

CERTIFICATE OF ANALYSIS

No.0259

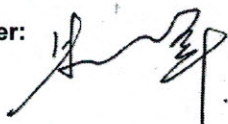
Product Name	VITAMIN B1 Thiamine Mononitrate	Manufacture Date	Feb.03,2019
Batch No.	TM201902017	Analysis Date	Feb.03,2019
Lot Size	1000kg	Expiry Date	3 Years
Executive Standard	BP2015/USP40	Order No.	

Analysis Item	Unit	Specification	Test Method	Result	
Appearance	---	White or almost white, crystalline powder or small, colourless crystals	Eyeballing	Almost white crystalline powder	
Solubility *	---	Sparingly soluble in water, freely soluble in boiling water, slightly soluble in ethanol and in methanol	Physical and chemical testing	Conform	
Identification *	---	Meet the requirement	IR, Physical and chemical identification	Conform	
Assay	%	98.0~101.0 (Dried substance)	Potentiometric titration	99.6	
pH	---	6.8~7.5	pH meter	7.2	
Appearance of Solution	---	Clear and not more intensely coloured than the reference solution	Colorimetric method	Conform	
Loss on Drying	%	≤1.0	Oven-drying method	0.2	
Sulphated Ash/Residue on Ignition *	%	≤0.1	Muffle	0.05	
Chloride *	%	≤0.06	Colorimetric method	<0.06	
Related substances	Any impurity *	≤1.0	HPLC	0.3	
	Total impurity *	≤1.5	HPLC	0.6	
Related Compounds *	%	≤1.0	HPLC	0.6	
Heavy Metals	Lead *	mg/kg	≤2	Flame Atomic Absorption Spectrophotometric	<2
	Arsenic*	mg/kg	≤1	Atomic fluorescence spectrometry	<1
Residual Solvent *	ppm	≤3000	GC	ND	

Conclusion: This batch of VITAMIN B1 Thiamine Mononitrate meets the requirements of BP2015/USP40.

Note: 1 The items labelled with * are tested at regular intervals.
2 Assay is analysed based on BP.

Quality Manager:




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