


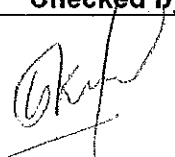
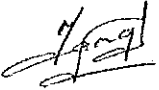
CERTIFICATE OF ANALYSIS
(Working Standard)

B1-Indoco

INDOCO REMEDIES LTD., GOA STERILE FORMULATION PLANT		QUALITY CONTROL DEPARTMENT	
Name of the sample	: Benzalkonium Chloride Solution BP	A.R. No.	: RM/0197/12
Batch No.	: I11A/0211/2908/13	WS No	: WS/BKC-IB/001
Mfg. Date	: 01/09/2011	Exp Date	: 31/08/2016
Manufacturer	: S.D.FINE CHEMICALS	Date of preparation	: 30/03/2013
Sampled by	: Nandesh	Valid Upto	: 29/03/2015
Testing Procedure No : WSAP/REF000066/I03			
Qualified against : Rs B.No. 1.1			

Sr. No.	Tests	Observations	Standards
1.	Description	A clear, colourless syrupy liquid; odour, aromatic.	A clear, colourless or slightly yellow, syrupy liquid; odour, aromatic.
2.	Identification		
A)	Chemical Reaction	A white precipitate is produced which is soluble in Ethanol (95 %).	A white precipitate is produced which is soluble in Ethanol (95 %).
B)	Colour Reaction	An orange red colour is produced.	An orange red colour is produced.
3.	Assay	50.1 % w/v.	Not less than 49.0 % w/v and not 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
		
Date 30/03/13	Date 30/03/13	Date 30/03/13






CERTIFICATE OF ANALYSIS
(Working Standard)

INDOCO REMEDIES LTD., GOA		QUALITY CONTROL DEPARTMENT	
STERILE FORMULATION PLANT			
Name of the sample	: Benzalkonium Chloride Solution BP	A.R. No.	: RM/0197/12
Batch No.	: I11A/0211/2908/13	WS No	: WS/BKC-IB/001
Mfg. Date	: 01/09/2011	Exp Date	: 31/08/2016
Manufacturer	: S.D.FINE CHEMICALS	Date of preparation	: 30/03/2013
Sampled by	: Nandesh	Valid Upto	: 29/03/2015
Testing Procedure No	: WSAP/REF000066/103		
Qualified against	: Rs B.No. 1.1		
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 molecular mass and ratio of alkyl components		
A)	C ₁₂ homologue	67.8 %	Minimum 40 %
B)	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 %



CERTIFICATE OF ANALYSIS
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INDOCO REMEDIES LTD., GOA STERILE FORMULATION PLANT		QUALITY CONTROL DEPARTMENT	
Name of the sample	: Benzalkonium Chloride Solution BP	A.R. No.	: RM/0197/12
Batch No.	: I11A/0211/2908/13	WS No	: WS/BKC-IB/001
Mfg. Date	: 01/09/2011	Exp Date	: 31/08/2016
Manufacturer	: S.D.FINE CHEMICALS	Date of preparation	: 30/03/2013
Sampled by	: Nandesh	Valid Upto	: 29/03/2015
Testing Procedure No : WSAP/RAF000066/103			
Qualified against : Rs B.No. 1.1			
Sr. No.	Tests	Observations	Standards
5.	Assay	501.8 g/L	475 g/L to 525 g/L of alkylbenzyltrimethylammonium chlorides, calculated using the average relative molecular mass. The solution may contain Ethanol (96 %).
Remark : The above consignment complies/does not comply according to the specification no. WSS/ REF000066/B03 and can be/cannot be used as working standard.			

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