

	Rev	.10		P / Ph Eur / NF / IP	Reference BP-2022, Ph Eur-10.0 USP-NF-2021, IP-2018	
FC	Specific	cation No	Supersedes Effective date		Page No.	
	QC/PH-FG/SPEC/33		Rev. 09 13 01 2022		1 of 5	
r.No.		Test	S	pecifications	Method of Analysis No.	
1	Descrip	otion	Transparent, clear liquid having char in 2) is neutral to	QC/PH-FG/SPEC/01-01 QC/PH-FG/SPEC/02-01 QC/PH-FG/SPEC/03-01 QC/PH-FG/SPEC/04-01		
2	Solubil	ity	alcohol, with ethe	er, with ethanol (96%),with er, with chloroform & with The vapour is flammable.	QC/PH-FG/SPEC/01-01 QC/PH-FG/SPEC/02-01 QC/PH-FG/SPEC/03-01	
3	Identifi	cation		50	QC/PH-FG/SPEC/01-03	
	a) Rela 20°C	ative density at	0.790 to 0.793 at 20°C		QC/PH-FG/SPEC/02-03	
	b) Chemical test		An intense red colour is produced which becomes violet with the addition of 3.5ml of acetic acid R.		QC/PH-FG/SPEC/01-04 QC/PH-FG/SPEC/02-04	
	c) Chemical test		A greenish-blue colour should be projuced		QC/PH-FG/SPEC/01-05 QC/PH-FG/SPEC/02-05	
d) By IR		1	be examine correlated the those with that of Aceto	billed with the substance to sponds in position & relative in the spectrum obtained one USP CRS or its working Index should not be less	QC/PH-FG/SPEC/03-03	
	e) By GC		The retention time of the test solution corresponds to that of Acetone USP CRS or its working standard (WS), as obtained in the Assay.		QC/PH-FG/SPEC/03-04	
4	Appear	rance of solution	The solution is clo	ear and colourless.	QC/PH-FG/SPEC/01-06 QC/PH-FG/SPEC/02-06	
5	5 Acidity or alkalinity		On addition of 0.5 ml of 0.01M sodium hydroxide, solution should be pink. On addition of 0.7 ml of 0.01M hydrochloric acid, solution should be red or orange.		QC/PH-FG/SPEC/01-07 QC/PH-FG/SPEC/02-07	
6	Specifi	c Gravity at 25°C	Not more than 0.	789 at 25°C	QC/PH-FG/SPEC/03-05	
	PREPARE		D BY	CHECKED BY	AUTHORIZED BY	
		Q.C	Section 1	Q.C	Q.A	
SIGNA	TURE	· whate		Ph	Papanelit.	
DATE		06/01/2020		07/01/2022	07/01/2022	



		CORPORATION LIMITED		
	Rev.10	ACETONE BP / Ph Eur / NF / IP SPECIFICATION		Reference BP-2022, Ph Eur-10.0 USP-NF-2021, IP-2018
FO	S Specification No	Supersedes	Supersedes Effective date	
	C/PH-FG/SPEC/33	Rev. 09	13/01/2022	2 of 5
Sr.No.	Test	Spe	ecifications	Method of Analysis No.
7	Weight per ml at 25°C	About 0.79 g at 25°	C	QC/PH-FG/SPEC/04-03
8	Reducing substances	The mixture should decolorized.	not be completely	QC/PH-FG/SPEC/01-08 QC/PH-FG/SPEC/02-08
9	Readily Oxidizable substances		color of the mixture does appear within 15 minutes.	QC/PH-FG/SPEC/03-08
10	Matter insoluble in water	The solution should be clear.		QC/PH-FG/SPEC/01-10 QC/PH-FG/SPEC/02-10
11	Boiling point	About 56°C		QC/PH-FG/SPEC/04-02
12	Residue on evaporation	Maximum 50 ppm		QC/PH-FG/SPEC/01-11 QC/PH-FG/SPEC/02-11
13	Nonvolatile residue	The weight of the residue does not exceed 2 mg (0.004%)		QC/PH-EG/SPEC/03-07
14	Water	Maximum 3 g/L		QC/PH-FG/SPEC/01-12 QC/PH-FG/SPEC/02-12
15	Water (By GC)	Not more than 0.5%	MH.	QC/PH-FG/SPEC/03-06
16	Assay (By GC)	Not less than 190	% on the anhydrous basis.	QC/PH-FG/SPEC/03-04
17	Related substances (By GC) a) Impurity A (Methanol) b) Impurity B (IPA) c) Impulity C (Benzene) d) Any other impurity	Not more than 0.05% v/v Not more than 0.05% v/v Not more than 2 ppm v/v Not more than 0.05% v/v		QC/PH-FG/SPEC/01-09 QC/PH-FG/SPEC/02-09
18	Residual solvents (By GC) Benzene	Not more than 2 pp	om (v/v)	QC/PH-FG/SPEC/01-13 QC/PH-FG/SPEC/02-13 QC/PH-FG/SPEC/03-09

