



ROQUETTE

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PRODUCT SPECIFICATION SHEET

SOLUTAB EDP

Definition

Product Identifier

Product name: SOLUTAB EDP

Croscarmellose Sodium.

Used in solid dosage formulations.

CAS: 74811-65-7

Specifications

PHYSICO-CHEMICAL SPECIFICATIONS

Appearance	White fine powder.
Odor	Odorless
Identification A,B,C	Positive
pH	5.0 - 7.0
Loss on drying(as shipped)	10.0 % max.
Degree of substitution	0.60 - 0.85
Settling volume	10.0 - 30.0 ml
Content of water soluble material	1.0 - 10.0 %
Sodium chloride and sodium glycolate	0.5 % max.
Residue on ignition	14.0 - 28.0 %
Retained on 200 mesh(75 microns)	2.0 % max
Retained on 325 mesh(45 microns)	10.0 % max.
Ethanol (residual solvent)	0.50 % max.

MICROBIOLOGICAL SPECIFICATIONS

Total aerobic microbial count	1000 cfu/g max.
Total combined mold and yeast count	100 cfu/g max.
Escherichia coli	Absent in 1 g
Pseudomonas aeruginosa	Absent in 1 g
Salmonella species	Absent in 10 g
Staphylococcus aureus	Absent in 1 g

Conformity

Complies with the current USP/NF and EP requirements.



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Storage

Store in dry area, in well-closed containers.

Retest date manufacturing date + 5 years.

Disclaimer

The information provided in this Product Specification Sheet relates only to the specific product designated and may not be applicable when such product is used in combination with other materials or in any process.

All information and instructions provided in this Product Specification Sheet are based on the current state of our knowledge at the latest revision date indicated. It is the responsibility of the user to be aware of and to follow the regulations applying to our product for its possession, handling and use.

Notes : All the dates are formatted like YYYY/MM/DD.