Lactose Monohydrate Batch 018216

Document State: Effective
Effective Date: 15 Dec 2010 09:14:55 GMT +02:00
Document Number: _0260 **Version: 5.0**
Lactose Monohydrate

Item Name	Lactose Monohydrate		
Item Number	103310	Specification Amendment Number	4432

To be completed by Quality Assurance			
Batch Number	B018216	Number of samples	80 X 1D 1 x Comp 1 x Comp

To be completed by Quality Control			
Specification amendment no.	4432	Analysis start date	20 Sep 2011
Workbook reference	A1223-094-S, AES1-031	Analysis end date	21 Sep 2011

*	Test	Specification LM15 Pg 04 A1228-048-KS	Result	Analyst name & initials
*	**CHARACTERS** Appearance	A white or almost white, crystalline powder.	Ref X0757214 Complies	Ndileka, NBM
	Solubility	Freely but slowly soluble in water, practically insoluble in ethanol 96 %.	Complies	Ndileka, NBM
*	**Identification**	First identification: A, D Second identification: B, C, E		
		A. Infrared spectrophotometry	Complies	Ndileka, NBM
		B. Thin layer chromatography	N/A	N/A
		C. A red colour develops.	N/A	N/A
		D. Complies with the test for water.	Complies	Ndileka, NBM
		E. Near Infrared spectrophotometry (Alternative In-House)	N/A	N/A
*	**Appearance of solution**	The solution is clear and not more intensely coloured than reference solution BY_7.	Complies	Cherise, CvB
*	**Acidity or Alkalinity**	Not more than 0.4 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink or red.	0.2ml	Cherise, CvB
*	**Specific optical rotation**	+ 54.4° to + 55.9°.	+55.5°	Cherise, CvB
*	**Absorbance** Test solution (a): at 400nm	Not more than 0.04.	0.01	Cherise, CvB
	Test solution (b): at 210 - 220 nm	Not more than 0.25.	<0.25	Cherise, CvB
	Test solution (c): at 270 - 300 nm	Not more than 0.07	0.05	Cherise, CvB
*	**Heavy metals**	Not more than 5 ppm.	<5ppm	CoA/CvB Cherise
*	**Water**	4.5 % to 5.5 %.	5.1%	Ndileka, NBM
*	**Sulphated ash**	Not more than 0.1 %.	<0.1%.	CoA/NBM, Ndileka
*	**Microbial limits** TAMC	Not more than 10^2CFU/g.	<10/g	Nyameka, NM
	Escherichia coli (per gram)	Absent.	Absent	Nyameka, NM
	Residual Solvents (Supplier)	No class 1,2 or 3 solvents used during production of material. (Vendor Certificate Of Compliance required)	Complies	COA
*	**Particle Size**	78 - 86 % is less than 75 µm	< 31µm	Cherise, CvB
	(In-house)	98 % is less than 180 µm	98% < 141µm	Cherise, CvB
*	**Bulk Density** (In house)	0.707 to 0.879 g/ml	0.781g/ml	Cherise, CvB

- Quality Assurance to identify with * the tests to be performed.
- Tests marked with * to be performed by the Quality Control Laboratory.
- Tests not marked with * may be taken from the Certificate of Analysis.
- Any test not included on the Certificate of Analysis will be performed by the Quality Control Laboratory.

Document State: Effective
Effective Date: 15 Dec 2010 09:14:55 GMT +02:00
Document Number: 0260 **Version: 5.0**
Title: 103310 - Lactose Monohydrate

Item Name	**Lactose Monohydrate**		
Item Number	103310	**Specification Amendment Number**	4432

To be completed by Quality Assurance			
Batch Number	B018216	**Number of samples**	30-80 comp: 1

To be completed by Quality Control			
COA attached	✓	**COA checked by**	

I declare that all samples have been tested and results checked/comments

	Name	**Signature**	**Date**
QC Department check 1	Ndileka		21 Sep 2011
	Name	**Signature**	**Date**
QC Department check 2	N. Mathwa		21 Sep 2011

Remarks/Comments

Quality Control Laboratory
APPROVED BY
QC Laboratory Manager
Sign Date 26 Sept 2011

