

CERTIFICATE OF ANALYSIS

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Product Name : L-SELENOMETHIONINE DCP CH
Product Code : 1912CH **SAP Code** : 120001143
Batch No. : C241126 **Date of Manufacture** : Jul 03rd - 2024
T R No. : 40000015317 **Date of Expiry** : Jul 02nd - 2029

CAS No	:	L-Selenomethionine: 3211-76-5		
Preparation type	:	Synthetic		
Starting Material	:	L- Methionine		
Molecular Formula	:	C5H11NO2Se		
Molecular Weight	:	196.1		
Chemical Name	:	2 amino-4-(methylseleno) butanoic acid		
Excipient used	:	Dicalcium phosphate		
Excipient Details		Name	%Used	CAS No.
		Dicalcium phosphate	More than 96%	7757-93-9
Parameter	Result	Limit	Reference	
Physical				
Description	Complies	White crystalline powder	Visual	
Odour	Complies	Characteristic odour	Ph. Eur. method 2.3.4; BP 2002, Vol II	
Identification	Complies	To comply by HPLC for L- Selenomethionine	USP	
Loss on drying	0.32 % w/w	Not more than 3.0% w/w (dried at 105°C)	USP <731>	
Tapped density	0.91 g/ml	Between 0.90g/ml and 1.50g/ml	USP <616>	
Bulk density	0.63 g/ml	Between 0.60g/ml and 1.20g/ml	USP <616>	
Sieve Test (Passes through)			USP <786>	
- 20 mesh	100.0 % w/w	Not less than 100% w/w		
- 40 mesh	99.85 % w/w	Not less than 95% w/w		
- 80 mesh	93.75 % w/w	Not less than 90% w/w		
Chemical				
Assay				
-Content of Dicalcium phosphate by Titration	98.99 % w/w	Not less than 96.0% w/w	USP	
-Content of L-Selenomethionine by HPLC	1.3 % w/w	Not less than 1.25% w/w and not more than 1.35% w/w	USP	
-Content of Selenium by ICP-OES	5052 mcg/g	Not less than 5000mcg/g and not more than 5500mcg/g	SLL/STP-S-013	
Elemental Contaminants (Heavy metals)				

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Lead	<0.2 ppm(µg/g)	Not more than 3ppm (µg/g)	USP <2232>
Arsenic	<0.2 ppm(µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Cadmium	<0.2 ppm(µg/g)	Not more than 1ppm (µg/g)	USP <2232>
Mercury	<0.02 ppm(µg/g)	Not more than 0.1ppm (µg/g)	USP <2232>

Others

Residual solvents	Complies	To comply as per USP	USP <467>
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Microbiological Profile

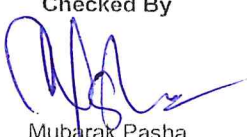
Total aerobic microbial count	<100 cfu/g	Not more than 1000cfu/g	USP <2021>
Total yeasts and molds count	<10 cfu/g	Not more than 100cfu/g	USP <2021>
Escherichia coli	Complies	Negative/10g	USP <2022>
Salmonella	Complies	Negative/10g	USP <2022>
Staphylococcus aureus	Complies	Negative/10g	USP <2022>
Pseudomonas aeruginosa	Complies	Negative/10g	USP <62>
Bile tolerant Gram negative bacteria	<10 cfu/g	Not more than 100cfu/g	USP <2021>
Coliforms	<10 cfu/g	Less than 10cfu/g	BAM Chapter 4

Additional Information

Sanitising treatment	Non-irradiated and not treated with ETO
Certification status (Kosher/Halal)	Kosher and Halal certified
BSE/TSE status	BSE / TSE free
Genetic Modification Status	Non-GMO
Country of origin	India
Storage Condition	Store at room temperature

Remarks : The product complies as per the specification No. FPS/ARD/639, Issue No. 5 Dated: 10.07.2024

Disclaimer: Suitability of this product for its particular use is at the sole discretion of the purchaser.

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Product Name : L-SELENOMETHIONINE DCP CH

Batch No. : C241126

Date:16-Jul-2024

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