

MANUFACTURERS & EXPORTERS OF BULK DRUGS & FINE CHEMICALS 2, B. B. D. BAG (E), POWER TOOLS BHAVAN, 3RD FLOOR, KOLKATA - 700 001, INDIA

Form No. PCC/QC/CA/FP

CERTIFICATE OF ANALYSIS

(Under the Drugs & Cosmetics Act. 1940 and the Drugs & Cosmetics Rules 1945 thereunder)

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PROCESS CHEMICALS CO.

Manufacturer & Exporter of Bulk Drugs Drug Licence No. 1021M B 8&9, Behala Industrial Estate Since 19 JUN 1974 Kolkata - 700 060, India

FPNT 2215 Report No.

Date. 19/Sep/2022

Name of the Item:

Mfg. Dt. August 2022

NIKETHAMIDE BP

Exp. Dt. July 2026

Batch No. NT 2215 **Batch Quantity:**

200.15 Kg.

11 Residual Solvents Toluene & 890 ppm Absent Complies wit		TEST	STANDARD (BP 2021)	RESULT	
(96%), with Chloroform and Ether. The substance under examination in liquid form and clear by slight heating and not more intensely coloured then reference solution Ys. 4 Identification By Spectrphotometry (A) Reaction with Sodium Hydroxide(C) Reaction with Cyanogen bromide (D) Fraction with Cyanogen bromide (D) 6.0 to 7.8 1.524 to 1.526 Sulphated Ash Sulphated Ash Water content Reference solution (a): ≤1% Reference solution (b):≤ 0.1% Reference solution (b):≤ 0.1% Reference solution (b):≤ 0.1% The spot not more intense than reference solution(a) 1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The materic Complies with 0.00 and 0.	1	Characters	liquid / crystalline mass with faint		
3 Appearance liquid form and clear by slight heating and not more intensely coloured then reference solution Y5. Complies 4 Identification By Spectrphotometry (A) Reaction with Sodium Hydroxide(C) Reaction with Cyanogen bromide (D) Complies Complies Complies Complies Complies Complies Complies 5 pH 6.0 to 7.8 7.35 6 Refractive Index 1.524 to 1.526 1.524 7 Sulphated Ash ≤ 0.1 % 0.039 % 8 Water content ≤ 0.3 % 0.12 % 9 Related Substance Reference solution (a): ≤1% Reference solution (b):≤ 0.1% The spot not more intense than reference solution(a) 1% The spot not more intense than reference solution(b) 0.1% 10 Assay 99.0% to 101.0% 100.14 % 11 Residual Solvents Toluene ≤ 890 ppm Absent The materic Complies with the spot not more intense than reference Solution (b) with the spot not more intense than reference solution (b) 0.1%	2	Solubility		Complies	
Reaction with Sodium Hydroxide(C) Reaction with Cyanogen bromide (D) Reaction with Sodium Hydroxide(C) Reaction with Cyanogen bromide (D) 6.0 to 7.8 6.0 to 7.8 7.35 6. Refractive Index 7. Sulphated Ash 8. Water content 9. Related Substance Reference solution (a): $\leq 1\%$ Reference solution (b): $\leq 0.1\%$ The spot not more intense than reference solution(a) 1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The material Complies with Cyanogen bromide (D) Complies Complies The material Complies with Cyanogen bromide (D) Complies Complies The material Complies with Cyanogen bromide (D) Complies The material Complies with Cyanogen bromide (D) The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The material Complies with Cyanogen bromide (D) The spot not more intense than reference solution(b) 0.1% The material Complies with Cyanogen bromide (D) The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1%	3	Appearance	liquid form and clear by slight heating and not more intensely coloured then	Complies	
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8 Water content $\leq 0.3\%$ 9 Related Substance Reference solution (a): $\leq 1\%$ Reference solution (b): $\leq 0.1\%$ 10 Assay 99.0% to 101.0% The spot not more intense than reference solution(b) 0.1% 11 Residual Solvents Toluene $\leq 890~\mathrm{ppm}$ Absent The materical Complies with the spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The materical Complies with the spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(a) 1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution(b) 0.1% The spot not more intense than reference solution (b) 0.1% The spot not more intense than reference solution (b) 0.1% The spot not more intense than reference solution (b) 0.1%	6	Refractive Index	1.524 to 1.526	1.524	
9 Related Substance Reference solution (a): $\leq 1\%$ The spot not more intense than reference solution(a) 1% The spot not more intense than reference solution(b) 0.1% 10 Assay 99.0% to 101.0% 100.14 % 11 Residual Solvents Toluene \leq 890 ppm Absent The materical Complies with Complimentary Complimentary Complies with Complimentary Complies with Complimentary Complies with Complimentary Complies with Complementary Complies with Complimentary Complies with Complementary Complies with Complementary Complementar	7	Sulphated Ash	≤ 0.1 %	0.039 %	
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11 Residual Solvents Toluene ≤ 890 ppm Absent The mater Complies wit	9	Related Substance	5 and w	reference solution(a) 1% The spot not more intense than	
11 Residual Solvents Toluene \(\) 890 ppm Absent Complies wit	10	Assay	99.0% to 101.0%	100.14 %	
	11	Residual Solvents	Toluene ≤ 890 ppm	Absent	The material Complies with BP 2021 in all respect

(R.DASGUPTA) 19/09/2022 Q.C. Chemist / Q.C. In-Charge

19/Sep/2022 **Date of Sampling**

Q.A. Chemist / Q.A. In-Charge

PHARMEXCIL ★ IDMA ★ BDMA(I) ★ ICMMA ★ BNCCI

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AN ISO 9001: 2008 CERTIFIED, cGMP COMPLIED UNIT