



NECRODEX® W

NECRODEX® - W is a White Dextrin which is a suspending agent; tablet binder; and a tablet and capsule diluent. It is used as an adhesive and stiffening agent for surgical dressings. In tablet and capsule formulations, dextrin is used as a diluent; as a binder for tablet granulation; as a sugar-coating ingredient that serves as a plasticizer and adhesive; and as a thickening agent for suspensions.

In addition, dextrin has been used as a source of carbohydrate by people with special dietary requirements because it has a low electrolyte content, is free of lactose and sucrose.

Applications

- Oral Dosage for Pharmaceutical and/or Nutraceuticals
 - Swallowable tablet
 - Chewable tablets
 - Effervescent tablets
 - Lozenge
 - Hard capsules
 - Soft capsules
 - Blends, Granules, Pellets Premix
 - Medicated Confectionary
 - Syrups, Suspension, liquids

Functional Properties

- High stability
- Free flowing
- Quick dispersion
- Quick dissolution
- Particle size (mean diameter about 130 microns)
- Micro granulated powder
- Imparts no taste or colour



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Necrodex® W is White Dextrin		
White Dextrin is prepared from Maize / Tapioca / Potato Starch CAS No. 9004-53-9		
DETERMINATION	SPECIFICATION	TEST METHOD
Description	A white or pale yellow powder, slight odor & characteristic free from any foreign matter.	As per IP
Identification	A purple color is produced after adding drops of iodine	As per IP
pH	Limit 5.0-7.0	In-House
Moisture Content	Not more than 12%	As per IP
Cold Water Soluble, Percent by Mass	35% to 100%	In-House
Bulk Density	550 g/lit ± 40 g/lit.	In-House
Tap Density	750 g/lit. ± 40 g/lit.	In-House
Sieve Test	Passes through 100 Mesh	In-House
Limit Of Sulfure Dioxide	NMT 50 PPM	As per IP
Reducing Sugar	NMT 10%	As per IP
Viscosity (Redwood Viscometer)	40-60 sec.	In-House
MICROBIAL LIMIT TEST:		
Total Aerobic Microbial	NMT 1000 Cfug	As per IP
Total Yeast and mould count	NMT 100 Cfug	As per IP
Escherichia coli	Should be absent	As per IP
Salmonella spp.	Should be absent	As per IP
Staphylococcus aureus	Should be absent	As per IP
Pseudomonas aeruginosa	Should be absent	As per IP

Comments

- Not intended for use in manufacture of parenteral dosage forms.
- Methods used by Necron may be the Pharmacopoeia methods or alternative validated methods which have been compared to the Pharmacopoeia methods.