

SPECIFICATIONS

BRAND NAME : ZONPea
PRODUCT NAME : PALMITOYLETHANOLAMIDE

TESTS	REQUIREMENTS
Description	White Crystalline powder
Solubility	Practically insoluble in water
Identification	
• By FTIR	The Infrared absorption spectrum of the sample should be concordant with the spectrum obtain from standard
• By HPLC	The retention time of the major peak in the chromatogram of the assay preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the assay.
Aroma	Characteristic
Assay by HPLC (%w/w) (on anhydrous basis)	Not less than 99.0 %
Water content by KF (%w/w)	Not more than 0.5 %
Melting Point (°C)	Between 98.0°C to 102. 0°C
Ash (%w/w)	Not more than 0.10 %
Particle size D (90)	90 % less than 60 µm
Bulk density	
a. Loose	Not less than 0.2 g/cc
b. Tapped	Not less than 0.3 g/cc
pH	Between 6.0 to 7.0
Related compound by HPLC (%w/w)	
a. Palmitic acid	Not more than 0.5%
b. Stearoylethanolamide (SEA)	Not more than 0.2%
c. Myristoylethanolamide (MEA)	Not more than 0.2%
d. Individual Maximum impurity	Not more than 0.1%
e. Total Impurities	Not more than 1.0%
Heavy Metals (by ICP-MS)	
a. Cadmium (Cd)	Not more than 0.5 ppm
b. Arsenic (As)	Not more than 0.5 ppm
c. Mercury (Hg)	Not more than 0.1 ppm
d. Lead (Pb)	Not more than 0.5 ppm
Microbiological Parameters	
Total plate count (TAMC)	Not more than 1000 cfu/g
Total Combined yeasts and moulds counts	Not more than 100 cfu/g
Tests for specified Organisms	
Escherichia Coli	Should be absent
Salmonella	Should be absent
Pseudomonas Aeruginosa	Should be absent
Staphylococcus Aureus	Should be absent
Residual Solvents	
Class III (Ethanol)	Not more than 5000 ppm