Not more than 3000 ppm (v/v)

Not more than 5000 ppm (v/v)

Methanol

IPA



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	SPECIFICATION		
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### GENERAL INFORMATION

Structure:

Molecular Formula: C<sub>3</sub>H<sub>6</sub>O

Molecular weight: 58.08

## Desirable Pack:

To be supplied in MS drums/SS containers/HDPE containers/HM-HDPE containers and Glass bottles, properly identified with a label having Name of the material, Name of the Manufacturer, Quantity, Manufacturer's Batch Number, Manufacturing Date, Expiry Date and or Retest Date.

# Storage Condition:

Protected from light, Preserve in tight containers, remote from fire.

## Handling precaution:

COBA Use PPE (Personal Protective Equipments) during handling of the material.

# Sampling SOP:

RENCE As per the current approved sampling procedure (SOP/QC/GE/

Quantity to be sampled:

Analysis Sample: About 1200 ml Control Sample: About 2400

Stability Sample: About

## Shelf Life:

Three years from the date of manufacturing.

### Note:

# 1. For Bullet, Filter, Supporting equipments Rinsing and Filter cleaning-

- If previous product is any grade of Acetone, then perform Appearance, Solubility, Identification by Relative density at 20°C & By IR and Water tests as per FG specification.
- If previous product is different then, perform Appearance, Solubility as per FG specification and calculate previous product carry over by using "Purity (By GC)" method from Raw material specification. (Limit -NMT 0.2%) QC/SPEC/ACETONE RM/01.

## For Tanker Rinsing-

- Perform Appearance, Solubility, Identification, Non volatile Residue, water, water (By GC), Assay and Related substances (By GC) tests as per FG specification.
- 3. Blending and Packing-
- Perform all tests as per FG specification. Residual solvents test to be perform only for packing.
- 4. For method of analysis refer current revision of FG specification of respective grade.

### For Stability testing-

Perform Appearance, Solubility, Identification, Non volatile Residue, water, water (By GC), Assay, Related substances (By GC) and residual solvents tests as per FG specification. (Stability sample quantity- About 700 ml for single analysis).



Rev.10	ACETONE BP	Reference BP-2022, Ph Eur-10.0 USP-NF-2021, IP-2018	
	SPECIFICATION		
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Document number	Supersedes	Changes made	Doggon for change
	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/33	1,55	Original issue	**
	Rev. 0	MOA updated only revising its Specification, General information and history	BP-2018 (Refer Change Control No RCPL/CC/QC/006-17) (Refer Deviation No. RCPL/DEV/QC/007-17)
	Rev. 1	Reference updated	IP-2018 (Refer Change Control No RCPL/CC/QC/002-18)
	Rev. 2	Reference Updated.     Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing.     Shelf Life is added.	USP-41 , NF-36 Refer Change Control No RCPL/CC/QC/003-18
	Rev. 3	Reference updated	Refer Change Control No. RCPL/CC/QC/010-18
	Rev. 4	Mentioner tests to be perform for Supporting equipments     Cyantity of Stability sample is added.	Refer Change Control No. RCPL/CC/PDN/003-18
R	Rev. 5	Reference updated     Test wise method of analysis (MOA) is prepared.     Method of Analysis No. is added.	USP-42 , NF-37 Refer Change Control No. RCPL/CC/QC/003-19
	Rev. 6	1. Reference updated.  2. Following points are added in general information.  a) Quantity to be sampled is modified by adding term "About"  b) Mentioned tests to be perform for stability testing.  c) Quantity for stability sample for single analysis is added.  d) Desirable pack updated for addition of HM-DHPE containers.  e) Filter cleaning is added.	BP-2020 Ph.Eur-10.0 (Refer Change Control No RCPL/CC/QC/007-19 RCPL/CC/QC/008-19 and RCPL/CC/QC/001-20)
	Rev. 7	In MOA No. QC/PH-FG/SPEC/03-03     Procedure is updated for addition of spectrum range, Working std. added with CRS.	(Refer Change Control No. RCPL/CC/QC/004-20)



