CERTIFICATE OF ANALYSIS

No.3180

Product Name	D-Calcium pantothenate	**Manufacture Date**	Mar.28,2025
Batch No.	CA2503071	**Analysis Date**	Mar.31,2025
Lot Size	5000kg	**Expiry Date**	Mar.27,2028
Executive Standard	BP2024/USP2024	**Order No.**	——

Analysis Item	Unit	Specification		Test Method	Result	
		BP2024	USP2024		BP2024	USP2024
Appearance	——	A white or almost white, slightly hygroscopic powder.	Slightly hygroscopic, white powder. Is odorless and has a bitter taste	Eyeballing	White powder	White powder
Solubility	——	Freely soluble in water, slightly soluble in ethanol (96 per cent) and practically insoluble in heptane.	Freely soluble in water,soluble in glycerin,practically insoluble in alcohol,in chloroform ,and ether	Weight/volume method	Conform	Conform
Identification of Calcium*	——	The layer is chloroform and the chloroform layer is red	White precipitate, insoluble in glacial acetic acid, soluble in hydrochloric acid	Calcium identification	Conform	Conform
Identification of TLC*	——	Comply with the standard	——	TLC	Conform	——
Infrared Identification*	——	Conform to standard spectrum	Conform to standard spectrum	IR	Conform	Conform
Specific rotation	°	+25.5 to +27.5	+25.0 to +27.5	Polarimeter	+27.0	+27.0
Assay	%	98.0-101.0	——	Perchloric acid titration	100.5	——
	%	——	98.0-102.0	HPLC	——	100.2
pH（5% solution）	——	6.8-8.0	——	pH meter	7.2	——
Clarity and color of the solution	——	Clear colorless	——	Eyeballing	Clear colorless	——
Alkalinity	——	——	Conform	Development process	——	Conform
Loss on Drying	%	≤3.0	≤5.0	Drying method	2.1	2.1
Content of Calcium	%	——	8.2-8.6	EDTA titration	——	8.28
Chlorides	%	≤0.02	——	EDTA titration	<0.02	——
β-Alanine and other aminocarboxylic acid impurities	%	≤0.5	≤0.5	Titration	0.4	0.4
Pantoic acid	%	≤0.8	≤1.0	HPLC	0.4	0.4
Pantolactone	%	≤0.3	≤0.5	HPLC	0.2	0.2
B-Alanyl pantothenamide	%	≤0.25	≤0.25	HPLC	ND	ND
3-[(3*E*)-5-(1-hydroxy-2-methylpropan-2-yl)-4-oxo-1,3-oxazolidin-3-yl]propanoic acid	%	≤0.15	——	HPLC	ND	——
Any unspecified impurity	%	≤0.10	≤0.2	HPLC	0.03	0.03
Total impurities	%	≤1.2	≤1.5	HPLC	0.63	0.63
Nitrogen content	%	5.7–6.0	5.7–6.0	USP<461> method I	5.9	5.9
Mercury *	ppm	≤0.1	≤0.1	ICP-MS	<0.01	<0.01
Lead *	ppm	≤2.0	≤2.0	ICP-MS	<0.05	<0.05
Arsenic *	ppm	≤1.0	≤1.0	ICP-MS	<0.01	<0.01
Cadmium *	ppm	≤1.0	≤1.0	ICP-MS	<0.01	<0.01
Total Plate Count *	cfu/g	$\leq 10^3$	$\leq 10^3$	Plating	<10	<10
Yeast & Molds *	cfu/g	$\leq 10^2$	$\leq 10^2$	Plating	<10	<10
E. Coli *	cfu/g	Negative	Negative	Plating	Negative	Negative
Salmonella *	25g	Negative	Negative	Plating	Negative	Negative

Conclusion: Complies with the requirements of BP2024/USP2024.

Note: The items marked with * are for internal sampling inspection, in which the results of hazardous elements are from the external inspection report, and the results of other items are from internal inspection.

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