish identity.

Absolute retention times of a given compound may vary from one chromatogram to the next.

Retention Volume (V_R): The retention volume is the volume of mobile phase required for elution of a component. It may be calculated from the retention time and the flow rate in mL/min:

$$V_R = t_R \times F$$

Resolution (R_S): The resolution is the separation of two components in a mixture, calculated by:

$$R_S = 2 \times (t_{R2} - t_{R1})/(W_1 + W_2)$$

where tR2 and tR1 are the retention times of the two components; and W2 and W1 are the corresponding widths at the bases of the peaks obtained by extrapolating the relatively straight sides of the peaks to the baseline.Where electronic integrators are used, it may be convenient to determine the resolution, by the equation:

$$R_S = 1.18 \times (t_{R2} - t_{R1})/(W_{1,h/2} + W_{2,h/2})$$

Separation Factor (ά): The separation factor is the relative retention calculated for two adjacent peaks (by convention, the value of the separation factor is always >1):

$$ά = k_2/k_1$$

Symmetry Factor (A_S): The symmetry factor, also known as the tailing factor, of a peak (see Figure 4) is calculated by:

$$A_S = W_{0.05}/2f$$

where $W_{0.05}$ is the width of the peak at 5% height and f is the distance from the peak maximum to the leading edge of the peak, the distance being measured at a point 5% of the peak height from the baseline.

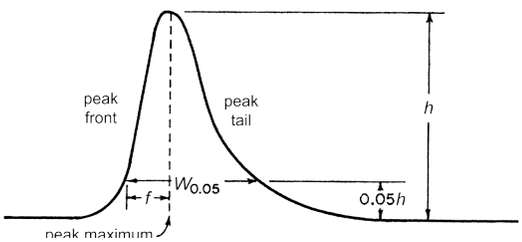

Figure 4. Asymmetrical chromatographic peak.

Tailing Factor (T): See Symmetry Factor.

SYSTEM SUITABILITY

System suitability tests are an integral part of gas and liquid chromatographic methods. These tests are used to verify that the chromatographic system is adequate for the intended analysis. The tests are based on the concept that the equipment, electronics, analytical operations, and samples analyzed constitute an integral system that can be evaluated as such. Factors that may affect chromatographic behavior include the following:

■ Composition, ionic strength, temperature, and apparent pH of the mobile phase
■Flow rate, column dimensions, column temperature, and pressure
■Stationary phase characteristics, including type of chromatographic support (particle-based or monolithic), particle or macropore size, porosity, and specific surface area
■Reverse-phase and other surface modification of the stationary phases, the extent of chemical modification (as expressed by end-capping, carbon loading, etc.)

The resolution, RS, is a function of the number of theoretical plates, N (also referred to as efficiency), the separation factor, a, and the capacity factor, k. [NOTE-All terms and symbols are defined in the preceding section Definitions and Interpretation of Chromatograms.] For a given stationary phase and mobile phase, N may be specified to ensure that closely eluting compounds are resolved from each other, to establish the general resolving power of the system, and to ensure that internal standards are resolved from the drug. This is a less reliable means to ensure resolution than is direct measurement. Column efficiency is, in part, a reflection of peak sharpness, which is important for the detection of trace components. Replicate injections of a standard preparation or other standard solutions are compared to ascertain whether requirements for precision are met.

Unless otherwise specified in the individual monograph, data from five replicate injections of the analyte are used to calculate the relative standard deviation, %RSD, if the requirement is 2.0% or less; data from six replicate injections are used if the relative standard deviation requirement is more than 2.0%. For the Assay in a drug substance monograph, where the value is 100% for the pure substance, and no maximum relative standard deviation is stated, the maximum permitted %RSD is calculated for a series of injections of the reference solution:

$$\%RSD = KB\sqrt{n}/t_{90\%,n-1}$$

where K is a constant (0.349), obtained from the expression $K = (0.6/\sqrt{2}) \times (t_{90\%,5}/\sqrt{6})$, in which $0.6/\sqrt{2}$ represents the required percentage relative standard deviation after six injections for B = 1.0; B is the upper limit given in the definition of the individual monograph minus 100%; n is the number of replicate injections of the reference solution ($3 < n > 6$); and $t_{90\%,n-1}$ is the Student's t at the 90% probability level (double sided) with n − 1 degrees of freedom. Unless otherwise prescribed, the maximum permitted relative standard deviation does not exceed the appropriate value given in the table of repeatability requirements. This requirement does not apply to tests for related substances.

