WRS C30-6





Working Standard Certificate of analysis

Product	:	Chlorpheniramine Maleate BP	Date of Manufacturing 0	DOX L	July, 2015
Batch No.		SLL/C/081615154	Date of re-test/Expiry		Jun, 2020
Quantity	<del></del>	1.0 g	Date of Release	:	14/11/2015
A.R. No.	- <del>  -</del> -	SLL/QC/FP/15/0688	Use before	:	14/11/2016

.No.	Test	Specifications	Results	
	Description	A white crystalline powder, odourless.	A white crystalline powder, odourless.	
	Solubility	Freely soluble in water, soluble in Ethanol (95%)	Conforms	
	Identification:		133	
	A. Melting Point ( <sup>0</sup> C)	Between 130 and 135		
	B. Identification by IR	The IR absorption spectrum should be	Positive	
	B. Identification of 22	concordant with that of Chlorpheniramine		
		Maleate		
	# # # # # # # # # # # # # # # # # # #	working standard	<u> </u>	
	a a distantian	$-0.10^{0}$ to $+0.10^{0}$	+0.090	
	C.Optical rotation	Resultant solution should be clear and	Resultant solution should be clear	
		not more intensely coloured than	less intensely coloured than	
١.	Appearance of solution	not more intensery coloured than	reference solution BY <sub>6</sub>	
		Reference solution BY <sub>6</sub> .	+0.090	
,	Optical rotation	$-0.10^{0}$ to $+0.10^{0}$		
	Related substances(By	×	a.0.01%	
	HPLC)	a. Not more than 0.2%	b.0.005%	
	a. Impurity A.	b. Not more than 0.1%	c.0.007%	
6	b. Impurity B	c. Not more than 0.1%	d.0.005%	
O	c. Impurity C	d. Not more than 0.1%	e.0.004%	
	d. Impurity D	e.Not more than 0.1%	f.0.031%	
	e. Unspecified impurities	f.Not more than 0.5%	1.0.0317	
	f. Total impurities		Complies	
	Heavy metals	Not more than 20 ppm	0.21%	
7	Loss on drying	Not more than 0.5% w/w	0.04%	
8	Sulphated ash	Not more than 0.1% w/w	99.95%	
9	Sulphated asir	Not less than 98.0% and Not more than		
10	Assay( By Titration)	Not less than 98.0% and 140 more	4 AS 15 BASIS 99.74	
	Content of Chlorphenamine	101.0% calculated on dried basis.		
	Maleate	th respect to above mentioned test as per BI	Specification	
Rei	marks: The product compiles wi	III rospoot to	Kory! 14/10/16	
^ .		12 San Alla	1 2 Mil Infinite	
	13. Alad 14/11/15	Checked by QC 14/ mlin	Approved By Head -QC	
	Complied by QC	Checked by Qo	Page 1 of 1	

Corporate office: 207/208, Udyog Bhavan, Sonawala Road, Goregaon [East], Mumbai – 400 063. Maharastra, India.

