

CERTIFICATE OF ANALYSIS

Ademetionine disulfate tosylate (SAME)

Batch No.: DR20150212	Piece: 262.1kg
Manufacture Date: 2015.02.12	Expiry Date: 2017.02.11

TESTS:

Items	Specification	Results
Appearance	White or off-white powder	White powder
Identification by HPLC	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of ademetionine in the system suitability solution as obtained in the assay	Conforms
Identification by IR	Consistent with the spectrum obtained with the reference standard	Conforms
Water(K.F.)	≤3.0%	1.02%
Solubility	Soluble in water	Conforms
TSFA by HPLC	21.7-23.5%	22.6%
Content of sulfate by IC	23.5-26.5%	25.6%
SAME ion Assay by HPLC	50%-53%	50.7%
Assay BY HPLC	≥95%	98.9%
Isomeric ratio by HPLC	S,S-isomer≥60%	83.1%
PH	1.0-2.0	1.27
Related compounds by HPLC	Adenine≤0.7% Methylthioadenosin≤0.7% Adenosine ≤0.5% S-adenosyl-homocysteine ≤0.7%	0.37% 0.20% 0.02% 0.16%
Residue on ignition	≤0.5%	0.17%
Heavy metals	≤20ppm	<10ppm
Packaging and storage: Preserve in light, light-resistant containers, and store in a refrigerator		
Conclusion: The results conform with Enterprise standard.		



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