Relative Standard Deviation Requirements

	Number of Individual Injections			
	3	4	5	6
B (%)	Maximum Permitted RSD			
2.0	0.41	0.59	0.73	0.85
2.5	0.52	0.74	0.92	1.06
2.5	0.62	0.89	1.10	1.27

The symmetry factor, A_S, a measure of peak symmetry, is unity for perfectly symmetrical peaks; and its value increases as tailing becomes more pronounced (see Figure 4). In some cases, values less than unity may be observed. As peak symmetry moves away from values of 1, integration, and hence precision, become less reliable.

The signal-to-noise ratio (S/N) is a useful system suitability parameter. The S/N is calculated as follows:

$$S/N = 2H/h$$

where H is the height of the peak measured from the peak apex to a baseline extrapolated over a distance ³5 times the peak width at its half-height; and h is the difference between the largest and smallest noise values observed over a distance ³5 times the width at the half-height of the peak and, if possible, situated equally around the peak of interest (see Figure 5).

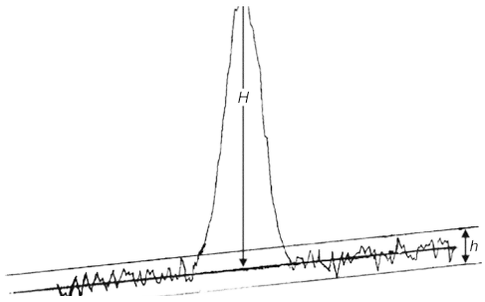

Figure 5. Noise and chromatographic peak, components of the S/N ratio.

These system suitability tests are performed by collecting data from replicate injections of standard or other solutions as specified in the individual monograph. The specification of definitive parameters in a monograph does not preclude the use of other suitable operating conditions. Adjustments to the specified chromatographic system may be necessary in order to meet system suitability requirements. Adjustments to chromatographic systems performed in order to comply with system suitability requirements are not to be made in order to compensate for column failure or system malfunction. Adjustments are permitted only when suitable standards (including Reference Standards) are available for all compounds used in the suitability test; and the adjustments or column change yields a chromatogram that meets all the system suitability requirements specified in the official procedure. If adjustments of operating conditions are necessary in order to meet system suitability requirements, each of the items in the following list is the maximum

variation that can be considered, unless otherwise directed in the monograph; these changes may require additional verification data. To verify the suitability of the method under the new conditions, assess the relevant analytical performance characteristics potentially affected by the change. Multiple adjustments can have a cumulative effect on the performance of the system and are to be considered carefully before implementation. In some circumstances, it may be desirable to use an HPLC column with different dimensions to those prescribed in the official procedure (different length, internal diameter, and/ or particle size). In either case, changes in the chemical characteristics ("L" designation) of the stationary phase will be considered a modification to the method and will require full validation. Adjustments to the composition of the mobile phase in gradient elution may cause changes in selectivity and are not recommended. If adjustments are necessary, change in column packing (maintaining the same chemistry), the duration of an initial isocratic hold (when prescribed), and/or dwell volume adjustments are allowed. Additional allowances for gradient adjustment are noted in the text below.

pH of Mobile Phase (HPLC): The pH of the aqueous buffer used in the preparation of the mobile phase can be adjusted to within ±0.2 units of the value or range specified. Applies to both gradient and isocratic separations.

Concentration of Salts in Buffer (HPLC): The concentration of the salts used in the preparation of the aqueous buffer employed in the mobile phase can be adjusted to within ±10% if the permitted pH variation (see above) is met. Applies to both gradient and isocratic separations.

