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PEG 300 PHARMA

SALES SPECIFICATION

Inspection Characteristic	Units	Lower	Upper	Method
Average molecular weight		285	315	1BAL01
Hydroxyl number	mg KOH/g	356	394	1BAL01
Clarity at 25°C	Free from haze and turbidity			1BAL02
Water solubility (25% aqueous)	Free from haze and turbidity			1BAL03
Suspended matter	Substantially free			1BAL04
Colour	PtCo		25	1BAL05
pH (5% aqueous)		4,5	7,0	1BAL06
Sulphated ash	% wt		0,1	1BAL10
Water	% wt		0,5	1BAL08
Residual ethylene oxide	ppm		1	1BAL09
Dioxane	ppm		5	1BAL09
The product also meets the following which whilst not determined on a routine basis is guaranteed by process control.				
Acidity (as acetic acid)	% wt		0,0150	1BAL11
Ethylene and diethylene glycol	% wt		0,20	1BAL12
Heavy Metals	ppm		5	1BAL14
Reducing Impurities	Pass test			1BAL40
Formaldehyde	ppm		15	1BAL44
Viscosity at 20°C	mm ² /s	71	94	1BAL16
Viscosity at 99°C	mm ² /s	5,4	6,4	1BAL16
Expiry date	Years		4	1BAL50
Food chemicals codex	Conform			
European pharmacopeia	Conform			
USP/NF pharmacopeia	Conform			
EEC and ICH guidelines	Conform			