

CERTIFICATE OF ANALYSIS

Product Name	N, N-Dimethylacetamide
Product Code	ARK2190
Compendial References	Ph.Eur. 9th Edition
Lot No/Batch Number	DMAC134-19
PharmaGrade™, Ph. Eur., Manufactured under appropriate GMP controls for pharma or biopharmaceutical production.	

No	SPECIFICATION	RESULT
1	Appearance (Ph. Eur.): Limit: Clear and not more intensely coloured than reference solution Y ₇	Clear and not more intensely coloured than reference solution Y ₇ (0.09 NTU)
2	Identification - Infra-Red (Ph. Eur.): Limit: Conforms to reference spectrum	Conforms
3	Acidity (Ph. Eur.): Limit: NMT 5.0 mL of 0.02 M KOH is req. to restore the original bluish-green colour.	0.7 mL of 0.02 M KOH is req. to restore the original bluish-green colour.
4	Alkalinity (Ph. Eur.): Limit: NMT 0.5 mL of 0.02 M HCl is required to restore the original yellow colour.	0.01 mL of 0.02 M HCl is required to restore the original yellow colour.
5	Related Substances GC (Ph. Eur.): Limit: NMT 0.1% Any Impurity NMT 0.3% Total Impurities.	LT LOQ Any Impurity LT LOQ Total Impurities
6	Purity GC (SAFC Spec.) Limit: NLT 99.8% area.	100.0%
7	Water Content (Ph. Eur.): Limit: NMT 0.1%.	0.01%
8	Elemental Impurities (Ph. Eur.): Limit: No elemental impurities exceeded the control threshold of option 1 limit as stated in ICH Q3D.	Conforms to ICH Q3D
9	Non-Volatile Matter (Ph. Eur.): Limit: NMT 20 ppm	2 ppm
10	Microbial Testing (Ph. Eur.): Total Aerobic Microbial Count NMT 100 CFU/mL Total Yeasts and Moulds Count NMT 10 CFU/mL Absence of <i>Escherichia coli</i> , <i>Salmonella</i> species, <i>Pseudomonas aeruginosa</i> , and <i>Staphylococcus aureus</i> .	LT 50 CFU/mL TAMC LT 10 CFU/mL TYMC Absence of <i>Escherichia coli</i> , <i>Salmonella</i> species, <i>Pseudomonas aeruginosa</i> , and <i>Staphylococcus aureus</i> .
11	Bacterial Endotoxin (Ph. Eur.): NMT 0.01EU/mg	LT 0.004 EU/mg

Date of Manufacture:	04 April 2019
Date of Approval:	30 May 2019
Retest Date:	04 April 2022
Approved by:	Stephen Kearns, QC Specialist
Signature:	
Date:	13 Jun 19