Ratio of Components in Mobile Phase (HPLC): The following adjustment limits apply to minor components of the mobile phase (specified at 50% or less). The amounts of these components can be adjusted by ±30% relative. However, the change in any component cannot exceed ±10% absolute (i.e., in relation to the total mobile phase). Adjustment can be made to one minor component in a ternary mixture. Examples of adjustments for binary and ternary mixtures are given below.

Binary Mixtures SPECIFIED RATIO OF 50:50: 30% of 50 is 15% absolute, but this exceeds the maximum permitted change of ±10% absolute in either component. Therefore, the mobile phase ratio may be adjusted only within the range of 40:60–60:40. SPECIFIED RATIO OF 2:98: 30% of 2 is 0.6% absolute. Therefore the maximum allowed adjustment is within the range of 1.4: 98.6–2.6: 97.4.

Ternary Mixtures

SPECIFIED RATIO OF 60:35:5: For the second component, 30% of 35 is 10.5% absolute, which exceeds the maximum permitted change of ±10% absolute in any component. Therefore the second component may be adjusted only within the range of 25%-45% absolute. For the third component, 30% of 5 is 1.5% absolute. In all cases, a sufficient quantity of the first component is used to give a total of 100%. Therefore, mixture ranges of 50:45:5–70:25:5 or 58.5: 35: 6.5–61.5: 35: 3.5 would meet the requirement.

Wavelength of UV-Visible Detector (HPLC): Deviations from the wavelengths specified in the procedure are not permitted. The procedure specified by the detector manufacturer, or another validated procedure, is used to verify that error in the detector wavelength is, at most, ±3 nm.

Stationary Phase

COLUMN LENGTH (GC): Can be adjusted by as much as ±70%.
COLUMN LENGTH (HPLC): See Particle Size (HPLC) below.
COLUMN INNER DIAMETER (HPLC): Can be adjusted if the linear velocity is kept constant. See Flow Rate (HPLC) below.
COLUMN INNER DIAMETER (GC): Can be adjusted by as much as ±50%.
FILM THICKNESS (CAPILLARY GC): Can be adjusted by as much as −50% to 100%.

Particle Size (HPLC): For isocratic separations, the particle size and/or the length of the column may be modified provided that the ratio of the column length (L) to the particle size (dp) remains constant or into the range between −25% to +50% of the prescribed L/dp ratio. Alternatively (as for the application of particle-size adjustment to superficially porous particles), other combinations of L and dp can be used provided that the number of theoretical plates (N) is within −25% to +50%, relative to the prescribed column. Caution should be taken when the adjustment results in a higher number of theoretical plates which generates smaller peak volumes, which may require adjustments to minimize extra-column band broadening by factors as instrument plumbing, detector cell volume and sampling rate, and injection volume. When particle size is not mentioned in the monograph, the ratio must be calculated using the largest particle size consigned in the USP definition of the column. For gradient separations, changes in length, column inner diameter and particle size are not allowed.

Particle Size (GC): Changing from a larger to a smaller or from a smaller to a larger particle size GC mesh support is acceptable if the chromatography meets the requirements of system suitability and the same particle size range ratio is maintained. The particle size range ratio is defined as the diameter of the largest particle divided by the diameter of the smallest particle.

Flow Rate (GC): The flow rate can be adjusted by as much as ±50%.

Flow Rate (HPLC): When the particle size is changed, the flow rate may require adjustment, because smaller-particle columns will require higher linear velocities for the same performance (as measured by reduced plate height).

Injection Volume (HPLC): The injection volume can be adjusted as far as it is consistent with accepted precision, linearity,and detection limits. Note that excessive injection volume can lead to unacceptable band broadening, causin-reduction in N and resolution. Applies to both gradient and isocratic separations.

Injection Volume and Split Volume (GC): The injection volume and split volume may be adjusted if detection and repeatabilityare satisfactory.

Column Temperature (HPLC): The column temperature can be adjusted by as much as ±10°. Column thermostating isrecommended to improve control and reproducibility of retention time. Applies to both gradient and isocratic separations.