Rev.10		Ph Eur / NF / IP ICATION	Reference BP-2022, Ph Eur-10.0 USP-NF-2021, IP-2018
FG Specification No	Supersedes	Supersedes Effective date	
QC/PH-FG/SPEC/33	Rev. 09	13/01/2022	5 of 5
	substance to b  2. In MOA No. a) Chromatogr for addition of and Column flot Hydrogen, Air time. b) The term sa substance to b c) Solution prej addition of test d) Working star	mple replaced by e examine. QC/PH-FG/SPEC/03-04 aphic condition is update Auxiliary gas, Purge flow ow, Makeup flow, flow and Equilibration imple replaced by e examine paration is updated for t solution. indard added with CRS.	d - T
Rev	08 1. Reference u	The state of the s	Refer change control No RCPL/CC/QC/001-21 & RCPL/CC/QC/002-21)
REF	2 "Residua so paded in SP an	otated. vents (By GC)" test of Ph.Eur specifications of QC/PH-FG/SPEC/01-1 /SPEC/02-13 are added.	BP-2022 Refer change control No. RCPL/CC/QC/004-21



Rev.13	ACET SPECIF	Reference	
	S. ZS. ISAMON		BP-2023
FG Specification No.	Supersedes	Effective date	Page No.
QC/PH-FG/SPEC/01	Rev.12	01/01/2023	1 of 5

Sr.No.	Test	Specifications	Method of Analysis No
1	Appearance	Volatile, clear, colourless liquid.	QC/PH-FG/SPEC/01-01
2	Solubility	Miscible with water and with ethanol (96%).	QC/PH-FG/SPEC/01-02
	Identification a) Relative density at 20°C	0.790 to 0.793 at 20°C	QC/PH-FG/SPEC/01-03
3	b) Chemical test	An intense red colour is produced which becomes violet with the addition of 3.5ml of acetic acid R.	QC/PH-FG/SPEC/01-04
	c) Chemical test	A greenish-blue colour should be produced.	QC/PH-FG/SPEC/01-05
4	Appearance of solution	The solution is clear and colourless.	QC/PH-FG/SPEC/01-06
5	Acidity or alkalinity	On addition of 0.5 ml of 0.01M sodium hydroxide, solution should be pink. On addition of 0.7 ml of 0.01M hydrochloric acid, solution should be red or orange.	QC/PK-FG/SPEC/01-07
6	Relative density at 20°C	0.790 to 0.793 at 20°C	QC/PH-FG/SPEC/01-03
7	Reducing substances	The nuxture should not be completely devalourised.	QC/PH-FG/SPEC/01-08
8	Related substances (By GC) a) Impurity A (Methanol) b) Impurity B (IPA) c) Impurity C (Benzene) d) Any other impurity	Not more than 0.05% v/v Not more than 0.05% v/v Not more than 2 ppm v/v Not more than 0.05% v/v	QC/PH-FG/SPEC/01-09
9	Matter insoluble in water	The solution should be clear.	QC/PH-FG/SPEC/01-10
10	Residue on evaporation	Maximum 50 ppm	QC/PH-FG/SPEC/01-11
11	Water	Maximum 3 g/L	QC/PH-FG/SPEC/01-12
12	Residual solvents (By GC) a) Benzene b) Methanol c) 2-Propanol	Not more than 2 ppm v/v Not more than 3000 ppm v/v Not more than 5000 ppm v/v	QC/PH-FG/SPEC/01-13

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Rev. 13	ACETO SPECIF	Reference	
	or Edition Tion		BP-2023
FG Specification No.	Supersedes	Effective date	Page No.
QC/PH-FG/SPEC/01	Rev.12	0110112023	2 of 5

## GENERAL INFORMATION

Structure:

H<sub>3</sub>C

Molecular Formula: C<sub>3</sub>H<sub>6</sub>O

Molecular weight: 58.08

## Desirable Pack:

To be supplied in MS drums/SS containers/HDPE containers/HM-HDPE containers and Glass bottles, properly identified with a label having Name of the material, Name of the Manufacturer, Quantity, Manufacturer's Batch Number, Manufacturing Date, Expiry Date and or Retest Date.

# Storage Condition:

Protected from light.

# Handling precaution:

Use PPE (Personal Protective Equipments) during handling of the material.

# Sampling SOP:

As per the current approved sampling procedure. (SOP/OCIGIO Quantity to be sampled: Analysis Sample: About 560 ml

Control Sample: About

Stability Sample A

## Shelf Life:

Three years from the date of manufacturing.

# Note:

- 1. For Bullet, Filter, Supporting equipments Rinsing and Filter cleaning-
- > If previous product is any grade of Acetone, then perform Appearance, Solubility, Identification by Relative density at 20°C and Water tests as per FG specification.
- If previous product is different then, perform Appearance and Solubility tests as per FG specification and calculate previous product carry over by using "Purity (By GC)" method from Raw material specification. (Limit - NMT 0.2%) QC/SPEC/ACETONE\_RM/01

# 2. For Tanker Rinsing-

- > Perform Appearance, Solubility, Identification, Related substances (By GC), Residue on evaporation and Water tests as per FG specification.
- 3. Blending and Packing-
- Perform all tests as per FG specification.
- Residual solvents (By GC) test to be perform only for Packing.
- 4. For stability testing-



Rev. 13	ACET( SPECIF	Reference	
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FG Specification No.	Supersedes	Effective date	Page No.
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Perform Appearance, Solubility, Identification, Related substances (By GC), Residue on evaporation, Water and Residual solvents (By GC) tests as per FG specification. (Stability sample quantity- About 530 ml for single analysis).

Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/01	Rev. 0	Format change –  1. General Information added. 2. History page added. 3. Reference updated	As per requirement of Schedule M. BP-2013
	Rev. 1	Reference updated	BP-2014
	Rev. 2	Reference updated     Detector temperature is reduced from 250°C to 225°C. Split ratio is adjusted from 1:50 to 1:5 And Column length and ID is increased form 50m to 60m and 0.30 to 0.32 respectively.  RUNA Logo inserted along with	BP-2015 Refer Change Control No. RCPL/CC/QC/001-15
		the name of company.	and Data control
	Rev. 3	Reference Updated     Mentioned brief protecture for     Appearance of solution and Matter     inshuble in water tests	BP-2016 (Refer Change Control No. RCPL/CC/QC/015-15)
	Kev. 4	Reference Updated.	BP-2017
RI	CEL		(Refer Change Control No RCPL/CC/QC/010-16)
7~	Rev. 5	Reference Updated.	BP-2018 (Refer Change Control No. RCPL/CC/QC/006-17)
	Rev. 6	Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing.     Shelf Life is added.	Refer Change Control No. RCPL/CC/QC/003-18)
	Rev. 7	Reference Updated.     Mentioned tests to be perform for.	BP-2019 (Refer Change Control No. RCPL/CC/QC/010-18)
		Supporting equipments.  3. Quantity of Stability sample is added.	(Refer Change Control No RCPL/CC/PDN/003-18)
	Rev. 8	Test wise method of analysis (MOA) is prepared. Method of Analysis No. is added.	(Refer Change Control No. RCPL/CC/QC/003-19)



