

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

B 8&9, Behala Industrial Estate
Kolkata - 700 060, India

Drug Licence No. 1021M
Since 19 JUN 1974

Report No. FPNT 2215
Date. 19/Sep/2022

Name of the Item:

NIKETHAMIDE BP

Batch No. NT 2215

Mfg. Dt. August 2022

Exp. Dt. July 2026

Batch Quantity: 200.15 Kg.

TEST	STANDARD (BP 2021)	RESULT	
1 Characters	Colourless or slightly yellowish oily liquid / crystalline mass with faint characteristic odour	Colourless oily liquid with faint characteristic odour	
2 Solubility	Miscible with Water, with Ethanol (96%), with Chloroform and Ether.	Complies	
3 Appearance	The substance under examination in liquid form and clear by slight heating and not more intensely coloured than reference solution Ys.	Complies	
4 Identification	By Spectrophotometry (A) Reaction with Sodium Hydroxide (C) Reaction with Cyanogen bromide (D)	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 material Complies with BP 2021 in all respects

(R.DASGUPTA)

Q.C. Chemist / Q.C. In-Charge

19/Sep/2022

Date of Sampling

(S.Bera)

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

MEMBER

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

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