Distributed by:
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ACCENT MICROCELL PRIVATE LIMITED
An ISO 9001 : 2008 & GMP Company

SPECIFICATIONS

Product : Cross Carmellose Sodium

Quality Control

Description	White to Off White, free flowing powder, very hygroscopic powder; practically insoluble in acetone,ethanol,ether and toluene .

Pharmacopoeial test items	**Specification**
Identification (A,B,C) , (1,2,3)	Have to correspond as **USP/BP/PH.EUR/JP**
Degree of Substitution	0.60 to 0.85 as **USP/BP/PH.EUR/JP**
Loss on Drying	NMT 10.0% as **USP/BP/PH.EUR/JP**
pH	5.0-7.0 as **USP/BP/PH.EUR/JP**
Content of water Soluble Substance	NMT 10.0 % as **USP/BP/PH.EUR/JP**
Residue on Ignition / (Sulphated Ash)	14.0% to 28.0% as **USP/BP/PH.EUR/JP**
Settling Volume	10 to 30 ml as **USP/BP/PH.EUR/JP**
Sodium Chloride & (Sodium Glycollate)	NMT 0.5 % as **USP/BP/PH.EUR/JP**
Heavy Metals	NMT 10 PPM as **USP/BP/PH.EUR/JP**
Arsenic	NMT 2 PPM as **USP/BP/PH.EUR/JP**

MICROBIAL LIMITS

Total Viable Aerobic Count	N.M.T 1000 CFU/gm as **USP/BP/PH.EUR/JP**
Total yeast & Mould Count	N.M.T 100 CFU/gm as **USP/BP/PH.EUR/JP**
Staphylococcus aureus	Absent as **USP/BP/PH.EUR/JP**
Escherichia Coli.	Absent as **USP/BP/PH.EUR/JP**
Pseudomonas aeruginosa	Absent as **USP/BP/PH.EUR/JP**
Salmomonella species	Absent as **USP/BP/PH.EUR/JP**

The raw materials, manufacturing process, and product do not contain any of solvents listed in Organic Volatile Impurities (USP<467>) & residual solvents (Ph – Eur<5.4>). except for ethanol (limit max. 3.0 %)

Storage recommendation: Preserve in tight containers.

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