Rev. 13	ACETONE BP SPECIFICATION		Reference
	020		BP-2023
FG Specification No.	Supersedes Effective date		Page No.
QC/PH-FG/SPEC/01	Rev.12	01(01/2023	4 of 5

Document number	Supersedes	Changes made	Reason for change
	Rev. 9	1. Reference updated. 2. In MOA No. QC/PH-FG/SPEC/01-01 a) Procedure is updated b) "Interpretation" is added. 3. In MOA No. QC/PH-FG/SPEC/01-02 a) Procedure is updated b) "Interpretation" is added. 4. In MOA No. QC/PH-FG/SPEC/01-03 a) The term "sample" replaced by "substance to be examine" b) "Limit" is added. 5. In MOA No. QC/PH-FG/SPEC/01-04 a) Solution preparation is updated. b) The term "sample" replaced by "substance to be examine" 6. In MOA No. QC/PH-FG/SPEC/01-05 a) Solution preparation is updated b) The term "sample" replaced by "substance to be examine" 7. In MOA No. QC/PH-FG/SPEC/01-05 a) Solution preparation is updated b) The term "sample" replaced by "substance to be examine" 7. In MOA No. QC/PH-FG/SPEC/01-07 a) Solution preparation is updated b) The term "sample" replaced by "substance to be examine". 9. In MOA No. QC/PH-FG/SPEC/01-08 a) Solution preparation is updated. b) In procedure "sample" term replaced by "substance to be examine". 10. In MOA No. QC/PH-FG/SPEC/01-09 a) chromatographic condition is updated for Column, Makeup, Hydrogen, Air flow and Equilibration time. b) In procedure "sample" term replaced by "Test solution" 11. In MOA No. QC/PH-FG/SPEC/01-11 a) The term "sample" term replaced by "Test solution" 11. In MOA No. QC/PH-FG/SPEC/01-11 a) The term "sample" and "Interpretation" replaced by "substance to be examine" and "Limit" respectively 12. In MOA No. QC/PH-FG/SPEC/01-12 a) The term "sample" is replaced by "substance" b) "Limit" is added. 13. Following points are added in general information.	Reason for change BP-2020 (Refer Change Control No. RCPL/CC/QC/007-19)



Rev. 13		ACETONE BP SPECIFICATION		Reference
			ICATION	BP-2023
FG Specification No.	S	upersedes	Effective date	Page No.
QC/PH-FG/SPEC/01		Rev.12	01/01/2023	5 of 5
		adding terr b) Mentioned stability tes c) Quantity for analysis is d) Desirable	tests to be perform for sting. or stability sample for sin added. pack updated for addition containers.	ngle
- R	ev.10	1. Reference u		BP-2021 (Refer Change Control No. RCPL/CC/QC/001-2
R	ev. 11	"The vapor is fl 3. In MOA No. chromatograph addition of Injection of Injection seque 4. Residual solution also new MOA 12 is alided: Sa stability testing. 5. Quantity to b	QC/PH-FG/SPEC/01-02 ammable" is removed. QC/PH-FG/SPEC/01-03 ic condition is updated to ction mode, Total Flow a edure is updated for noc. yents (By OC) test is ad lo:QC/PH-FG/SPEC/0 ame test is added in	No. RCPL/CC/QC/004-2
R	ev. 12	1. Reference U		BP-2023 (Refer Change Control No. RCPL/CC/QC/009-22)



Rev.11	ACETONE NF SPECIFICATION		Reference USP-NF - 2021
FG Specification No	Supersedes	Effective date	Page No
QC/PH-FG/SPEC/03	Rev. 10	10/07/2021	1 of 5

