PARAGON organics

CERTIFICATE OF ANALYSIS	
Product Name	Pregabalin IP (Micronized)
Mfg By	Paragon Organics
Batch No.	PRG/PR/2411048
Date of Mfg.	Nov-2024
Date of Expiry	Oct-2029
Batch Qty.	212.80 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or almost white powder.	White powder
2.	Identification test by a) Infrared absorption spectrophotometry	Compare the spectrum with that obtained with pregabalin IP RS or with the reference spectrum of pregabalin.	Concordant
	b) HPLC	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in chromatogram obtained with the reference solution (a).	Complies
3.	Solubility	Sparingly soluble in water	Complies
4.	Loss on Drying	Not more than 0.50 % w/w	0.23 % w/w
5.	Sulphated Ash	Not more than 0.10 % w/w	0.011 % w/w
6.	Heavy Metals	Not more than 20 ppm	Less than 20 ppm
7.	Enantiomeric purity by HPLC Pregabalin impurity - B	Not more than 0.15 %	0.098 %
8.	Assay by HPLC (On dried basis)	Not less than 98.0 % and not more than 102.0 % w/w	99.84 % w/w

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

Prepared By	Checked By	Approved By
07/12/2024	07/12/2024	07/12/2024

Office & Works : Plot No. 582, E. C. P. Road, Nr. Jaspur Chokdi, Village : Luna, Ta. Padra, Dist. Vadodara - 391 440 Gujarat, INDIA.
Mobile No. : 99099 75888 E-mail. : (O) info@popl.co.in (F) works@popl.co.in Web. : www.popl.co.in

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Mfg By	Paragon Organics
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Date of Mfg.	Nov-2024
Date of Expiry	Oct-2029
Batch Qty.	212.80 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
9.	Related substances by HPLC		
	a) Test -A for polar impurities		
	i) Pregabalin impurity - C	Not more than 0.10 %	ND
	ii) Single max. impurity	Not more than 0.10 %	0.010 %
	b) Test -B for Nonpolar impurities		
	i) Pregabalin impurity - A	Not more than 0.15 %	0.053 %
	ii) Pregabalin impurity - D	Not more than 0.15 %	ND
	iii) Single max. impurity	Not more than 0.10 %	ND
	Total impurities test-A & test-B	Not more than 0.50 %	0.069 %
10.	**Additional Test**		
10.1	Particle Size by Malvern Master sizer	For Information	90 % below 30 micron
10.2	Residual Solvent by GC-HSS		
	a) Methanol	Not more than 3000 ppm	Not Detected
	b) Isopropyl Alcohol	Not more than 5000 ppm	136 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

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N. A Dey 07/12/2024	R. Mishra 07/12/2024	07/12/2024

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PARAGON organics

CERTIFICATE OF ANALYSIS	
Product Name	Pregabalin USP
Mfg By	Paragon Organics
Batch No.	PRG/PR/2406034
Date of Mfg.	Jun-2024
Date of Expiry	May-2029
Batch Qty.	213.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white to off white powder	White powder
2.	Identification test by a) Infrared absorption spectrophotometry	The infrared spectrum of the sample should be concordant with the spectrum of Pregabalin working standard.	Concordant
	b) Assay by HPLC	The retention time of the major peak of the sample solution corresponds to that of standard solution, as obtained in the Assay.	Complies
3.	Residue on Ignition	Not more than 0.1 % w/w	0.010 % w/w
4.	Chlorides	The turbidity produced in the sample solution is NMT that produced in the standard solution (0.1 %)	Complies
5.	Sulphate	The turbidity produced in the sample solution is NMT that produced in the standard solution (0.1 %)	Complies
6.	Loss on drying	Not more than 0.5 % w/w	0.24 % w/w
7.	Enantiomeric purity by HPLC Pregabalin related compound-A	Not more than 0.15 %	0.069 %

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

Prepared By	Checked By	Approved By
18/06/2024	18/06/2024	18/06/2024

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PARAGON organics

CERTIFICATE OF ANALYSIS	
Product Name	Pregabalin USP
Mfg By	Paragon Organics
Batch No.	PRG/PR/2406034
Date of Mfg.	Jun-2024
Date of Expiry	May-2029
Batch Qty.	213.20 Kg

8.	Related substance by HPLC		
	a) Mandalic acid	Not more than 0.10 %	Not Detected
	b) Isobutylglutaric acid	Not more than 0.15 %	Not Detected
	c) Isobutylglutarmonoamide	Not more than 0.15 %	Not Detected
	d) Pregabalin related compound-C	Not more than 0.15 %	Not Detected
	e) Any unspecified impurity	Not more than 0.10 %	0.054 %
	f) Total impurities	Not more than 0.8 %	0.091 %
9.	Assay by HPLC (On dried basis)	Between 98.0 % to 102.0 % w/w	99.92 % w/w
	Additional Test		
1.	Residual Solvent		
	a) Isopropyl Alcohol	Not more than 5000 ppm	310 ppm
	b) Methanol	Not more than 3000 ppm	130 ppm
	c) Chloroform	Not more than 60 ppm	Not Detected

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

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PARAGON organics

CERTIFICATE OF ANALYSIS	
Product Name	Pregabalin BP /EP
Mfg By	Paragon Organics
Batch No.	PRG/PR/2212059
Date of Mfg.	Dec-2022
Date of Expiry	Nov-2027
Batch Qty.	210.20 Kg

Sr. No.	TEST	SPECIFICATION	RESULT
1.	Description	A white or almost white powder.	White powder
2.	Solubility	Sparingly soluble in water, very slightly soluble in methanol, practically insoluble in heptanes.	Complies
3.	Identification test by a) Infrared absorption spectrophotometry	The infrared spectrum of the sample should be concordant with the spectrum of Pregabalin working standard.	Concordant
	b) Enantiomeric purity (HPLC)	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with the reference solution.	Complies
4.	Water content by KF	Not more than 0.5 %	0.11 %
5.	Sulphated Ash	Not more than 0.1 %	0.03 %
6.	Enantiomeric purity by HPLC Impurity – B	Not more than 0.15%	0.10 %

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

Prepared By	Checked By	Approved By
24/12/2022	24/12/2022	24/12/2022

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Mobile No. : 99099 75888 **E-mail.** : (O) info@popl.co.in (F) works@popl.co.in **Web.** : www.popl.co.in

PARAGON organics

CERTIFICATE OF ANALYSIS	
Product Name	Pregabalin BP /EP
Mfg By	Paragon Organics
Batch No.	PRG/PR/2212059
Date of Mfg.	Dec-2022
Date of Expiry	Nov-2027
Batch Qty.	210.20 Kg

7.	Related substance by HPLC **a) Test -A for polar impurities** i) Impurity -C ii) Single maximum impurities iii) Total impurities **b) Test -B for Non-polar impurities** i) Impurity -A ii) Single maximum impurities iii) Total impurities	 Not more than 0.15 % Not more than 0.10 % Not more than 0.5 % Not more than 0.15 % Not more than 0.10 % Not more than 0.5 %	 0.02 % 0.03 % 0.06 % 0.03 % 0.03 % 0.06 %
8.	Assay by HPLC (On anhydrous basis)	98.0 % to 102.0 % w/w	100.54 % w/w

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

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