To be completed by Quality Assurance					
Special labeling instructions	Moisture: Spill,	**Expiry / Retest date**	22 Sept 2013	**Approved / Rejected**	Approved

	Name	**Signature**	**Date**
1st Stage Unblocking by QA Department	Anthea		26 Sep 2011
Status label			
Labels attached by QA Department	IGNATIUS		27/09/2011
2nd Stage Unblocking by QA Department	Anthea		28 Sep 2011

Additional labeling (for subsequent quarantine or reject purposes)					
Reason			**Reason**		
QA signature		**Date**	**QA signature**		**Date**
Quarantine label			**Reject label**		
Labels attached by QA Department	**Signature**	**Date**	**Labels attached by QA Department**	**Signature**	**Date**

DMV-Fonterra Excipients
The ingredients of success

306717 F

Certificate of analysis

Issue date
2011.02.28
Purchase order
306717
Delivery item
80459613 000010
Order item
349801 000010
Total Quantity Item
17.000 KG

Material:
Pharmatose 200M
Monohydrate Lactose USP/NF,Ph.Eur.,JP
In multi layer paper bag with a poly-
ethylene innerbag contents 25 kg net. [NZ]
Manufacturing site : Fonterra Limited, Kaponga, New Zealand
Product name : Pharmatose 200M
Conforms to USP/NF, Ph.Eur.,JP, Lactose monohydrate monograph, current at time of manufacture.
Product description: A white or almost white, crystalline powder freely but slowly soluble in water, practically insoluble in ethanol
Residual solvents
(CPMP/ICH/283/95) : No class 1,2,3 solvents are used during production
Identification : Complies with Pharmacopoeia when tested

Manuf.batch no. : BU240028 **Manuf.date :** 2010.09.24 **Quantity:** 17.000 KG
Supplier lot no.: BU240028 **Expiry date:** 2013.09.22

Characteristic	SPECIFICATION Unit	Lower Limit	Upper Limit	Value
Water (KF)	%	4,5	5,5	5,2
Loss on drying	%		0,5	0,1
Specific rotation 20 °C anhydr	NON	54,4	55,9	55,3
Residue on ignition/Sulph.Ash	%		0,10	< 0,10
Absorb.1% , 1cm at 270-300 nm	NON		0,07	0,01
Absorb.1% , 1cm at 210-220 nm	NON		0,25	0,03
Absorb.10% , 1cm at 400 nm	NON		0,04	0,00
Appearance of Solution (Ph.Eur Clear and not more coloured than ref.BY7			Passes test	Passes test
Clarity and Colour of Solution Clear and colourless			Passes test	Passes test

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DMV-Fonterra Excipients
The ingredients of success

Certificate of analysis

Issue date
2011.02.28
Purchase order
306717
Delivery item
80459613 000010
Order item
349801 000010
Total Quantity Item
17.000 KG

Manuf.batch no. : BU240028 **Manuf.date :** 2010.09.24 **Quantity:** 17.000 KG
Supplier lot no.: BU240028 **Expiry date:** 2013.09.22

Characteristic	SPECIFICATION Unit	Lower Limit	Upper Limit	Value
or nearly colourless				
Acidity (ml 0.1N NaOH/6 g)	ml/6g		0,4	0,2
Heavy metals(max. 5 ppm)			Passes test	Passes test
Particle size (PSD) % <75 µm	%	78	86	85
Particle size (PSD) % <180 µm	%	98		100
Total aerobic microbial count	cfu/g		100	10
Yeasts and moulds	cfu/g		10	10
E.coli in 10 g			negative	negative
Salmonella in 100 g			negative	negative

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Document State: Effective
Effective Date: 10 Aug 2010 08:54:51 GMT +02:00
Document Number: GNF_SF_MBL_0622 **Version: 2.0**
Title: Microbiological Investigation Record: Total Viable Aerobic Count &' Pathogens

Date	Laboratory Number	MB
20 APR 2011	4501	126330
Item nr	**Amend nr**	**Batch nr**
103310	4432	B018216
Product		**Pack Number**
Lactose Monohydrate (Unit 2)		N/A