Sr.No.	Test	Specifications	Result
1	Description	Transparent, colorless, mobile, volatile liquid having characteristic odour. A solution (1 in 2) is neutral to litmus.	QC/PH-FG/SPEC/03-01
2	Solubility	Miscible with water, with alcohol, with ether, with chloroform & with most volatile oils	QC/PH-FG/SPEC/03-02
3	Identification a) By IR	The spectrum obtained with the substance to be examine corresponds in position & relative intensity to those in the spectrum obtained with that of Acetone USP CRS or its working standard (Purity Index should not be less than 0.99)	QC/PH-FG/SPEC/03-03
	b) By GC	The retention time of the test solution corresponds to that of Acetone USP CRS or its working standard (WS), as obtained in the Assay.	QC/PH-FG/SPEC/03-04
4	Specific Gravity at 25°C	Not more than 0.789	OC/PH-18/SPEC/03-05
5	Water (By GC)	Not more than 0.5%	QC/PH-FG/SPEC/03-06
6	Nonvolatile residue	The weight of the residue does not exceed 2 mg (0.004%)	QC/PH-FG/SPEC/03-07
7	Readily Oxidizable substances	The perpanglinate color of the mixture does not completely disappear within 15 minutes.	QC/PH-FG/SPEC/03-08
8	Assay (By GC)	Not less than 99.0% on the anhydrous basis.	QC/PH-FG/SPEC/03-04
9	Residual selvel its		QC/PH-FG/SPEC/03-09
	a) Benzene	Not more than 2 ppm (v/v)	
A.	b) Methanol	Not more than 3000 ppm v/v	24
	c) 2-Propanol	Not more than 5000 ppm v/v	

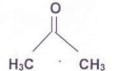
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Rev.11	ACETO	ONE NF	Reference USP-NF - 2021
	SPECIF	ICATION	
FG Specification No	Supersedes	Effective date	Page No
QC/PH-FG/SPEC/03	Rev. 10	10/07/204	2 of 5

## GENERAL INFORMATION

Structure:



Molecular Formula: C3H6O

Molecular weight: 58.08

## Desirable Pack:

To be supplied in MS drums/SS containers/HDPE containers/HM-HDPE containers and Glass bottles, properly identified with a label having Name of the material, Name of the Manufacturer, Quantity, Manufacturer's Batch Number, Manufacturing Date, Expiry Date and or Retest Date.

# Storage Condition:

Preserve in tight containers, remote from fire.

# Handling precaution:

ERENCE COPY Use PPE (Personal Protective Equipments) during handling of the material.

# Sampling SOP:

As per the current approved sampling procedure.

# Quantity to be sampled:

Analysis Sample: About 550 ml Control Sample: About 1100 Stability Sample: About

## Shelf Life:

Three years from the date of manufacturing.

### Note:

- 1. For Bullet, Filter, Supporting equipments rinsing and Filter cleaning-
- If previous product is any grade of Acetone, then perform Description, Solubility, Identification By IR tests as per specification.
- If previous product is different then, perform Appearance, Solubility as per FG specification and calculate it's carry over by using "Purity (By GC)" method from Raw material specification. (Limit - NMT 0.2%) QC/SPEC/ACETONE RM/01

## 2. For Tanker Rinsing-

- Perform Description, Solubility, Identification, Specific Gravity at 25°C, Non volatile residue, Assay (By GC) and Water (By GC) tests as per FG specification.
- 3. Blending and Packing-
- Perform all tests as per FG specification. >
- Residual solvents test to be perform only for packing.
- 5. For Stability testing-



Rev.11	ACETONE NF		Reference
	SPECIF	ICATION	USP-NF - 2021
FG Specification No	Supersedes ,	Effective date	Page No
QC/PH-FG/SPEC/03	Rev. 10	10/07/2021	3 of 5

Perform Description, Solubility, Identification, Specific Gravity at 25°C, Non volatile residue, Assay (By GC), Water (By GC) and Residual solvents tests as per FG specification. (Stability quantity- 500 ml for single analysis).

