



四川青益纯医药科技有限公司  
SICHUAN BENEPURE PHARMACEUTICAL CO., LTD.

Tel: +86 28 8679 9990  
Email: [info@benepure.com](mailto:info@benepure.com)

Fax: +86 28 8679 9924  
Website: [www.benepure.com](http://www.benepure.com)

## CERTIFICATE OF ANALYSIS

<b>Product Name</b>	Mildronate Dihydrate	<b>CAS No.</b>	76144-81-5
<b>Batch No.</b>	P010561417A	<b>Mfg. Date</b>	May 09, 2017
<b>Quantity</b>	500kg	<b>Retest Date</b>	May 08, 2019
<b>Packing</b>	25kg/Drum	<b>Report Date</b>	May 18, 2017
<b>Specification</b>	Oral Grade		

ITEM	SPECIFICATION	RESULT
<b>Appearance</b>	White or almost white crystalline powder	Complies
<b>Identification</b>	A) Should be positive respond B) IR: Conforms to the reference standard	Complies
<b>Solubility</b>	Freely soluble in water, soluble in 95% Ethanol	Complies
<b>pH</b>	7.0~9.0	7.76
<b>Clarity</b>	Should be clear and colorless	Complies
<b>Color</b>	Should be lighter than the standard solution	Complies
<b>Water</b>	19.0%~21.0%	19.67%
<b>Chlorides</b>	≤0.01%	Complies
<b>Sulfates</b>	≤0.05%	Complies
<b>Sulfated Ash</b>	≤0.1%	Complies
<b>Heavy Metals</b>	≤10ppm	Complies
<b>Assay(Titration)</b>	99.0%~101.0%	99.92%
<b>Related Substances</b>		
Total Impurities	≤1.0%	0.15%
<b>Residual Solvents</b>		
Methanol	≤3000ppm	Complies
Ethanol	≤5000ppm	Complies
<b>Conclusion</b>	The product conforms to the specification.	
<b>Remarks</b>	N/A	

Analyst:

QC Manager:

QA: