Issued on 30/04/2013

Hetero Drugs Limited

S.No.s, 213, 214 & 255, Bonthapally Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA.
Phone: +91-8458-275314/275777, Fax: +91-8458-275271

HETERO DRUGS LIMITED QA RELEASED QUALITY ASSURANCE 30/04/2013

CERTIFICATE OF ANALYSIS

Product	: Amlodipine Besilate	Reference STP No.	: AB-002-15
Batch No.	: AB0220413	Reference	: Ph.Eur.
Date of Manufacture	: April - 2013	Batch Quantity	: 308.97 Kg
Analytical Report No.	: AB048/13	Date of Analysis	: 30/04/2013
		Retest date	: March - 2018
		Status	: Initial certification

S.No.	Test	Specifications	Results	Reference
1	Appearance	White or almost white powder	Almost white powder	Visual Inspection
2	Solubility	Slightly soluble in water and freely soluble in methanol,sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol.	Complies	Visual Inspection
3	Identification by	a) IR: The Infra Red absorption spectrum of the finely ground sample in mineral oil (liquid paraffin) dispersion should exhibit maxima only at the same wave numbers as that of a similar preparation of Amlodipine Besilate working standard.	Matches with the standard spectrum	Ph.Eur. < 2.2.24 >
		b) HPLC: The retention time of the major peak in the Chromatogram of the standard solution-1 corresponds to that of the Assay preparation-1 obtained as directed in the Assay on anhydrous basis by HPLC.	Matches with the standard	Ph.Eur. < 2.2.29 >
4	Optical rotation	Should be between (-) 0.10° and (+) 0.10°	(+) 0.004°	Ph.Eur. < 2.2.7 >
5	Related Substances by HPLC	3-ethyl 5-methyl (4RS)-4-(2-chlorophenyl)-2-[[2-(1,3-dioxo-1,3-dihydro-2H-Isoindol-2-yl)ethoxy]methyl]-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate (Impurity-A) : Not more than 0.10 %	Below LOQ (LOQ=0.003%)	Ph.Eur. < 2.2.29 >
		3-ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methylpyridine-3,5-dicarboxylate (Impurity-D) : Not more than 0.20 %	Below LOQ (LOQ=0.009%)	
		diethyl (4RS)-2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate (Impurity-E): Not more than 0.15%	Not detected	
		dimethyl (4RS)-2-{(2-aminoethoxy)methyl}-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate (Impurity-F) : Not more than 0.15 %	Not detected	
		Maximum single unknown impurity : Not more than 0.10 %	Not detected	
		Total impurities : Not more than 0.50%	Not detected	
6	Water by KF	Not more than 0.5 % w/w	0.07 % w/w	Ph.Eur. < 2.5.12 >

Compiled by: Date: 30/04/2013

Checked by: Date: 30/04/2013

Authorised signatory: Date: 30/04/2013

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S.No.	Test	Specifications	Results	Reference
* 7	Loss on drying	Not more than 0.5 % w/w	0.26 % w/w	Ph.Eur. < 2.2.32 > In-House
8	Sulfated ash	Not more than 0.2 % w/w	0.09 % w/w	Ph.Eur. < 2.4.14 >
*9	Heavy metals	Not more than 0.002 % w/w	Less than 0.002%w/w	Ph.Eur. < 2.4.8 > Method C In-House
10	Assay on anhydrous basis by HPLC	Not less than 97.0% and not more than 102.0% w/w	99.6 % w/w	Ph.Eur. < 2.2.29 >
* 11	Content of Methyl benzene sulphonate by HPLC	Not more than 80 ppm	Below LOQ (LOQ=80ppm)	Ph.Eur. < 2.2.29 > In-House
* 12	Residual solvents by GC**	Methanol : Not more than 300 ppm	Below LOQ (LOQ=75ppm)	Ph.Eur. < 2.2.28 > In-House
		Methylene chloride : Not more than 300 ppm	Below LOQ (LOQ=138ppm)	
		Ethyl acetate : Not more than 500 ppm	Below LOQ (LOQ=75ppm)	
* 13	Particle size analysis	10% of the particle should be less than 10 µm	3.1 µm	Ph.Eur. < 2.9.31 >
		50% of the particle should be less than 25 µm	11.8 µm	
		90% of the particle should be less than 100 µm	37.6 µm	
*14	Besilate ion content by titration	Should be between 27.0 % w/w and 28.5 % w/w	27.9 % w/w	Ph.Eur. < 2.2.20 > In-House

* In-House specifications

** No potential for the class-1 solvents as specified by ICH to be present in Amlodipine besilate, as they are not used in the manufacturing process. The material if tested for these solvents, will comply with the established standards.

The Product **conforms** to the above specifications

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