Test	Growth on Plates	Test Results	Limits
Bacterial	<10 cfu/g	-ve	NMT 100 cfu/g
Yeasts & Moulds	<10 cfu/g	-ve	NMT 100 cfu/g
E. Coli	Absent	-ve	Absent
Salmonella			
Pseudomonas aeruginosa		N/A	
Staphylococcus aureus			

Effective

Microbiologist's Signature: _____ Date: 28 APR 2011

Reviewed by: _____ Date: 28 APR 2011

Material released	Material rejected
Signature: _____	Signature: N/A
Date: 28 APR 2011	Date: _____

Lactose Monohydrate B021515

Document State: Effective
Effective Date: 15 Dec 2010 09:14:55 GMT +02:00
Document Number: _0260 **Version: 5.0**
Title: Lactose Monohydrate

Item Name	Lactose Monohydrate		
Item Number	103310	Specification Amendment Number	4432

To be completed by Quality Assurance			
Batch Number	B021515	Number of samples	Id-80 Comp-1 Bulk-1

To be completed by Quality Control			
Specification amendment no.	4432	Analysis start date	29 NOV 2011
Workbook reference	RM 17 pg 92., AR277 pg 062-065P	Analysis end date	15 Dec 2011

*	Test	Specification	Result	Analyst name & initials
*	**CHARACTERS** Appearance	A white or almost white, crystalline powder.	complies	Thobela, T.M
	Solubility	Freely but slowly soluble in water, practically insoluble in ethanol 96 %.	complies	Thobela, T.M
*	**Identification**	First identification: A, D. Second identification: B, C, D.		Althea, PJS
		A. Infrared spectrophotometry.	complies	
		B. Thin layer chromatography	N/A	N/A
		C. A red colour develops.	N/A	N/A
		D. Complies with the test for water.	complies	Thobela, T.M
		E. Near Infrared spectrophotometry (Alternative In-house)	N/A	N/A
*	**Appearance of solution**	The solution is clear and not more intensely coloured than reference solution BY_7.	complies	Thobela, T.M
	Acidity or Alkalinity	Not more than 0.4 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink or red.	0.2 ml	COA
	Specific optical rotation	+ 54.4° to + 55.9°.	+55.4°	COA
	Absorbance Test solution (a): at 400nm	Not more than 0.04.	0.00	COA
	Test solution (b): at 210 - 220 nm	Not more than 0.25.	0.04	COA
	Test solution (c): at 270 - 300 nm	Not more than 0.07	0.01	COA
	Heavy metals	Not more than 5 ppm.	<5ppm	COA
*	**Water**	4.5 % to 5.5 %.	4.5%	Thobela, T.M
	Sulphated ash	Not more than 0.1 %.	<0.10%	COA
*	**Microbial limits** TAMC	Not more than 10^2CFU/g.	<10 cfu/g	Mariske, MS
	Escherichia coli (per gram)	Absent.	Absent	Mariske, MS
	Residual Solvents (Supplier)	No class 1,2 or 3 solvents used during production of material. (Vendor Certificate Of Compliance required)	complies	COA
*	**Particle Size**	78 - 86 % is less than 75 µm	<75µm	Thobela, T.M
	(In-house)	98 % is less than 180 µm	160µm	Thobela, T.M
*	**Bulk Density** (In house)	0.707 to 0.879 g/ml	0.936g/ml	Thobela, T.M

- Quality Assurance to identify with * the tests to be performed.
- Tests marked with * to be performed by the Quality Control Laboratory.
- Tests not marked with * may be taken from the Certificate of Analysis.
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Effective Date: 15 Dec 2010 09:14:55 GMT +02:00
Document Number: 0260 Version: 5.0
Title: 103310 - Lactose Monohydrate

Item Name	**Lactose Monohydrate**		
Item Number	103310	**Specification Amendment Number**	4432

To be completed by Quality Assurance			
Batch Number	B021515	**Number of samples**	1a-8 comp-1 Bulk-1

To be completed by Quality Control			
COA attached	✓	**COA checked by**	

I declare that all samples have been tested and results checked. Comments

	Name	**Signature**	**Date**
QC Department check 1	T. Mhlanga		15 Dec 2011
QC Department check 2	S P MTAMA		19 DEC 2011

