

May 1st, 2021

## Specification Sheet

Product Name: L-GLUTATHIONE USP

  
**OPITAC**<sup>TM</sup>

Analysis Item	Specification	Test Method
<b>Descriptions</b>		
Appearance	It occurs as a white crystalline powder	JP
Odor and taste	Almost odorless and taste sour	JP
Solubility	It is freely soluble in water, and practically insoluble in ethanol (99.5%)	JP
<b>Identification</b>		
Ninhydrin test	Positive	JP
Lead acetate test	Positive	JP
Infrared Spectroscope	Corresponds	USP
Optical rotation	-15.5° ~ -17.5°, at 20°C	USP
Melting point	About 185°C	JP
ASSAY	98.0 % ~ 101.0 %	USP
<b>Impurities</b>		
Ammonium	Not more than 200 ppm	USP
Arsenic	Not more than 2 ppm	USP
Cadmium	Not more than 2 ppm	USP
Lead	Not more than 3 ppm	USP
Mercury	Not more than 1 ppm	USP
Chloride	Not more than 200 ppm	USP
Sulfate	Not more than 300 ppm	USP
Heavy metals	Not more than 10 ppm	USP
Iron	Not more than 10 ppm	USP
Residue on ignition	Not more than 0.1 %	USP
Organic impurities	Individual impurity: Not more than 1.5 % for the impurity with the relative retention time of about 4 Total impurities: Not more than 2.0 %	USP
<b>Specific tests</b>		
Clarity and color of solution	Clear and colorless	USP
Loss on drying	Not more than 0.5 %	USP
<b>Microbiological Analysis</b>		
Total Plate Count	Not more than 1000 cfu/g	USP
Yeast and Mold	Not more than 100 cfu/g	USP
S.aureus	Negative /10g	USP
E.coli	Negative /10g	USP
Salmonella	Negative /10g	USP

Expiry Date: 3 years

Storage: Store at room temperature without moisture

In conformity to USP-NF 2021