

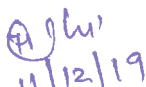


dishman

CERTIFICATE OF ANALYSIS

PRODUCT	CHLORHEXIDINE DIGLUCONATE SOLUTION Ph. Eur.		REF.:	FG06CDV1-00
BATCH No.	119CDV0006	MFG. DATE	December-2019	
BATCH SIZE	9045.0 Kg	RETEST DATE	May-2021	
INSPECTION LOT NO.	40000049660	RELEASE DATE	11-12-2019	
CERTIFICATE VERSION	00	RE-ISSUE/REANALYSIS DATE	--	
SN	TESTS	RESULTS	METHOD REFERENCES	SPECIFICATIONS
1.	Characters (i) Appearance (ii) Solubility	Almost colourless liquid. Miscible with water, with less than 3 parts of acetone and with less than 5 parts of ethanol (96 per cent)	Ph. Eur.	Almost colourless or pale yellowish liquid. Miscible with water, with not more than 3 parts of acetone and with not more than 5 parts of ethanol (96 per cent)
2.	Identification A. IR-Spectrum B. Thin-layer chromatography	IR spectrum of the test preparation is concordant to that of standard The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution	Ph. Eur. (2.2.24) Ph. Eur. (2.2.27)	IR spectrum of the test preparation to be concordant to that of standard The principal spot in the chromatogram obtained with the test solution to be similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution
3.	Relative density	1.065	Ph. Eur. (2.2.5)	1.06 to 1.07
4.	pH	6.25	Ph. Eur. (2.2.3)	5.5 to 7.0
5.	Impurity P (Chloroaniline)	20	Ph. Eur. (2.2.25)	Not more than 500 ppm
6.	Related substances (By HPLC) Impurity N Impurity H Impurity A Impurity J Impurity K Impurity I & O Impurity G Impurity B Impurity F Impurity L Impurity Q Unspecified impurity Total impurities	0.18 0.15 BDL BDL BDL 0.11 0.12 BDL BDL BDL BDL BDL BDL 0.56	ADMVR/CHG/ 041A/00 & ADL- 16092	Not more than 1.0 % Not more than 0.5 % Not more than 0.4 % Not more than 0.4 % Not more than 0.4 % Not more than 0.4 % Not more than 0.3 % Not more than 0.2 % Not more than 0.2 % Not more than 0.2 % Not more than 0.2 % Not more than 0.2 % Not more than 0.10 % Not more than 3.0 %
7.	Assay	202.0	Ph. Eur. (2.2.20)	190 g/L to 210 g/L
Additional test				
8.	Residual solvents 2-Propanol Methanol	257 Not detected	AMV/CHG/01/00	Not more than 5000 ppm Not more than 3000 ppm

Note: BDL= Below disregard limit (less than 0.05 %), BDL*=Below detection limit, BQL=Below quantification limit
REMARKS: The product conforms to Ph. Eur. & In-house specifications.

Prepared by: 
(T. H. Joshi)

Reviewed by: 
(Amit Sharma)

Approved by: 
(K. J. Rana)

Dishman Carbogen Amcis Limited

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Government Recognised Export House
CIN No. : L74900GJ2007PLC051338



CERTIFICATE OF ANALYSIS

PRODUCT	CHLORHEXIDINE GLUCONATE SOLUTION USP	Ref.:	FG08CDV1-00
BATCH No.	119CDV0006	MFG. DATE	December-2019
BATCH SIZE	9045.0 Kg	RETEST DATE	May-2021
INSPECTION LOT No.	40000049660	RELEASE DATE	11-12-2019
CERTIFICATE VERSION	00	RE-ISSUE/REANALYSIS DATE	--

SN	TESTS	RESULTS	METHOD REFERENCE	SPECIFICATIONS
1.	Description Solubility	Almost colourless, clear liquid Complies	USP USP	Almost colourless or pale yellow, clear liquid. Miscible with glacial acetic acid and with water; miscible with three times its volume of acetone & with five times its volume of dehydrated alcohol; further addition of acetone or dehydrated alcohol yields a white turbidity.
2.	Identification A. Infrared absorption B. Thin layer chromatography identification test	Concordant Complies	USP <197K> USP<201>	IR spectrum of the test preparation to be concordant to that of Reference standard. The principal spot from the sample solution corresponds in color, size, and Rf value to that from the standard solution
3.	Assay	20.1	USP <621>	Not less than 19.0 % w/v and not more than 21.0 % w/v
4.	Impurities Organic impurities Chlorhexidine oxazinone analog Specified unidentified impurity 1 Chlorhexidine amine Chlorhexidine guanidine Chlorhexidine urea p-Chlorophenyl urea Chlorhexidine nitrile Chlorhexidine dimer o-Chlorhexidine and specified unidentified impurity 2 Chlorhexidine glucityl triazine Oxochlorhexidine Any individual unspecified impurity Total impurities Limit of p-Chloroaniline	BDL BDL 0.12 0.18 BDL BDL BDL 0.15 0.11 BDL BDL BDL 0.56 9	ADMVR/CHG/ 041A/00 & ADL-16092 USP <621>	Not more than 0.2 % Not more than 0.2 % Not more than 0.3 % Not more than 1.0 % Not more than 0.2 % Not more than 0.2 % Not more than 0.4 % Not more than 0.5 % Not more than 0.4 % Not more than 0.4 % Not more than 0.4 % Not more than 0.10 % Not more than 3.0 % Not more than 500 µg/mL
5.	Specific tests Specific gravity pH	1.064 6.25	USP <841> USP <791>	1.06 - 1.07 5.5 - 7.0
	Additional test			
6.	Residual solvents 2-Propanol Methanol	257 Not detected	AMV/CHG/01/00	Not more than 5000 ppm Not more than 3000 ppm

Note: BDL= Below disregard limit (less than 0.05 %), BDL*=Below detection limit, BQL=Below quantification limit

REMARKS: The product conforms to USP & In-house specifications.

Prepared by: 
(T. H. Joshi) 11/12/19

Reviewed by: 
(Amit Sharma) 11/12/19

Approved by: 
(K. J. Rana) 11/12/19

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