Remarks/Comments

Quality Control Laboratory
APPROVED BY
QC Laboratory Manager
Sign Date 19 Dec 2011

To be completed by Quality Assurance					
Special labeling instructions	Moisture: 4.5%	**Expiry/ Retest date**	06 Mar 2014	**Approved/ Rejected**	Approved

	Name	**Signature**	**Date**
1st Stage Unblocking by QA Department	JOY SWAPE		19 Dec 2011

Status APPROVED

Description: Lactose Monohydrate Cryst Pdr EP 6th Edi
Item Number: 103310 Date: 19-DEC-2011
Lot Number: B021515 Expiry Date: 6-MAR-2014
Label No: 0 Potency: No Potency
Instructions: Moisture: 4.5%

1X620 labels printed.

	Name	**Signature**	**Date**
Labels attached by QA Department	Whitney		20 Dec 2011
2nd Stage Unblocking by QA Department	JOY SWAPE		19 Dec 2011

Additional labeling (for subsequent quarantine or reject purposes)

Reason				**Reason**			
QA signature		**Date**		**QA signature**		**Date**	
Quarantine label				**Reject label**			
Labels attached by QA Department	**Signature**	**Date**		**Labels attached by QA Department**	**Signature**	**Date**	

308890

DMV-Fonterra Excipients
The ingredients of success

Certificate of analysis

Issue date
2011.08.02
Purchase order
308890
Delivery item
80471864 000010
Order item
358600 000010
Total Quantity Item
17.000 KG

Material:
Pharmatose 200M
Monohydrate Lactose USP/NF,Ph.Eur.,JP
In multi layer paper bag with a poly-
ethylene innerbag contents 25 kg net. [NZ]
Manufacturing site : Fonterra Limited, Kaponga, New Zealand
Product name : Pharmatose 200M
Conforms to USP/NF, Ph.Eur.,JP, Lactose monohydrate monograph, current at time of manufacture.
Product description: A white or almost white, crystalline powder freely but slowly soluble in water, practically insoluble in ethanol
Residual solvents
(CPMP/ICH/283/95) : No class 1,2,3 solvents are used during production
Identification : Complies with Pharmacopoeia when tested

Manuf.batch no. : 08.03.2011 **Manuf.date :** 2011.03.08 **Quantity:** 17.000 KG
Supplier lot no.: HV080028 **Expiry date:** 2014.03.06

Characteristic	SPECIFICATION Unit	Lower Limit	Upper Limit	Value
Water (KF)	%	4,5	5,5	5,1
Loss on drying	%		0,5	0,1
Specific rotation 20 °C anhydr	NON	54,4	55,9	55,4
Residue on ignition/Sulph.Ash	%		0,10	< 0,10
Absorb.1% , 1cm at 270-300 nm	NON		0,07	0,01
Absorb.1% , 1cm at 210-220 nm	NON		0,25	0,04
Absorb.10% , 1cm at 400 nm	NON		0,04	0,00
Appearance of Solution (Ph.Eur Clear and not more coloured than ref.BY7			Passes test	Passes test
Clarity and Colour of Solution Clear and colourless			Passes test	Passes test

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DMV-Fonterra Excipients
The ingredients of success

Certificate of analysis

Issue date
2011.08.02
Purchase order
308890
Delivery item
80471864 000010
Order item
358600 000010
Total Quantity Item
17.000 KG

Manuf.batch no. : 08.03.2011 **Manuf.date :** 2011.03.08 **Quantity:** 17.000 KG
Supplier lot no.: HV080028 **Expiry date:** 2014.03.06

Characteristic	SPECIFICATION Unit	Lower Limit	Upper Limit	Value
or nearly colourless				
Acidity (ml 0.1N NaOH/6 g)	ml/6g		0,4	0,2
Heavy metals(max. 5 ppm)			Passes test	Passes test
Particle size (PSD) % <75 µm	%	78	86	79
Particle size (PSD) % <180 µm	%	98		98
Total aerobic microbial count	cfu/g		100	10
Yeasts and moulds	cfu/g		10	10
E.coli in 10 g			negative	negative
Salmonella in 100 g			negative	negative

(This is an electronic document valid without signature)

