



BIMAL PHARMA PVT. LTD., MUMBAI, INDIA
(ISO 9001 : 2015 & AEO T1 Certified Co.)

TYPICAL CERTIFICATE OF ANALYSIS

Name of the Product : **POTASSIUM SORBATE GRANULAR**
(PHARMA GRADE)

Shelf Life : **2 Years**

Sr. No.	TEST	SPECIFICATION	RESULTS
1.	Description	White to off white Granular	White Granular
2.	Solubility	Freely soluble in Water Practically insoluble in Ether	Passes
3.	Heat Stability	No change in color after heating for 90 Minutes at 105°C	Passes
4.	Identification	(1) Potassium test : Passes test (2) Test of double bonds : Passes test (3) UV : conforms with standard spectrum (4) Melting point : 133.0 ~ 135.0 °C	Passes
5.	Appearance of Solution	Solution S is clear and not more intensely colored than reference solution Y5	Complies
6.	Assay	99.0% - 101.0%	99.3%
7.	Loss on Drying	1.0% Max.	0.3%
8.	Alkalinity (As K ₂ CO ₃)	≤ 0.25 ml. of 0.1 N Hydrochloric Acid	Passes
9.	Aldehydes	0.1% Max.	< 0.1%
10.	Arsenic	1.5 mg/ Kg. Max. (1.5 ppm)	< 1.5 mg/ Kg.
11.	Lead	10 mg/ Kg. Max. (10 ppm)	< 2 mg/ Kg.
12.	Mercury	1.5 mg/ Kg. Max. (1.5 ppm)	< 1 mg/ kg.
13.	Heave Metals	10 mg/ Kg. Max. (10 ppm)	< 10 mg/ Kg.
14.	Cadmium	0.5 mg/ Kg. Max. (0.5 ppm)	< 0.5 mg/ Kg.
15.	Chlorides (as Cl)	0.018% Max.	< 0.018%
16.	Sulphate (as SO ₄)	0.038% Max.	< 0.038%
17.	Bacterial Count	1000 cfu/ gms. Max.	< 1000 cfu/gms.
18.	Total Count Colony	100 cfu/ gms. Max.	< 100 cfu/gms.
19.	Fungal Count	100 cfu/ gms. Max.	< 100 cfu/gms.
20.	Escherichia coli	Absent	Absent
21.	Staphylococcus aureus	Absent	Absent
22.	Pseudomonas aeruginosa	Absent	Absent
23.	Salmonella spp.	Absent	Absent

Conclusion : The quality of our Potassium Sorbate Granules meets the Standards of IP / BP / EP / USP.