

CERTIFICATE OF ANALYSIS

MANUFACTURER: QIANJIANG YONGAN PHARMACEUTICAL CO., LTD
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Name of product: TAURINE WITH 0.5% ANTI-CAKING AGENT	CAS No.107-35-7	
Batch size: 16000kgs	Packing in 25KG carton	Batch No.: XK23063159
Manufacture date: Jun.24,2023	Expiry date: Jun.23,2026	Reported date: Jun.30,2023

Item of Inspection	Standard of JP17	Standard of USP42	Testing result	Testing Method of JP17	Testing Method of USP42
Characteristics:	A white crystalline powder, odorless		A white crystalline powder, odorless	Visual , Organoleptic	Visual , Organoleptic
1. Identification:	Positive	A. Infrared Absorption B. Retention Time	Positive Positive	Infrared spectrophotometry (JP17:General tests 2.25)	(USP42 chapter <197K>)
2. Clarity and color of solution:	Clear and colorless	-----	Pass test	Page 1643 (JP17 Monographs)	-----
3. Chloride:	Max 0.011%	Max 0.05%	<0.010%	Chloride limit test (JP17:General tests 1.03)	Chloride limit test (USP42 chapter <221>)
4. Sulfate:	Max 0.010%	Max 0.03%	<0.010%	Sulfate limit test (JP17:General tests 1.14)	Sulfate limit test (USP42 chapter <221>)
5. Ammonium:	Max 0.02%	-----	<0.015%	Ammonium limit test (JP17:General tests 1.02)	-----
6. Heavy metals:	NMT 10ppm	-----	<8ppm	Heavy metals limit test (JP17:General tests 1.07)	-----
7. Iron:	NMT 10ppm	NMT 30ppm	<10ppm	(JP17:General tests 1.10)	(USP42 chapter <241>)
8. PH:	4.1~5.6	-----	5.0	Page 1643 (JP17)	-----
9. Related substances:	0.2% Max	NMT0.5%	Meet to requirement	(JP17:General tests 2.03)	(USP42 chapter <621>)
10. Loss on drying:	0.20%(105°C, 2 hours)max	0.3%(105°C, 3hours)max	0.11%	Loss on drying test (JP17:General tests 2.41)	1g/105° C/3hrs (USP42 chapter <731>)
11. Residue on ignition:	0.1%max	0.3%max	0.09%	Residue on ignition test (JP17: General tests 2.44)	Residue on ignition test (USP42 chapter <281>)
12. Assay (dried):	99.0%~101.0%	98.0%~102.0%	99.4%	Titrimetry (JP17:General tests 2.50)	HPLC (USP42)
13. Total plate count:	NMT 1000/g	NMT 1000/g	<10/g	Microbial limit testing method (CP2015 :Addenda XI J)	
14. Mold:	NMT 100/g	NMT 100/g	<10/g		
15. Yeast:	NMT 100/g	NMT 100/g	<10/g		
16. E.Coli	Negative/10g	Negative/10g	Negative		

*Remark: Lead: <0.1 ppm(Testing methodGB/T5009.75-2003)

*Mercury <0.1ppm(Testing methodGB/T5009.75-2003)

* COLIFORMS: Negative *SALMONELLA: Negative/375/g

* tapped density: 0.92 g/ml *bulk density:0.65g/ml

*Cadmium <0.1ppm(Testing methodGB/T5009.75-2003)

*Arsenic: <0.5 ppm (Testing method:CP2015 Addenda VIII J)

*STAPHYLOCOCCUS AUREUS: Negative/25/g

*particle size:Not less than 90% pass 40 mesh

Remarks: * for the parameters tested by 3rd party on a periodical basis.

Conclusion: Comply with JP17/USP42--NF37

We hereby declare our product comply with GMP, ISO9001:2008,ISO22000.

We hereby certify our product is BSE/TSE free.

AUTHORIZOR:



CHECKER:



TESTER:

