ALKEM LABORATORIES LIMITED,
167/2, Mahatma Gandhi Udyog Nagar,
Dabhel, Daman - 396210.

ALKEM

CERTIFICATE OF ANALYSIS
(RAW MATERIAL)

Material Name: Cefpodoxime Proxetil USP (Covalent)

Item Code	RRC115	**Vendor Batch No.**	CPCM200010
A.R. No.	03RM20002154	**SAP Batch No.**	2014R01604
Specification No.	RE/RMSPEC/2020/0136-001	**Inspection Lot No.**	010001251718
Manufacturer Name	Covalent Laboratories Pvt. Ltd.	**Supplier Name**	Covalent Laboratories Pvt. Ltd.
Mfg. Date	06/2020	**Exp. Date**	05/2022
G.R.N. No.	5004966105	**Received Date**	05-12-2020
Qty. Received	493.583 kg	**Containers Received**	20
Date of Sampling	12-11-2020	**Containers Sampled**	20
Sampled By	Kundan	**Date of Release**	09-12-2020 16:50

S. No.	TEST	SPECIFICATION	RESULT
1	**Description**	White to light brownish white powder, odorless or having faint odor and has a bitter taste.	White powder.
2	**Solubility**	Insoluble in water, soluble in acetonitrile and in methanol, freely soluble in dehydrated alcohol and Insoluble in ether.	Insoluble in water, soluble in acetonitrile and in methanol, freely soluble in dehydrated alcohol and Insoluble in ether.
3	**Identification**		
3.1	**By IR**	The infra-red absorption spectrum of the sample should exhibit similar intensities of absorption at the same wave number as that of Cefpodoxime Proxetil working standard.	The infra-red absorption spectrum of the sample exhibit similar intensities of absorption at the same wave number as that of Cefpodoxime Proxetil working standard.
3.2	**By Ultraviolet absorption**	The UV absorption spectra of sample should exhibit maxima at the same wavelength as that of the Cefpodoxime Proxetil working standard.	The UV absorption spectra of sample exhibits maxima at the same wavelength as that of the Cefpodoxime Proxetil working standard.
3.3	**By Chemical test**	A red-purple color develops.	A red-purple color develops.
4	**Specific rotation (10 mg/ml in Methanol, on anhydrous basis)**	Between + 35.0 ° and + 48.0 °	38.8 °
5	**Water Content (By K.F. Titration) (w/w)**	Not more than 3.0 %.	1.2 %
6	**Residue on ignition (w/w)**	Not more than 0.2 %.	0.1 %

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Jignesh.Patel	Approved By	Hemil.Patel
Checked On	09-12-2020 10:36	Approved On	09-12-2020 16:50
Printed by: Hemil.Patel		**Printed on: 09-12-2020 16:58**	
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S. No.	TEST	SPECIFICATION	RESULT
7	**Isomer ratio (By HPLC)**	The ratio is between 0.5 and 0.6	0.5
8	**Chromatographic purity (By HPLC, w/w)**		
8.1	**Impurity A (Cefpodoxime acid)**	Not more than 0.50 %.	0.03 %
8.2	**Impurity B (Desacetoxy CPDP)**	Not more than 0.50 %. (Sum of two peaks)	0.33 %
8.3	**Impurity C (Delta 2-isomer)**	Not more than 2.0 %.	0.4 %
8.4	**Impurity D (Anti isomer 1,2)**	Not more than 1.0 %. (Sum of two peaks)	0.2 %
8.5	**Impurity F (N-Formyl CPDP 1,2)**	Not more than 0.30 %. (Sum of two peaks)	0.03 %
8.6	**Impurity G (N-Acetyl CPDP 1,2)**	Not more than 0.30 %. (Sum of two peaks)	0.10 %
8.7	**Impurity H (CPDP Dimer)**	Not more than 1.0 %. (Sum of two peaks)	0.1 %
8.8	**Impurity I (N-Isopropoxy carbomate 1,2)**	Not more than 0.30 %. (Sum of two peaks)	0.26 %
8.9	**Any Unspecified impurity**	Not more than 0.10 %.	0.09 %
8.10	**Total Impurities**	Not more than 4.0 %.	1.9 %
9	**Assay (By HPLC , w/w)**		
9.1	**on anhydrous basis**	Not less than 690 µg and not more than 804 µg as Cefpodoxime (C15H17N5O6S2) per mg.	759 µg
9.2	**On as is basis**	Not less than 669.30 µg and not more than 804 µg as Cefpodoxime (C15H17N5O6S2) per mg.	750.00 µg
10	**Residual Solvents (By GC) (Method-I)**		
10.1	**Methanol**	Not more than 3000 ppm.	182 ppm
10.2	**Acetone**	Not more than 5000 ppm.	7 ppm

