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passion & smart processes

FINORGA
Avenue du Lac BP 30
F-64150 Mourenx
France

20 SEP. 2019 *dra*

Certificate of Analysis

Date 03.09.2019
Delivery - Item / date
80008658 - 900003 / 13.09.2019
Order - Item / date
7640 - 000010
Customer number
1150001

MYLAN Laboratories SAS
Route de Belleville ZI NORD
01400 CHATILLON SUR CHALARDAINE

FRAA | | | Ech. destiné au labo - QQ_PCMP 3/3

Article:
BETAHISTINE DIHYDROCHLORIDE (N)

Code art.:	Lot:	Lot ctrl:	Système	Date/Signature
1040366	50116040	10001632388	GEP(410)	

Romain CHIRAT

19 SEP. 2019

Warning



1040366 - Betahistine dihydrochloride

Comments: Product has been manufactured and tested in accordance with GMP requirements and complies with the requirements of the Marketing Authorisation(s)

Batch number 0030007667
Inspection lot 30000022784

Prod. Date/G.R. 06.05.2019
Item Finorga 2000548

Purchase order 4500674078
Quantity of delivery 775,110 KG

Inspection Plan 2091
BETAHISTINE DICHLORHYDRATE
Analytique CQ-M-MNG-0162

Tests	Specifications		Unit	Result Value
	Lower Limit	Upper Limit		
Characterisation :				
- DESCRIPTION White to off-white, very hygroscopic and sometimes clumped, crystalline material	Complies			Complies ✓
- DESCRIPTION White or slightly yellow powder	Complies			Complies ✓
Identifications :				
- INFRARED SPECTRUM	Same as reference			Complies ✓
- HPLC IDENTIFICATION Retention time corresponds to retention time of standard	Positive identification			Complies ✓
- IDENTIFICATION OF CHLORIDES	Positive identification			Complies ✓
Tests :				
- CLARITY OF SOLUTION	Clear			Clear ✓
- COLOR OF SOLUTION	Not more than B8			Colorless ✓
- pH OF SolutON	2,0	3,0		2,1 ✓
- LOSS ON DRYING		< 1,0	%	0,2 ✓
- SULPHATED ASH		0,1	%	0,0 ✓
- HEAVY METALS	Not more than 20 ppm			Complies ✓

Commitment

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03 OCT. 2019

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FINORGA SAS au capital de 1.589.008 Euro - Siège social : 497 Route de Givors BP 9 - 38670 Chasse-sur-Rhône - France
Tél. : +33 (0)4 72 49 19 60 - Fax : +33 (0)4 72 49 19 73 - 662 019 322 RCS Vienne - T.V.A. EU : FR 50 662 019 322 - APE : 2110Z
Unités de production : F-38670 Chasse-sur-Rhône 497 route de Givors BP 9 Tél. : +33 (0)4 72 49 19 60 Fax : +33 (0)4 72 49 19 73
F-64150 Mourenx Avenue du Lac BP30 Tél. : +33 (0)5 59 60 79 00 Fax : +33 (0)5 59 60 79 49

Betahistine dihydrochloride
 Batch number **0030007667**
 Inspection lot **30000022784**

Delivery - Item
80008658 - 900003
 Date **13.09.2019**

MYLAN Laboratories SAS
 Route de Belleville ZI NORD
 01400 CHATILLON SUR CHALARONNE

Tests	Specifications		Unit	Result Value
	Lower Limit	Upper Limit		
- RESIDUAL ETHANOL BY GC (w/w)	Not more than 0.2%			Less than 0.2% ✓
- HEXANES(Calculated as N-Hexane) BY GC (w/w)	Not more than 0.02 %			Less than 0.02% ✓
- RESIDUAL BENZENE BY GC (HEAD-SPACE)	Not more than 2 ppm			Complies ✓
- Purity (in w/w) related substances : N-Methylbis[b-(2-pyridyl)ethyl] amine trihydrochloride	0,2		%	< LR(0,05%) ✓
- 2-Vinylpyridine hydrochloride	0,1		%	< LR(0,05%) ✓
- 2-Pyridylethanol hydrochloride	0,2		%	< LR(0,05%) ✓
- Unspecified impurity(each)(Calculated as betahistine dihydrochloride)	0,10		%	< LR(0,05%) ✓
- Sum of specified and unspecified impurities(unspecified calculated as betahistine dihydrochloride)	0,5		%	0,06 ✓
- 2-Vinylpyridine Hydrochloride	For information only			Less than 31 ppm ✓

Assays :

- CHLORIDE, IN DRIED SUBSTANCE (W/W)	33,2	34,6	%	34,3 ✓
- ASSAY BY HPLC (W/W) (DRIED SUBSTANCE)	98,5	102,0	%	99,2 ✓

Review :

- MANUFACTURING BATCH REVIEW	Complies	Complies
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Decision : **Complies** / 02.09.2019

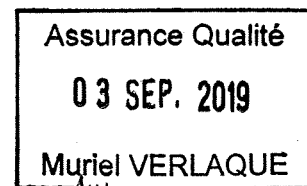
Re-evaluation Date : 05.2020

Inspection lot validated by :

Muriel Verlaque

Assistante AQ Mourenx

*** End of document ***


 02 OCT. 2019
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 03 OCT. 2019
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