Document number	Supersedes	Changes made	Reason for change
QC/PH-FG/SPEC/03	· Rev. no. 0	Format change –  1. General Information added.  2. History page added.  3. Referaence updated	As per requirement of Schedule M.  USP-36 NF-31
	Rev. no. 1	Reference updated	USP-37 NF-32
	Rev. no. 2	For Assay (By GC) testing Detector temperature is reduced from 280°C to 230°C. For Water (By GC) testing Split ratio is adjusted from 4.5:1 to 1:10 Column length and column hold time is increased from 50m to 60m and 0-15.	Refer Change Control No RCPL/CC/QC/001-15
		respectively for water (By GC) text.  2. RUNA Logo Tisetted along with name of company.	As per SOP of Documen and Data control
	Rev. no. 3	Rejerence undated	USP-38 NF-33
D.F.	Payano	Reference updated	USP-39 NF-34
	10. 10	neterence apaated	(Refer Change Control No RCPL/CC/QC/002-16)
	Rev. no. 5	Reference updated	USP-40 NF-35
			(Refer Change Control No RCPL/CC/QC/002-17)
	Rev. no. 6	<ol> <li>Reference updated.</li> <li>Mentioned tests to be perform for Bullet Rinsing, Filter Rinsing and Tanker Rinsing.</li> <li>Shelf Life is added.</li> </ol>	USP-41 NF-36 (Refer Change Control No RCPL/CC/QC/003-18)
	Rev. no. 7	Mentioned tests to be perform for Supporting equipments     Quantity of Stability sample is added.	Refer Change Control No RCPL/CC/PDN/003-18
	Rev. no. 8	1. Reference updated	USP-42, NF-37
		<ol><li>Test wise method of analysis (MOA) is prepared. Method of Analysis No. is added.</li></ol>	Refer Change Control No. RCPL/CC/QC/003-19
	Rev. no. 9	In MOA No. QC/PH-FG/SPEC/03-01     Procedure is updated     b) "Interpretation" is added.	(Refer Change Control No RCPL/CC/QC/004-20)



Rev.11		ONE NF	Reference
	SPECIF	ICATION	USP-NF - 2021
G Specification No	Supersedes	Effective date	Page No
C/PH-FG/SPEC/03	Rev. 10	10/07/2021	4 of 5
	0 1- 1404 14	00/01/00/00/00	
		QC/PH-FG/SPEC/03-02	
	a) Procedure i		
	b) "Interpretati		
		QC/PH-FG/SPEC/03-03	
	The state of the s	s updated for addition of	
	1 383	e, Working std. added wit	h
	CRS		
	b) Purity index		1
		mple replaced by substan	ce
5 . A Top 1 1 . T a	to be examine	on" in added	· .
	d) "Interpretation	QC/PH-FG/SPEC/03-04	
	The state of the s	aphic condition is updated	
		Auxiliary gas, Purge flow	
		w, Makeup flow, Hydroge	
		uilibration time.	PI
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	to be examine	inple replaced by sursicili	ce
	The State of State State State of the	paration is updated for	
	addition of tes		
		Nard added with CRS	
0:		QC/PH-FG/SPEC/03-05	
		mple replaced by substant	ce
OHIL	to be examine	, , , , , , , , , , , , , , , , , , , ,	
KL	b) "Limit" is add	ded.	
		QC/PH-FG/SPEC/03-06	
		aphic condition is updated	
The same of the sa		Auxiliary gas, Linear	
		flow, Column flow and	
	Equilibration tin		8
	b) Solution pre	paration is updated for	
	addition of test	solution.	
	c) In procedure	term sample replaced by	3
	Test solution		
77	7. In MOA No. 0	QC/PH-FG/SPEC/03-07	-
	a) The term san	nple replaced by substanc	е
	to be examine		
	b) "Limit" is add	ed.	
4 1 1 1	8. In MOA No. 0	QC/PH-FG/SPEC/03-08	
9 7 8	a) The term san	nple replaced by subsatno	e
	to be examine		,
	9. In MOA No. 0	QC/PH-FG/SPEC/03-09	
	a) Chromatogra	phic condition is updated	



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		Auxiliary gas, Purge flow	
	Air flow and Edb) In procedure Test solution 10. Following prinformation. a) Filter cleaning b) Quantity to be adding term "Acc) Mentioned to stability testing	be sampled is modified by bout" ests to be performed for stability sample for single	
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time in an oven.