
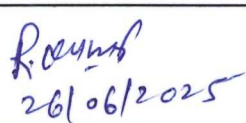
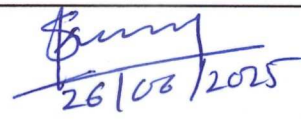


CERTIFICATE OF ANALYSIS

Product Name	Fenofibrate - IP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2506024
CAS No.	49562-28-9
Date of Mfg.	Jun-2025
Date of Expiry	May-2030
Batch Qty.	504.10 Kg

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	A white or almost white crystalline powder	A white powder
2.	Identification (By IR)	The infrared spectrum of the sample should be concordant with the spectrum of Fenofibrate working Standard.	Concordant
3.	Solubility	Very soluble in dichloromethane, slightly soluble in ethanol (95%) and practically insoluble water.	Complies
4.	Appearance of solution	5.0 % w/v solution in acetone should be clear and not more intensely coloured than reference solution BYS6.	Complies
5.	Acidity	Not more than 0.2 ml of 0.1M sodium hydroxide is required to change the colour of the indicator to pink.	Complies
6.	Heavy Metal (Method B)	Not more than 20 ppm	Less than 20 ppm
7.	Chlorides	Not more than 100 ppm	Less than 100 ppm
8.	Sulphates	Not more than 100 ppm	Less than 100 ppm
9.	Sulphated Ash	Not more than 0.10 % w/w	0.012 % w/w
10.	Loss on drying	Not more than 0.50 % w/w	0.24 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per IP


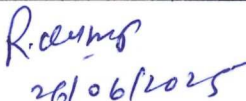
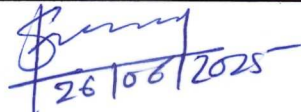
Prepared By	Checked By	Approved By
 26/06/2025	 26/06/2025	 26/06/2025

CERTIFICATE OF ANALYSIS

Product Name	Fenofibrate - IP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2506024
CAS No.	49562-28-9
Date of Mfg.	Jun-2025
Date of Expiry	May-2030
Batch Qty.	504.10 Kg

Sr. No.	TEST	SPECIFICATION	RESULTS
11.	Related substance by HPLC		
	a) Impurity-A	Not more than 0.10 %	Not Detected
	b) Impurity-B	Not more than 0.10 %	0.004 %
	c) Impurity-C	Not more than 0.10 %	Not Detected
	d) Impurity-D	Not more than 0.10 %	0.010 %
	e) Impurity-E	Not more than 0.10 %	0.026 %
	f) Impurity-F	Not more than 0.10 %	Not Detected
	g) Impurity-G	Not more than 0.20 %	0.008 %
	h) Any other individual impurity	Not more than 0.10 %	0.057 %
	i) Total impurities	Not more than 0.50 %	0.144 %
12.	Assay by HPLC (Dried basis)	Not less than 98.0 % and not more than 102.0 % w/w	99.43 % w/w
13.	Additional Test		
13.1	Particle Size by Malvern Master sizer	For Information	90 % below 10 micron
13.2	Residual Solvent		
	a) Acetone	Not more than 5000 ppm	Not Detected
	b) Isopropyl Alcohol	Not more than 5000 ppm	308 ppm
	c) Toluene	Not more than 890 ppm	Not Detected
	d) Chloroform	Not more than 60 ppm	Not Detected

Remark :- In the opinion of undersigned the material of the standard Quality as per IP

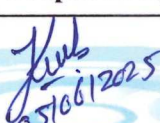
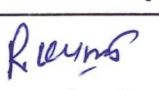
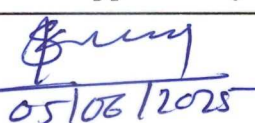
Prepared By	Checked By	Approved By
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CERTIFICATE OF ANALYSIS

Product Name	Fenofibrate - USP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2505019
Cas No.	49562-28-9
Date of Mfg.	May-2025
Date of Expiry	Apr-2030
Batch Qty.	504.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	A white or almost white crystalline powder	A white powder
2.	Identification (By IR)	The infrared spectrum of the sample should be concordant with the spectrum of Fenofibrate working Standard.	Concordant
3.	Solubility	Practically insoluble in water, very soluble in methylene Chloride, slightly soluble in alcohol.	Complies
4.	Colour and Achromicity	The sample solution is not more intensely coloured than the reference solution.	Complies
5.	Acidity	Not more than 0.2 ml of 0.1M sodium hydroxide is required to change the colour of the indicator to pink.	Complies
6.	Melting point	79°C to 82°C	80.5°C to 81.6°C
7.	Chlorides	It should be not more than 0.15 ml consumed of 0.020 N hydrochloric acid	Complies
8.	Sulphates	It should be not more than 0.15 ml consumed of 0.020 N sulphuric acid	Complies
9.	Residue on ignition	Not more than 0.10 % w/w	0.010 % w/w
10.	Loss on drying	Not more than 0.50 % w/w	0.24 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per USP

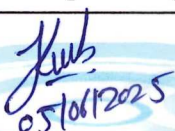
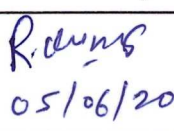
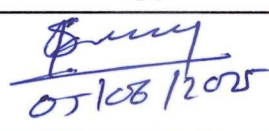
Prepared By	Checked By	Approved By
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CERTIFICATE OF ANALYSIS