Enalapril Maleate X111972/B011429

Document State: Effective
Effective Date: 13 Nov 2009 09:33:56 GMT +02:00
Document Number: 0259 **Version: 4.0**
Title: 134700 - Enalapril Maleate

Item Name	Enalapril Maleate		
Item Number	134700	Specification Amendment Number	4290

To be completed by Quality Assurance			
Batch Number	B011429	Number of samples	ID. 14 Comp. 2

To be completed by Quality Control			
Specification amendment no.	4290	Analysis start date	20 Jan 2010
Workbook reference	AE39 pg 035	Analysis end date	22 Jan 2010

*	Test	Specification K28 pg 184	Result Ref: B006107	Analyst name & initials
*	*DESCRIPTION	A white to off-white, crystalline powder. Melts at about 144 °C.	146 °C Complies.	Ndileka, NB
*	SOLUBILITY	Practically insoluble in nonpolar organic solvents; slightly soluble in semipolar organic solvents; sparingly soluble in water; soluble in alcohol; freely soluble in methanol and in dimethylformamide.	Complies	Ndileka, NB
*	**IDENTIFICATION	A. Infrared absorption The IR absorption spectrum of the sample, finely ground and dispersed in mineral oil, exhibits maxima only at the same wavelength as that observed for the USP enalapril maleate reference standard.	Complies	Ndileka, NB
		B. The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.	Complies	CoA
		C. Near Infrared Spectrophotometry (*Alternative In-house*)	N/A	N/A
	SPECIFIC ROTATION	-41.0° to -43.5°.	- 41.9 °	CoA
*	LOSS ON DRYING	It loses not more than 1.0 % of its weight.	0.1 %	Tobisa, TB
*	PARTICLE SIZE (In-house control)	90 % less than 30 µm.	20 µm	Ndileka, NB
	RESIDUE ON IGNITION	Not more than 0.2 %.	0.1 %	CoA
	HEAVY METALS	Not more than 0.001 %.	< 0.001 %	CoA
	RESIDUAL SOLVENTS (Supplier) Acetonitrile	Not more than 410 ppm.	Not detected	CoA
	Ethanol	Not more than 5000 ppm.	0.007 %	CoA

Document State: Effective
Effective Date: 13 Nov 2009 09:33:56 GMT +02:00
Document Number: 0259 Version: 4.0
Title: 134700 - Enalapril Maleate

Item Name	**Enalapril Maleate**		
Item Number	134700	**Specification Amendment Number**	4290

To be completed by Quality Assurance			
Batch Number	B011429	**Number of samples**	10 + 4 comp. 2

*	Test	Specification	Result	Analyst name & initials
	RELATED COMPOUNDS Any impurity (having a relative retention time of about 1.10)	Not more than 1.0 %.	Not detected	CoA
	Any other individual impurity	Not more than 0.3 %.	Not detected	CoA
	Total impurities	Not more than 2 %.	0.28 %	CoA
*	**ASSAY** % m/m Enalapril Maleate	98.0 - 102.0 % m/m, calculated on the dried basis.	1 - 100.0 % 2 - 100.2 % $\bar{x}$ - 100.1 %	Tobisa, TB

- Quality Assurance to identify with * the tests to be performed.
- Tests marked with * to be performed by the Quality Control Laboratory.
- Tests not marked with * may be taken from the Certificate of Analysis.
- Any test not included on the Certificate of Analysis will be performed by the Quality Control Laboratory.

Document State: Effective
Effective Date: 13 Nov 2009 09:33:56 GMT +02:00
Document Number: 0259 Version: 4.0
Title: 134700 - Enalapril Maleate

Item Name	**Enalapril Maleate**		
Item Number	134700	**Specification Amendment Number**	4290

To be completed by Quality Assurance			
Batch Number	B011429	**Number of samples**	10 14 - Comp 2.

