

CERTIFICATE OF ANALYSIS (Working Standard)

QUALITY CONTROL DEPARTMENT INDOCO REMEDIES LTD., GOA STERILE FORMULATION PLANT : RM/0197/12 Name of the sample : Benzalkonium Chloride Solution BP A.R. No. : WS/BKC-IB/001 WS No Batch No. : I11A/0211/2908/13 : 31/08/2016 Mfg. Date : 01/09/2011 Exp Date : S.D.FINE CHEMICALS Date of preparation: 30/03/2013 Manufacturer Valid Upto : 29/03/2015 Sampled by : Nandesh Testing Procedure No: WSAP/REF000066/I03 Qualified against ; Rs B.No. 1.1 **Standards** Sr. Tests **Observations** No. 1. Description A clear, colourless syrupy liquid; A clear, colourless or slightly yellow, syrupy liquid; odour, odour, aromatic. aromatic. 2. Identification A white precipitate is produced A) Chemical Reaction A white precipitate is produced which is soluble in Ethanol which is soluble in Ethanol (95 %). (95 %). An orange red colour is produced. An orange red colour is produced. Colour Reaction B) Not less than 49.0 % w/v and not 50.1 % w/v. 3. Assay more than 51.0 % w/v of alkylbenzyldimethylammonium chlorides Remark: The above consignment complies/does not comply according to the specification no. WSS/ REF000066/I03 and can be/cannot be used as working standard.

Analysed by	Checked by	Approved by
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Date 30/03/13	Date 90/03/13	Date 30/03/13





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	CO REMEDIES LTD., G		CONTROL DEPARTMENT	
Nam Batc Mfg. Manu Sam Testi	h No. : I11A/ Date : 01/09	alkonium Chloride Solution BP A.F 0211/2908/13 W 0/2011 Ex INE CHEMICALS Di lesh Va P/REF000066/103	S No : WS/BRC-IB/001 tp Date : 31/08/2016 ate of preparation : 30/03/2013 alid Upto : 29/03/2015	
Sr. No.	Tests	Observations	Standards	
1.	Characters			
	Appearance	A clear, colourless slightly yellowish liquid.	A clear, colourless or slightly yellowish liquid.	
2.	Identification			
A) -	UV – visible absorption spectrophotometry	The solution showing absorption maxima at 257 nm, 263 nm and 269 nm and a shoulder at 250 nm.	The solution shows absorption maxima at 257 nm, 263 nm and 269 nm and a shoulder at about 250 nm.	
B)	High performance liquid Chromatography.	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peaks in the chromatogram obtained with the Reference solution.	The principal peak in the chromatogram obtained with the test solution are similar in retention time to the principal peaks in the chromatogram obtained with the Reference solution.	
C)	Melting point	The crystals melt at 129.2°C	The crystals melt at 127°C to 133°C.	
D)	Reaction (a) of Chlorides	A curdled, white precipitate is formed which dissolves on addition of Ammonia R.	A curdled, white precipitate is formed which dissolves on addition of Ammonia R.	
3.	Average relative molec	ular mass and ratio of alkyl compor		
A)	C ₁₂ homologue	67.8 %	Minimum 40 %	
В)	C ₁₄ homologue	32.2 %	Minimum 20 %	
C)	Sum of C ₁₂ and C ₁₄ homologues	100.0 %	Minimum 70 %	
4.	Impurities A, B and C			
A)	Impurity A	0.04 %	Not more than 0.5 %	
B)	Impurity B	0.04 %	Not more than 0.15 %	
C)	Impurity C	0.001 %	Not more than 0.05 %	



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	ILE FORMULA				
Nam	e of the sample	; Benz	alkonium Chloride Solution BP	A.R. No.	: RM/0197/12
	n No.	: I11A/	0211/2908/13	WS No	: WS/BKC-IB/00
	Date	: 01/09		Exp Date	: 31/08/2016
	ıfacturer		INE CHEMICALS	Date of prepara	ation: 30/03/2013
	oled by	. Nand		Valid Upto	: 29/03/2015
Testi	na Procedure No		P/RAF000066/103	•	
	ified against		No. 1.1		
Sr.	Tests		Observations		Standards
No.					
5.	Assay		501.8 g/L	chlorides, ca average rela The solution (96 %).	limethylammonium alculated using the ative molecular mass. may contain Ethano
Rem WSS	ark : The above / REF000066/B0	consign 03 and c	ment complies/does not compl an be/cannot be used as worki	y according to th ng standard.	e specification no.

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30/03/13	Date 30/03/13	Date 30/03/13	