Oven Temperature (GC): The oven temperature can be adjusted by as much as ±10%.

Oven Temperature Program (GC): Adjustment of temperatures is permitted as stated above. When the specified temperature
must be maintained or when the temperature must be changed from one value to another, an adjustment of up to ±20% is permitted.Unless otherwise directed in the monograph, system suitability parameters are determined from the analyte peak. Measured values of Rr, RF, or tR for the sample substance do not deviate from the values obtained for the reference compound and mixture by more than the statistically determined reliability estimates from replicate assays of the reference compound.Relative retention times may be provided in monographs for informational purposes only to aid in peak identification.There are no acceptance criteria applied to relative retention times.

Suitability testing is used to ascertain the effectiveness of the final operating system, which should be subjected to this testing. Make injections of the appropriate preparation(s) as required in order to demonstrate adequate System suitabi ity (as described in the Chromatographic system section of the method in a monograph) throughout the run.

The preparation can be a standard preparation or a solution containing a known amount of analyte and any additional materials (e.g., excipients or impurities) useful in controlling the analytical system. Whenever there is a significant change in the chromatographic system (equipment, mobile phase component, or other components) or in a critical reagent, System suitability is to be reestablished. No sample analysis is acceptable unless the suitability of the system has been demonstrated.

QUANTITATION

During quantitation, disregard peaks caused by solvents and reagents or arising from the mobile phase or the sample matrix. In the linear range, peak areas and peak heights are usually proportional to the quantity of compound eluting. The peak areas and peak heights are commonly measured by electronic integrators but may be determined by more classical approaches. Peak areas are generally used but may be less accurate if peak interference occurs. The components measured are separated from any interfering components. Peak tailing and fronting is minimized, and the measurement of peaks on tails of other peaks are avoided when possible.

Although comparison of impurity peaks with those in the chromatogram of a standard at a similar concentration is preferred, impurity tests may be based on the measurement of the peak response due to impurities and expressed as a percentage of the area of the drug peak. The standard may be the drug itself at a level corresponding to, for example, 0.5% impurity, assuming similar peak responses. When impurities must be determined with greater certainty, use a standard of the impurity itself or apply a correction factor based on the response of the impurity relative to that of the main component.

External Standard Method: The concentration of the component(s) quantified is determined by comparing the response(s) obtained with the sample solution to the response (s) obtained with a standard solution.

Internal Standard Method: Equal amounts of the internal standard are introduced into the sample solution and a standard solution. The internal standard is chosen so that it does not react with the test material, is stable, is resolved from the component(s) quantified (analytes), and does not contain impurities with the same retention time as that of the analytes. The concentrations of the analytes are determined by comparing the ratios of their peak areas or peak heights and the internal standard in the sample solution with the ratios of their peak areas or peak heights and the internal standard in the standard solution.

Normalization Procedure: The percentage content of a component of the test material is calculated by determining the area of the corresponding peak as a percentage of the total area of all the peaks, excluding those due to solvents or reagents or arising from the mobile phase or the sample matrix and those at or below the limit at which they can be disregarded.

Calibration Procedure: The relationship between the measured or evaluated signal y and the quantity (e.g., concentration, mass) of substance x is determined, and the calibration function is calculated. The analytical results are calculated from the measured signal or evaluated signal of the analyte and its position on the calibration curve. In tests for impurities for both the External Standard Method, when a dilution of the sample solution is used for comparison, and the Normalization Procedure, any correction factors indicated in the monograph are applied (e.g., when the relative response factor is outside the range 0.8–1.2). When the impurity test prescribes the total of impurities or there is a quantitative determination of an impurity, choice of an appropriate threshold setting and appropriate conditions for the integration of the peak areas is important. In such tests the limit at or below which a peak is disregarded is generally 0.05%. Thus, the threshold setting of the data collection system corresponds to at least half of this limit. Integrate the peak area of any impurity that is not completely separated from the principal peak, preferably by valley-to-valley extrapolation (tangential skim).