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Certificate of Analysis

PRODUCT	**CETRIMIDE Ph. Eur.**	**REF.**	**NDQC-SP60-CAA-06**
BATCH NO.	**318CAA00031**	**MFG DATE**	**January – 2018**
BATCH SIZE	**3502.80 kg**	**RETEST DATE**	**December – 2022**
INSP LOT NO.	**40000042019**	**REISSUED DATE**	**06.04.2018**

SR. NO.	TEST	RESULT	METHOD REFERENCE	SPECIFICATION
1.0	Characters Appearance Solubility	White voluminous, free flowing powder. Freely soluble in water and in alcohol.	<Ph. Eur.> <Ph. Eur.>	White or almost white, voluminous, free flowing powder. Freely soluble in water and in alcohol.
2.0	Identification			
	A Ultraviolet absorption spectrophotometry	0.011	<Ph. Eur. (2.2.25)>	Absorbance of 1.0 % w/v solution in alcohol R at 260 nm to 280 nm has a maximum of 0.05
	B Colour development	A yellow precipitate is formed.	<Ph. Eur.>	A yellow precipitate is formed with potassium ferricyanide.
	C Solution characterisation	2 % w/v solution is froths copiously when shaken.	<Ph. Eur.>	2 % w/v solution in water froths copiously when shaken.
	D Thin layer chromatography	Complies with working reference standard.	<Ph Eur. (2.2.27)>	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour and size to the principal spot in the chromatogram obtained with the working reference standard solution.
	E Bromide	Yellow precipitate observed.	<Ph. Eur. (2.3.1)>	It gives reaction (a) of bromides.
3.0	Appearance of solution (2 % w/v solution in water)	The solution is clear. The solution is colourless and not more intensely coloured than reference solution B_9	<Ph. Eur. (2.2.1)> <Ph. Eur. Method II, (2.2.2)>	For clarity : The solution is clear i.e compared against reference suspension I For colour of solution: The solution is colourless and it should not be more intensely coloured than reference solution B_9
4.0	Acidity or alkalinity	0.08 ml of 0.1 M hydrochloric acid is used.	<Ph. Eur.>	Not more than 0.1 ml of 0.1M hydrochloric acid or 0.1M sodium hydroxide is required.
5.0	Amines and amine salts	Two inflexion observed. Volume of titrant used 0.7 ml 0.1 M tetra butyl ammonium hydroxide solution.	<Ph. Eur.>	Not more than 2.0 ml of 0.1 M tetra butyl ammonium hydroxide solution.
6.0	Loss on drying (at 105 °C for 2 hours)	0.23	<Ph. Eur. (2.2.32)>	Maximum 2.0 % w/w
7.0	Sulfated ash	0.07	<Ph. Eur. (2.4.14)>	Maximum 0.5 % w/w
8.0	Assay (on dried basis)	98.5	<Ph. Eur.>	Minimum 96.0 % w/w and Maximum 101.0 % w/w
	Additional test			
9.0	Related substances (TLC) 1.) Each individual spot 2.) Total number of spots	 Complies Complies	AMV R-001-00/II	 Maximum 1.0 % Maximum 2
10.0	Residual solvent 1.) Isopropyl alcohol	BDL	AMV R-001-00/IV	Maximum 3000 ppm
11.0	Aerobic microbial count and yeast/mould → Total Aerobic microbial count → Total combined yeast/mould count	 Complies Complies	<Ph. Eur., (2.6.12)>	 Not more than 1000 CFU/gm Not more than 100 CFU/gm

Remark : The material conform to the above specification.

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