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Jignesh.Patel	Approved By	Hemil.Patel
Checked On	09-12-2020 10:36	Approved On	09-12-2020 16:50
Printed by: Hemil.Patel		**Printed on: 09-12-2020 16:58**	
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(RAW MATERIAL)

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Specification No.	RE/RMSPEC/2020/0136-001	**Inspection Lot No.**	010001251718
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Mfg. Date	06/2020	**Exp. Date**	05/2022
G.R.N. No.	5004966105	**Received Date**	05-12-2020
Qty. Received	493.583 kg	**Containers Received**	20
Date of Sampling	12-11-2020	**Containers Sampled**	20
Sampled By	Kundan	**Date of Release**	09-12-2020 16:50

S. No.	TEST	SPECIFICATION	RESULT
10.3	**Isopropyl alcohol**	Not more than 5000 ppm.	312 ppm
10.4	**Acetonitrile**	Not more than 410 ppm.	66 ppm
10.5	**Ethyl acetate**	Not more than 5000 ppm.	63 ppm
10.6	**Toluene**	Not more than 890 ppm.	36 ppm
11	**Residual Solvents (By GC) (Method-II)**		
11.1	**N,N-Dimethylacetamide**	Not more than 1090 ppm.	123 ppm
12	**Residual Solvents (By GC) (Method-III)**		
12.1	**Triethylamine**	Not more than 320 ppm.	Not Detected
13	**Residual Solvents (By GC) (Method - IV)**		
13.1	**Dimethyl Carbonate (CMD)**	Not more than 100 ppm.	Not detected
14	**Residual Solvents (By GC) (Method-V)**		
14.1	**Benzene**	Not more than 2 ppm.	Not detected
15	**Particle Size (By Malvern analyzer)**		
15.1	**D(90)**	Not more than 15 µm	4 µm
15.2	**D(50)**	Not more than 7 µm	2 µm
15.3	**D(10)**	Not more than 4 µm	1 µm

Test Plan Remarks: Note: Only class 1 and class 2A and class 3 (Molybdenum, chromium and copper) elements are likely to be present in accordance to the ICH Q3D and USP <232> in the above material as per manufacturer's declaration.

Remarks: APPROVED (Sample Conforms to above Specification)

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Checked On	09-12-2020 10:36	Approved On	09-12-2020 16:50
Printed by: Hemil.Patel		**Printed on: 09-12-2020 16:58**	
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COVALENT LABORATORIES PRIVATE LIMITED

(A VIRCHOW GROUP COMPANY)

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Factory : Survey No. 374, Gundla Machanoor Village, Hathnoor Mandal, Sangareddy Dist - 502 296.
Telangana, INDIA. Tele Fax : +91-40 - 49483210 / 49483211

CERTIFICATE OF ANALYSIS

Product	**CEFPODOXIME PROXETIL USP**	QC Ref No.	20FP02981
Batch No.	CPCM200010	Packed Qty.	493.583Kg (19 x 25Kg,18.583Kg)
Mfg. date	June 2020	Retest date	May 2022
Date of release	30.10.2020	CAS No.	[87239-81-4]
Mfg. Lic. No.	07/MD/AP/2003/B/R		
Storage: Preserve in tight containers, between 2^0C and 8^0C			

S. No.	Test	Result	Specification
01.	Description	Off white powder, having faint odor and bitter taste.	White to light brownish white powder, odorless or having faint odor and has a bitter taste.
02.	Solubility	Complies	Insoluble in water; soluble in acetonitrile and in Methanol; freely soluble in Dehydrated alcohol; and insoluble in ether.
03.	Identification a)by IR	a) Conforms	a) The infra-red absorption spectrum of sample should exhibit similar intensities of absorption at the same wave numbers of cefpodoxime proxetil working standard.
	b)by UV	b) Complies	b) UV spectra of sample should exhibit absorption maxima at the same wavelengths as that of cefpodoxime proxetil working standard.
	c)by chemical	c) A red purple color developed	c) Should develop red purple color.
04.	Specific rotation	+39.4°	Between +35.0°and +48.0°
05.	Water content by KF (%w/w)	1.6	Not more than 3.0
06.	Residue onignition(%w/w)	0.09	Not more than 0.2
07.	Isomer ratio	0.50	Between 0.5 and 0.6
08.	Related Substances by HPLC (% w/w)		
	Impurity A (Cefpodoxime acid)	0.023	Not more than 0.50
	Impurity B (Desacetoxy CPDP)	0.320	Not more than 0.50 (Sum of Two Peaks)
	Impurity C (Delta 2-isomer)	0.353	Not more than 2.0
	Impurity D (Anti isomer 1,2)	0.182	Not more than 1.0 (Sum of Two Peaks)
	Impurity F (N-Formyl CPDP 1,2)	0.047	Not more than 0.30 (Sum of Two Peaks)
	Impurity G (N-Acetyl CPDP 1,2)	0.097	Not more than 0.30 (Sum of Two Peaks)
	Impurity H (CPDP Dimer)	0.048	Not more than 1.0 (Sum of Two Peaks)
	Impurity I (N-IsopropoxyCarbomate 1,2)	0.245	Not more than 0.30 (Sum of Two Peaks)
	Any unspecified impurity	0.078	Not more than 0.10
	Total Impurities	1.70	Not more than 4.0

	Prepared by	Reviewed by	Approved by
Name	**B. Ramanjaneyulu**	**A. Rama Rao**	**A. Brahmaiah**
Signature			
Date	31.10.2020	31.10.2020	31.10.2020

COVALENT LABORATORIES PRIVATE LIMITED

(A VIRCHOW GROUP COMPANY)

AN USFDA & WHO-GMP Certified Company

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CERTIFICATE OF ANALYSIS

Product	**CEFPODOXIME PROXETIL USP**	QC Ref No.	20FP02981
Batch No.	CPCM200010	Packed Qty.	493.583Kg (19 x 25Kg,18.583Kg)
Mfg. date	June 2020	Retest date	May 2022
Date of release	30.10.2020	CAS No.	[87239-81-4]
Mfg. Lic. No.	07/MD/AP/2003/B/R		
Storage: Preserve in tight containers, between 2^0C and 8^0C			

S. No.	Test	Result	Specification
09.	Assay by HPLC (µg/mg, as cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) on anhydrous basis	784	Between 690 and 804
	*On as is basis	771	Not less than 669.30µg and Not more than 804µg of cefpodoxime ($C_{15}H_{17}N_5O_6S_2$) per mg.
10.	Residual solvents by GC Method-1(ppm)		
	Methanol	114	Not more than 3000
	Acetone	Below detection limit	Not more than 5000
	Isopropyl alcohol	195	Not more than 5000
	Acetonitrile	Not detected	Not more than 410
	Ethyl acetate	Below LOQ Level (<41)	Not more than 5000
	Toluene	43	Not more than 890
11.	Residual solvents by GC Method-2(ppm)		
	N,N-Dimethylacetamide	81	Not more than 1090
12.	Residual solvents by GC Method-3(ppm)		
	Triethylamine	Not detected	Not more than 320
13.	Residual solvents by GC Method-4(ppm)		
	CMD	Not detected	Not more than 100
14.	Residual solvents by GC Method-5(ppm)		
	Benzene	Not detected	Not more than 2
15.	*Particle size by Malvern mastersizer– Dry method (Microns)		
	90% Particles	2.4	Not more than 15µm
	50 % Particles	1.3	Not more than 7µm
	10 % Particles	0.7	Not more than 4µm

Conclusion: *The product conforms to USP & customer specifications.*

** Indicates customer specifications.*

	Prepared by	Reviewed by	Approved by
Name	**B. Ramanjaneyulu**	**A. Rama Rao**	**A. Brahmaiah**
Signature			
Date	31.10.2020	31.10.2020	31.10.2020

11/11/2020