To be completed by Quality Control					
COA attached	✓	**COA checked by**			
I declare that all samples have been tested and results checked. Comments					
	Name	**Signature**	**Date**		
QC Department check 1	Tobise		29 Jan 10		
	Name	**Signature**	**Date**		
QC Department check 2	Delray		22 Jan 2010		
Remarks/Comments	Quality Control Laboratory APPROVED BY QC Laboratory Manager Sign Date 22-Jan-2010				
To be completed by Quality Assurance					
Special labeling instructions	LOD 0.1%	**Expiry/ Retest date**	29 2013	**Approved/ Rejected**	Approved
1st Stage Unblocking by QA Department	**Name** C. Fourie	**Signature**		**Date**	25 Jan 2010
Status label	442: APPROVED Description: Enalapril Maleate Item Number: 134700 Date: 25-JAN-2010 Lot Number: B011429 Expiry Date: 1 AUG-2013 Label No: 0 Potency: 100.1% Instructions: LOD 0.1%				14 labels. 25 Jan 2010
Labels attached by QA Department	**Name** Clevedon	**Signature** CM	**Date** 26 Jan 10		
2nd Stage Unblocking by QA Department	**Name** C. Fourie	**Signature**	**Date** 25 Jan 2010		
Additional labeling (for subsequent quarantine or reject purposes)					
Reason		**Reason**			
QA signature	**Date**	**QA signature**	**Date**		
Quarantine label		**Reject label**			
Labels attached by QA Department	**Signature** / **Date**	**Labels attached by QA Department**	**Signature** / **Date**		

浙江华海药业股份有限公司
HUAHAI ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

中国 浙江 临海市汛桥
XUNQIAO,LINHAI
ZHEJIANG 317024,CHINA
Tel:+86(576)85010288
Fax:+86(576)85091062
Email:sales@huahaipharm.com
http://www.huahaipharm.com

CERTIFICATE OF ANALYSIS

PRODUCT: ENALAPRIL MALEATE USP32	
Batch No.: 5111-09-046(M)	Manufacture date: 2009.09.22
Batch size: 200kg	Retest date: 2013.08
Quantity: 200kg	Report date: 2009.11.10
Manufacture site: XUNQIAO, LINHAI, ZHEJIANG 317024, CHINA	Storage: Preserve in well-closed containers

TEST ITEM	SPECIFICATION	TEST RESULTS
Appearance	White or off-white crystalline powder	White crystalline powder
Identification	A: The infrared absorption spectrum is concordant with Enalapril Maleate RS.	Conforms
	B: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that of the Standard preparation obtained as directed in the Assay.	Conforms
Specific rotation	-41.0° ~ -43.5°	-41.9°
Loss on drying	Not more than 1.0%	0.1%
Residue on ignition	Not more than 0.2%	0.1%
Heavy metals	Not more than 0.001%	<0.001%
Related substances		
[1]Impurity B	Not more than 0.3%	N.D
[2]Impurity C	Not more than 0.3%	0.12%
[3]Impurity D	Not more than 0.3%	0.05%
[4]Impurity H	Not more than 0.3%	0.11%
Any unknown impurity	Not more than 0.1%	N.D
Total unknown impurities	Not more than 0.3%	N.D
Total impurities	Not more than 1.0%	0.28%
Assay (HPLC)	Not less than 98.0% and not more than 102.0%, calculated on the dried basis	99.8%
Residual solvents (GC)		
Methanol	Not more than 0.3%	N.D
Ethanol	Not more than 0.5%	0.007%
Acetonitrile	Not more than 0.041%	N.D
Benzene	Not more than 0.0002%	N.D
Dichloromethane	Not more than 0.06%	N.D
Particle Size	90% < 30um	10um
Conclusion	Complies with USP32	

Signature: Zhu Yan (QC MANAGER) Date: NOV. 27. 2009

Signature: (QA MANAGER) Date: Nov. 27. 2009

1 Impurity B: (2S)-2-[[(1S)-1-(ethoxycarbonyl)-3-phenylpropyl]amino]propanoic acid
2 Impurity C: (2S)-1-[(2S)-2-[[(1S)-1-carboxy-3-phenylpropyl]amino]propanoyl]pyrrolidine-2-carboxylic acid
3 Impurity D:ethyl (2S)-2-[(3S),8aS]-3-methyl-1,4-dioxo-octahydropyrrolo[1,2-a]pyrazin-2-yl]-4-phenylbulanoate
4 Impurity H: (2S)-1-[(2S)-2-[[(1S)-3-cyclohexyl-1-(ethoxycarbonyl)propyl]amino]propanoyl]pyrrolidine-2-carboxylic acid

