

Product Sales Specifications

Report Id : WH0296

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Plasdone S-630

Chemical Description:

60% Vinyl Pyrrolidone/40% Vinyl Acetate Copolymer Pharmaceutical Grade (Copovidone K25-30)

Specifications:

Appearance @ 25 deg. C - White Powder	Pass
Identification Test A (W1125)	Pass
Identification Test B (Current USP-NF)	Pass
European Color Test - BY Color (W731)	>=5
European Color Test - B Color (W731)	>=5
European Color Test - R Color (W731)	>=5
K-Value (1% solids in aq. soln., W655)	>=25.2 - <=30.8
% Loss on Drying (W1126)	<=5.0
ppm Vinyl Acetate (HPLC, W1693)	<=5.0
ppm Aldehydes (Calculated as acetaldehyde, W1411)	<=500
ppm Vinyl Pyrrolidone (HPLC, W1693)	<=5.0
% 2-Pyrrolidone (HPLC, W1693)	<=0.50
% Nitrogen (solids basis, W1118)	>=7.0 - <=8.0
ppm Peroxide Content (W1378)	<=400
ppm Heavy Metals (as Lead, W1494)	<=10
pH (10% as is, in distilled water, W622)	>=3.0 - <=7.0
%Vinyl Acetate component (SAP# x 0.1534, W715)	>=35.3 - <=41.4
Saponification Value (W715)	>=230 - <=270
ppm Hydrazine (W403)	<=1.0
% Ash (residue on ignition or sulphated, W1381)	<=0.10
Total Aerobic Plate Count CFU/g (Q200)- Pass equals <=100	Pass
Mold and Yeast CFU/g (Q200)- Pass equals <=100	Pass
Staphylococcus Aureus CFU/g (Q200)- Pass equals Negative	Pass

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Specifications:

Salmonella CFU/g (Q200)- Pass equals Negative	Pass
Pseudomonas aeruginosa CFU/g (Q200)- Pass equals Negative	Pass
E. Coli CFU/g (Q200)- Pass equals Negative	Pass

Material meets the requirements for Copovidone and Copolyvidone in current European Pharmacopoeia and JPE respectively and Copovidone in the USP/NF.

Mod+Base Code : 201_72473

Material Codes : 830843, 830847, 858554

Responsible Manufacturing Plants : Texas City

2/29/2016

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