	<p align="center">SIONC PHARMACEUTICALS PVT. LTD.</p> <p>Factory: Plot No. 34A, Road No. 1, JN Pharma City, IDA Parawada, Thanam(V), Visakhapatnam-531021, Andhra Pradesh, India, Ph: +91-8924-236117/236118, Fax: +91-8924-236119, E-mail: info@sioncpharma.co.in</p>
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CERTIFICATE OF ANALYSIS


Name of the Product	: CHLORAMBUCIL	Page No.	: 1 of 3
Batch Number	: 2027/2/010/17	A.R.No	: CB/FP/0044/17
Manufacturing Date	: 21/12/2017	Expiry/ Re-test Date	: 20/12/2020
Batch Quantity	: 970.0 grams	Dispatch Quantity	: ---
Customer Name	: ---	Date of Analysis	: 10/01/2018

S. No.	Test Parameter	Specification	Result
1.	Description	Off-white, slightly granular powder.	Off-white, slightly granular powder.
2.	Identification		
	a) by IR	The IR spectrum of the sample should be match with that of standard spectrum.	Complies
	b) by HPLC	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that of the standard preparation, in Assay by HPLC.	Complies
	c) Absence of chloride ion and presence of Ionizable chlorine	No opalescence is observed immediately (Absence of chloride ion) Warm the solution on a stream bath: Opalescence shall develops (Presence of Ionizable chlorine).	Complies
3.	Melting Point	Between 65°C and 69°C	66.2°C to 68.1°C

Compiled by	Checked by	Approved by
<i>GR</i> 21/02/2018	<i>T.R</i> 21/02/18	<i>M.N</i> 21/02/2018
G.Ravi Kumar	T.Ravi Kumar	M.Nagababu
Asst.Manager-QC	Asst.Manager-QC	Dy.Manager-QA

Office Address: Regd. Off: #43-11-56, Subbalakshmi Nagar, Railway New Colony, Visakhapatnam-530016, Andhra Pradesh, India, Ph: +91-891-2712885, Fax: +91-891-2712875.

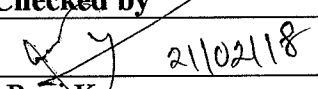
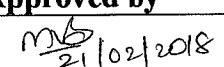
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CERTIFICATE OF ANALYSIS


Name of the Product	:	CHLORAMBUCIL	Page No.	:	2 of 3
Batch Number	:	2027/2/010/17	A.R.No	:	CB/FP/0044/17
Manufacturing Date	:	21/12/2017	Expiry/ Re-test Date	:	20/12/2020
Batch Quantity	:	970.0 grams	Dispatch Quantity	:	---
Customer Name	:	---	Date of Analysis	:	10/01/2018

S. No.	Test Parameter	Specification	Result
4.	Solubility	Freely soluble in acetone, soluble in dilute alkali, very slightly soluble in water.	Complies
5.	Water content by KF	Not more than 0.5 %w/w	0.16 %w/w
6.	Sulphated Ash	Not more than 0.1 %w/w	0.06 %w/w
7.	Assay by Titrimetry (On anhydrous basis)	Not less than 98.5 %w/w and Not more than 101.0 %w/w	99.4 %w/w
8.	Heavy metals	Not more than 20 ppm	Less than 20 ppm
9.	Impurity G Content by HPLC	Not more than 0.4 %w/w	Not Detected
10	Related substances by HPLC		
	a) Impurity B	Not more than 0.4 %w/w	Not Detected
	b) Impurity E	Not more than 0.6 %w/w	0.11 %w/w
	c) Unspecified single maximum Impurity	Not more than 0.1 %w/w	0.04 %w/w
	d) Total Impurities	Not more than 1.0 %w/w	0.24 %w/w
11.	Assay by HPLC (On anhydrous basis)	Not less than 98.0 %w/w and Not more than 101.0 %w/w	99.4 %w/w

Compiled by	Checked by	Approved by
ER 21/02/2018	 21/02/18	 21/02/2018
G.Ravi Kumar	T.Ravi Kumar	M.Nagababu
Asst.Manager-QC	Asst.Manager-QC	Dy.Manager-QA

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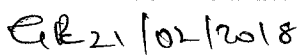
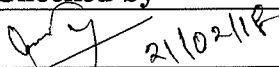
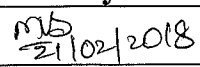
CERTIFICATE OF ANALYSIS

Name of the Product	:	CHLORAMBUCIL	Page No.	:	3 of 3
Batch Number	:	2027/2/010/17	A.R.No	:	CB/FP/0044/17
Manufacturing Date	:	21/12/2017	Expiry-/ Re-test Date	:	20/12/2020
Batch Quantity	:	970.0 grams	Dispatch Quantity	:	---
Customer Name	:	---	Date of Analysis	:	10/01/2018

S. No.	Test Parameter	Specification	Result
12.	Residual solvents by GC		
	a) Methanol	Not more than 3000 ppm	BQL
	b) Acetonitrile	Not more than 410 ppm	BDL
	c) Methyl Tertiary Butyl ether	Not more than 5000 ppm	286 ppm
	d) n-Hexane	Not more than 290 ppm	67 ppm
	e) Ethyl Acetate	Not more than 5000 ppm	BDL
	f) Benzene	Not more than 2 ppm	BDL
	g) n-Heptane	Not more than 5000 ppm	441 ppm

BDL: Below Detection Limit BQL: Below Quantitation Limit

REMARKS: The material complies as per the In-house specification.

Compiled by	Checked by	Approved by
 G. Ravi Kumar Asst. Manager-QC	 T. Ravi Kumar Asst. Manager-QC	 M. Nagababu Dy. Manager-QA

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