Product Name	Fenofibrate - USP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2505019
Cas No.	49562-28-9
Date of Mfg.	May-2025
Date of Expiry	Apr-2030
Batch Qty.	504.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULTS
11.	Related substance by HPLC		
	a) (4-Chlorophenyl)(4-hydroxyphenyl) methanone (Related compound-A)	Not more than 0.10 %	Not Detected
	b) 2-[4-(4-Chlorobenzoyl)phenoxy]-2-methyl-propanoic acid (Related compound-B)	Not more than 0.10 %	0.005 %
	c) (3RS)-3-[4-(4-Chlorobenzoyl)phenoxy] butan-2-one (Impurity-C)	Not more than 0.10 %	Not Detected
	d) Methyl 2-[4-(4-chlorobenzoyl)phenoxy] -2-methyl-propanoate (Impurity-D)	Not more than 0.10 %	0.013 %
	e) Ethyl 2-[4-(4-chlorobenzoyl)phenoxy] -2-methyl-propanoate (Impurity-E)	Not more than 0.10 %	0.032 %
	f) (4-Chlorophenyl)[4-(1-methylethoxy) phenyl] methanone (Impurity-F)	Not more than 0.10 %	Not Detected
	g) 1-Methylethyl 2-[[2[4-(4-chloro benzoyl) phenoxy] 2-methyl propanoyl] oxy]-2-methylpropanoate (Related compound-C)	Not more than 0.20 %	0.018 %
	h) Any other individual impurity	Not more than 0.10 %	0.070 %
	i) Total impurities	Not more than 0.50 %	0.179 %
12.	Assay by HPLC (Dried basis)	Not less than 98.0 % and not more than 102.0 % w/w	100.95 % w/w
13.	Additional Test		
13.1	Particle Size by Malvern Master sizer	For Information	90 % below 10 micron
13.2	Residual Solvent by GC-HSS		
	a) Acetone	Not more than 5000 ppm	Not Detected
	b) Isopropyl Alcohol	Not more than 5000 ppm	281 ppm
	c) Toluene	Not more than 890 ppm	Not Detected
	d) Chloroform	Not more than 60 ppm	Not Detected

Remark :- In the opinion of undersigned the material of the standard Quality as per USP

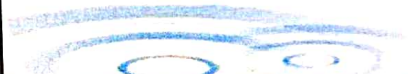
Prepared By	Checked By	Approved By
 05/06/2025	 05/06/2025	 05/06/2025

REFERENCE COPY**CERTIFICATE OF ANALYSIS**

Product Name	Fenofibrate BP/EP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2407051
Date of Mfg.	Jul-2024
Date of Expiry	Jun-2029
Batch Qty.	505.10 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or almost white crystalline powder	White powder
2.	Identification by a) Melting point b) Infrared spectroscopy	Between 79° C to 82° C The infrared spectrum of the sample should be concordant with the spectrum of reference standard.	79.2° C to 81.5° C Concordant
3.	Solubility	Practically insoluble in water, very soluble in methylene chloride, slightly soluble in ethanol (96 per cent).	Complies
4.	Appearance of solution	5% w/v solution in acetone should be clear and not more intensely coloured than reference solution BY ₆ .	Complies
5.	Acidity	Not more than 0.2 ml of 0.1M Sodium Hydroxide is required to change the colour of the indicator to pink colour.	Complies
6.	Chlorides	Not more than 100 ppm	Less than 100 ppm
7.	Sulphates	Not more than 100 ppm	Less than 100 ppm
8.	Sulphated Ash	Not more than 0.10 % w/w	0.010 % w/w
9.	Loss on drying	Not more than 0.50 % w/w	0.27 % w/w

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

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CERTIFICATE OF ANALYSIS	
Product Name	Fenofibrate BP/EP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/FF/2407051
Date of Mfg.	Jul-2024
Date of Expiry	Jun-2029
Batch Qty.	505.10 Kg

10.	Related substance by HPLC		
	a) Impurity-A	Not more than 0.15 %	ND
	b) Impurity-B	Not more than 0.15 %	BQL
	c) Impurity-C	Not more than 0.10 %	ND
	d) Impurity-D	Not more than 0.10 %	0.011 %
	e) Impurity-E	Not more than 0.10 %	0.010 %
	f) Impurity-F	Not more than 0.10 %	ND
	g) Impurity-G	Not more than 0.20 %	0.007 %
	h) Unspecified impurity	Not more than 0.10 %	0.053 %
	i) Total impurities	Not more than 0.50 %	0.126 %
11.	Assay by HPLC (Dried Basis)	Between 98.0 % to 102.0 % w/w	100.87 % w/w
Additional Test			
1.	Particle Size by Malvern Master sizer	For Information	90% below 10 micron
2.	Residual Solvent		
	a) Acetone	Not more than 5000 ppm	ND
	b) Isopropyl Alcohol	Not more than 5000 ppm	105 ppm
	c) Toluene	Not more than 890 ppm	ND
	d) Chloroform	Not more than 60 ppm	ND

Remark :- In the opinion of undersigned the material of the standard Quality as per BP/EP

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