



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

Fax: +86 28 8679 9924  
Website: www.benepure.com

## CERTIFICATE OF ANALYSIS

|                      |                         |                    |               |
|----------------------|-------------------------|--------------------|---------------|
| <b>Product Name</b>  | Donepezil Hydrochloride | <b>CAS No.</b>     | 120011-70-3   |
| <b>Batch No.</b>     | P010860117A             | <b>Mfg. Date</b>   | Aug. 10, 2017 |
| <b>Quantity</b>      | 200kg                   | <b>Retest Date</b> | Aug. 09, 2019 |
| <b>Packing</b>       | 25kg/Drum               | <b>Report Date</b> | Aug. 20, 2017 |
| <b>Specification</b> | USP37                   |                    |               |

| ITEM                                | SPECIFICATION   | RESULT                   |
|-------------------------------------|---|--------------------------|
| <b>Appearance</b>                   | Off white to white crystalline powder   | White crystalline powder |
| <b>Solubility</b>                   | Freely soluble in chloroform, soluble in water and Acetic acid, slightly soluble in Acetonitrile and ethanol, insoluble in Ethylacetoacetate and n-hexane | Complies                 |
| <b>Identification</b>               | A. By IR absorption, to match with working standard   | Complies                 |
|                                     | B. The retention time of the major peak of the sample corresponds to that of the standard solution, as obtained in Assay                                  | Complies                 |
|                                     | C. Chloride, responds to the test for Chlorides   | Complies                 |
| <b>Assay(on Anhydrous basis)</b>    | 98.0%~102.0%  | 99.51%                   |
| <b>Heavy Metals</b>                 | ≤ 20ppm   | Complies                 |
| <b>Residue on Ignition</b>          | ≤ 0.1%  | 0.04%                    |
| <b>Organic Impurities</b>           |   |                          |
| Desbenzyl donepezila                | ≤0.15%  | Undetected               |
| Donepezil pyridine analogb          | ≤0.15%  | Undetected               |
| Donepezilzilbenzyl bromidec         | ≤0.15%  | Undetected               |
| Dehydrodeoxy donepezild             | ≤0.15%  | Undetected               |
| Deoxy donepezile                    | ≤0.15%  | Undetected               |
| Any Individual Unspecified impurity | ≤0.1%   | 0.03%                    |
| Total Impurities                    | ≤0.5%   | 0.08%                    |
| <b>Water</b>                        | ≤0.4%   | 0.16%                    |
| <b>Residual Solvents</b>            |   |                          |
| Methanol                            | ≤3000ppm  | Undetected               |
| Ethanol                             | ≤5000ppm  | Undetected               |
| Ethyl Acetate                       | ≤5000ppm  | Undetected               |
| Toluene                             | ≤890ppm   | Undetected               |
| Acetic acid                         | ≤5000ppm  | Undetected               |
| <b>Conclusion</b>                   | The product conforms to USP37.  |                          |
| <b>Remarks</b>                      | N/A   |                          |

Analyst:

QC Manager:

QA: