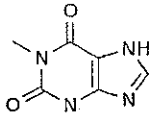


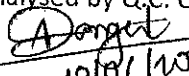

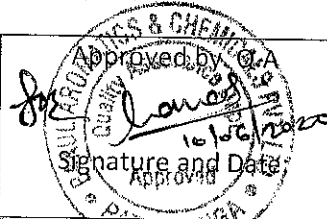
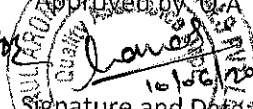
## Certificate of Analysis

A.R. No. AR/960/20

Product Name	Theophylline Anhydrous B. P		
Molecular Formula	C <sub>7</sub> H <sub>8</sub> N <sub>4</sub> O <sub>2</sub>		
CAS No.	58-55-09		
Molecular Weight	180.02		
Batch No.	TP/20/003	Batch Size	410.05 kg
Quantity Release	410.0 kg	Retest Date.	MAY-2021
Date of Mfg.	JUN 2020	Date of Exp.	MAY 2025
Analysis Date	10/06/2020	Release Date	10/06/2020
		Mfg. Lic. No.	867

Reference: B. P

Sr. No.	Test	Standard Specifications	Observation/Result
1.	Characteristics	White or almost white crystalline powder	White crystalline powder
2.	Odour	Odourless	Odourless
3.	Solubility	Slightly soluble in water. Sparingly in ethanol. It dissolve in dilute alkali hydroxide, in ammonia and mineral acid	Passes the test
4.	Identification	A 270-274 °C B I R C Red color developed D LOD E Xanthine test	A 272-273 °C B Passes C Passes D Passes E Passes
5.	Appearance of Solution	Dissolve 0.5 gm with heating in 75 mL CO <sub>2</sub> free water, cool. Solution is clear and colourless	Passes the test
6.	Acidity	Not more than 1.0 mL of 0.01 M NaOH / 0.33 g	0.70 mL required

7.	Relates Substances by HPLC	<b>Impurity</b> A. Caffeine NMT 0.1 %  B. 3-methyl-3,7-dihydro- 1H- purine-2,6-dione NMT 0.1 %  C. N-(6-amino-1,3-dimethyl-2,4- dioxo-1,2,3,4- tetrahydropyrimidin-5-yl) formamide NMT 0.1 %  D. (N-methyl-5-(methylamino)-1 H-imidazole-4 carboxamide NMT 0.1%  Any other impurity 0.1 % Total impurities 0.5 %	<b>Limit</b>          Nil 0.040 % Nil Nil  Nil 0.048 %
8.	Heavy Metals	Limit 20 ppm max.	Passes the test
9.	Sulphated Ash	Not more than 0.1 %	0.079 %
10.	Loss on drying at 105 °C	Not more than 0.5 %	0.28 %
11	Assay C <sub>7</sub> H <sub>8</sub> N <sub>4</sub> O <sub>2</sub> Calculated on dried basis	99 % to 101.0 %	100.04 %
Remarks: The above referred product Theophylline Anhydrous complies as per B. P. Specifications			
Analysed by Q.C. Chemist  10/06/2020 Signature and Date:		Checked by Q.C. Manager  10/06/2020 Signature and Date:	 Approved by Q.C. Manager  10/06/2020 Signature and Date: