

WRS-E26-1

Cipla
Patalganga

WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD			
ITEM :	ETHIONAMIDE BP/Ph.Eur.	EVALUATED WITH: EPCRS/PG/E15/05 BATCH No. : 1	
DATE OF QUALIFICATION :	10.07.2015		
DIRECTION FOR STORAGE :	Store between 2°C to 8°C in well closed container and protected from light [#] .		
DIRECTION FOR USE :	Use as such.		
VALIDITY OF USE :	09.07.2017		
WORKING STANDARD No. :	WS/C/E6/06		
A.R.No. :	PG1511722		
SOURCE B. No. :	201503326	SOURCE A.R. No.:	PE1505507
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REFERENCE: Protocol No.: WP/BP/WS/C/E6/01

Sr. No.	TESTS	STANDARDS	RESULTS
1)	CHARACTERS A) APPEARANCE	A yellow, crystalline powder or small, yellow crystals.	Complies
2)	IDENTIFICATION A) By Melting point C)*By Infrared Spectrophotometry	Between 158°C to 164°C. The infrared absorption spectrum of sample, exhibits maxima only at the same wavelength as that of a similar preparation of Ethionamide CRS.	162°C. Complies
3)	RELATED SUBSTANCES (By TLC)	Any spot in the chromatogram obtained with the test solution, apart from the principal spot, is not more than intense than the spot in the chromatogram obtained with the reference solution (a) (0.5 per cent) and at most 1 such spot is more intense than the spot in the chromatogram obtained with reference solution (b) (0.2per cent).	Complies
4)	LOSS ON DRYING	Not more than 0.50 % w/w.	0.30 % w/w.
5)	SULFATED ASH	Not more than 0.10 % w/w.	0.06 % w/w
6)	ASSAY (By Potentiometry)	Ethionamide contains not less than 98.5 % w/w and not more than 101.0 % of $C_8H_{10}N_2S$, calculated with reference to the dried substance.	100.0 % w/w
7)	^*RELATED SUBSTANCES (By HPLC)	4-Thioisonicotinamide :Not more than 0.25% 2-Methyl -4-thioisonicotinamide :Not more than 0.15% 2,6-Diethyl -4-thioisonicotinamide :Not more than 0.15% Single maximum unknown impurity :Not more than 0.10% Total impurities :Not more than 0.75%	0.11 % 0.05 % 0.01 % 0.05 % 0.27 %
8)	PURITY (By mass balance method)	On as such basis. On dried basis.	99.4 % 99.7 %

REMARKS: *Test/s qualified with EPCRS. All other tests complies with BP 2015/ Ph.Eur.8.0 and Inhouse Specification and Certified to be used as Working Standard.

Note : # Third party may store as per specification.
: ^ Inhouse tests.HEAD QUALITY CONTROL
DATE :HEAD LAB QA
DATE :

Cipla Ltd., Cipla house, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, India

Phone : (91 22) 25756210

e-mail : savlo@cipla.com WebSite : www.cipla.com