

FOR REGULATORY PURPOSE

CERTIFICATE OF ANALYSIS

Date
24-AUG-2020

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BETAHISTINE DIHYDROCHLORIDE (N)

Material	Batch	Prod. Date	Retest Date
1040366	50101081	11.2018	11.2019

Characteristic	Unit	Result	Specification
Appearance			
White to off white, sometimes clumped, crystalline material		complies	see characteristic
Identification : IR spectrum		complies	corresponds to spectrum of the standard
Identification : Betahistine (RT. HPLC)		complies	corresponds to reference standard
Identification : Chlorides		complies	corresponds to the test on chloride
Appearance of solution		complies	clear, < = B8
pH		2.0	2.0 .. 3.0
Loss on drying	%	0.7	< = 1.0
Sulphated ash	%	0.0	< = 0.1
Ter. amine trihydrochloride *	%	< 0.05	< = 0.2
2-vinylpyridine hydrochloride *	%	< 0.05	< = 0.1
2-pyridylethanol hydrochloride *	%	< 0.05	< = 0.2
Relative substance : each unspecified impurity *	%	0.07	< = 0.10
Relative substance : sum of specified and unspecified impurities *	%	0.10	< = 0.5
Residual solvent : Hexanes (GC)	%	< 0.02	< = 0.02
Residual solvent : Ethanol (GC)	%	< 0.2	< = 0.2
Chlorides (on dried substance)	%	33.8	33.2 .. 34.6
Betahistine dihydrochloride (on dried substance)	%	100.7	98.5 .. 102.0

* Relative percentage of betahistine diHCl theoretical content

Results taken from the certificate of analysis of the supplier except for the tests "Appearance, IR spectrum, Chlorides and Loss on drying"

The batch has been manufactured and released according to our specifications.

Dominique PARIS

Quality Control Manager

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QC Manager