Enalapril Maleate B022065

Document State: Effective
Effective Date: 14 Nov 2011 08:11:39 GMT +02:00
Document Number: _0259 **Version: 5.0**
Title: 134700 - Enalapril Maleate

Item Name	**Enalapril Maleate**		
Item Number	134700	**Specification Amendment Number**	4290

To be completed by Quality Control:			
Batch Number	B022065	**Number of samples**	Ext-20 Comp-1 Retain-1

To be completed by Quality Control				
Specification amendment no.	4290		**Analysis start date**	05 DEC 2011
Workbook reference	A1263 pg 137-L ; A1255 pg 188-V		**Analysis end date**	08 Dec 2011
* **Test**	**Specification** A1213 - 057 M		**Result** (Ref X-ray Ext)	**Analyst name & initials**
* ***DESCRIPTION AND SOLUBILITY**	A white to off-white, crystalline powder. Melts at about 144 °C. Practically insoluble in nonpolar organic solvents; slightly soluble in semipolar organic solvents; sparingly soluble in water; soluble in alcohol; freely soluble in methanol and in dimethylformamide.		Complies 142°C Complies	Zikhona, ZT
* ****IDENTIFICATION**	A. Infrared absorption The IR absorption spectrum of the sample, finely ground and dispersed in mineral oil, exhibits maxima only at the same wavelength as that observed for the USP enalapril maleate reference standard.		A) Complies	Xolani, XR
	B. The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.		B) Complies	Naqilah, NS
	C. Near Infrared Spectrophotometry *(Alternative In-house)*		N/A	N/A.
SPECIFIC ROTATION	-41.0° to -43.5°		-42.0°	COA.
* **LOSS ON DRYING**	It loses not more than 1.0 % of its weight.		0.00%.	Naqilah, NS.
* **PARTICLE SIZE** (In-house control)	90 % less than 30 µm.		20.um	Zikhona, ZT.
RESIDUE ON IGNITION	Not more than 0.2 %.		0.1%.	COA.
HEAVY METALS	Not more than 0.001 %.		< 0.001%.	COA.
RESIDUAL SOLVENTS (Supplier) Acetonitrile	Not more than 410 ppm.		ND	COA
Ethanol	Not more than 5000 ppm.		1ppm	COA

Document State: Effective
Effective Date: 14 Nov 2011 08:11:39 GMT +02:00
Document Number: _0259 **Version: 5.0**
Title: 134700 - Enalapril Maleate

Item Name	**Enalapril Maleate**		
Item Number	134700	**Specification Amendment Number**	4290

To be completed by Quality Control:			
Batch Number	B022C65	**Number of samples**	Id-20 Comp-1 Ind-1

*	Test	Specification	Result	Analyst name & initials
	RELATED COMPOUNDS Any impurity (having a relative retention time of about 1.10)	Not more than 1.0 %.	<1.0%.	COA
	Any other individual impurity	Not more than 0.3 %.	ND.	COA
	Total impurities	Not more than 2 %.	0.3%.	COA.
*	**ASSAY** % m/m Enalapril Maleate	98.0 - 102.0 % m/m, calculated on the dried basis.	1. 100.6% 2. 100.5% $\bar{x}$. 100.6%.	Nailah/NS

- Quality Control to identify with * the tests to be performed.
- Tests marked with * to be performed by the Quality Control Laboratory.
- Tests not marked with * may be taken from the Certificate of Analysis.
- Any test not included on the Certificate of Analysis will be performed by the Quality Control Laboratory.

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Item Name	**Enalapril Maleate**		
Item Number	134700	**Specification Amendment Number**	4290

To be completed by Quality Control:			
Batch Number	B022065	**Number of samples**	Id - 20 Comp - 1 Duplic - 1

To be completed by Quality Control			
COA attached	✓	**COA checked by**	

I declare that all samples have been tested and results checked. Comments

	Name	**Signature**	**Date**
QC Department check 1	Naailah Searle	N.S (pp)	08 Dec 2011
QC Department check 2	Delay		09 Dec 2011

Remarks/Comments

Quality Control Laboratory
APPROVED BY
QC Laboratory Manager
Sign: Date: 09/12/2011

To be completed by Quality Assurance					
Special labeling instructions	LOD: 0.00%	**Expiry/ Retest date**	July 2015	**Approved/ Rejected**	Approved
1st Stage Unblocking by QA Department	**Name** Joy Swartz	**Signature**		**Date**	12 Dec 2011

Status label

442: APPROVED
Description: Enalapril Maleate
Item Number: 134700 Date: 12-DEC-2011
Lot Number: B022065 Expiry Date: 1-JUL-2015
Label No: 0 Potency: 100.6%
Instructions: LOD 0.00%

12 Dec 2011

1 x 20 labels printed.

Labels attached by QA Department	**Name** N. Viney	**Signature**	**Date** 12 DEC 2011
2nd Stage Unblocking by QA Department	**Name** Joy Swartz	**Signature**	**Date** 12 Dec 2011

Additional labeling (for subsequent quarantine or reject purposes)

Reason			**Reason**		
QA signature		**Date**	**QA signature**		**Date**
Quarantine label			**Reject label**		
Labels attached by QA Department	**Signature**	**Date**	**Labels attached by QA Department**	**Signature**	**Date**

浙江华海药业股份有限公司
HUAHAI ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.
中国 浙江 临海. 汛桥
XUNQIAO,LINHAI
ZHEJIANG 317024,CHINA.
Tel:+86(576)85010288
Fax:+86(576)85991062
Email:sales@huahaipharm.com
http://www.huahaipharm.com

CERTIFICATE OF ANALYSIS

PRODUCT: ENALAPRIL MALEATE USP34	
Batch No.: 5111-11-036M	Manufacture date: 2011.08.01
Batch size: 300kg	Retest date: 2015.07
Quantity:300kg	Report date: 2011.08.24
Manufacture site: XUNQIAO, LINHAI, ZHEJIANG 317024, CHINA	Storage: Preserve in well-closed containers

TEST ITEM	SPECIFICATION	TEST RESULTS
Appearance	White or off-white crystalline powder	White crystalline powder
Identification	A: The infrared absorption spectrum is concordant with Enalapril Maleate RS.	Conforms
	B: The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that of the Standard preparation obtained as directed in the Assay.	Conforms
Specific rotation	-41.0° ~ -43.5°	-42.0°
Loss on drying	Not more than 1.0%	0.1%
Residue on ignition	Not more than 0.2%	0.1%
Heavy metals	Not more than 0.001%	<0.001%
Related substances [1]Impurity B [2]Impurity C [3]Impurity D [4]Impurity H Any unknown impurity Total unknown impurities Total impurities	 Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.3% Not more than 0.1% Not more than 0.3% Not more than 1.0%	 N.D 0.20% 0.04% 0.13% N.D N.D 0.37%
Assay (HPLC)	Not less than 98.0% and not more than 102.0%, calculated on the dried basis	99.5%
Residual solvents (GC) Methanol Ethanol Acetonitrile Benzene Dichloromethane	 Not more than 0.3% Not more than 0.5% Not more than 0.041% Not more than 0.0002% Not more than 0.06%	 N.D 0.001% N.D N.D N.D
Particle Size	90% < 30um	12um
Conclusion	Complies with USP34	

Signature: _____ (QC MANAGER) Date: Aug. 30. 2011

Signature: _____ (QA MANAGER) Date: Aug. 29. 2011

1 Impurity B: (2S)-2-[[(1S)-1-(ethoxycarbonyl)-3-phenylpropyl]amino]propanoic acid
2 Impurity C: (2S)-1-[(2S)-2-[[(1S)-1-carboxy-3-phenylpropyl]amino]propanoyl]pyrrolidine-2-carboxylic acid
3 Impurity D:ethyl (2S)-2-[(3S),6aS]-3-methyl-1,4-dioxo-octahydropyrrolo[1,2-a]pyrazin-2-yl]-4-phenylbutanoate
4 Impurity H: (2S)-1-[(2S)-2-[[(1S)-3-cyclohexyl-1-(ethoxycarbonyl)propyl]amino]propanoyl]pyrrolidine-2-carboxylic acid