

PRODUCT SPECIFICATION

PRODUCT: White Petroleum Jelly

GRADE: Ophthalmic

TYPICAL PROPERTIES:

CHARACTERS:

Sr. no.	Characteristic	Test Method	Specification
1	Appearance	Visual	A white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted
2	Solubility	BP / USP	Complies
3	Colour (as per USP)	USP	Complies
4	Colour lovibond, y	IP 17	Not more than 1.0

IDENTIFICATION (as per Ph. Eur.):

Ref. alphabet	Identification	Test Method	Specification
A	Drop point, °C	BP / Ph. Eur.	35 – 70
C		BP / Ph. Eur.	The solid upper layer is violet pink or brown
D	Appearance	BP / Ph. Eur.	The substance is white. The melted mass is not more intensely coloured than a mixture of 1 volume of yellow primary solution and 9 volumes of 10 g/l solution of <i>hydrochloric acid</i>

IMPURITIES:

Sr. no.	Type of impurity	Test Method	Specification
1	Residue on ignition	USP	Not more than 0.05%
2	Organic acids	USP	Complies
3	Polycyclic aromatic hydrocarbons (PAH)	Ph. Eur.	Complies
4	Fixed Oils, Fats and Rosin	USP	Complies

TESTS:

Sr. no.	Test	Test Method	Specification
1	Alkalinity	USP	Complies
2	Acidity	USP	Complies
3	Consistency at 25°C (0.1 mm)	ASTM D 937	150 – 200
4	Sulphated ash	Ph. Eur.	Not more than 0.05%
5	Kinematic Viscosity at 100 °C, cst	ASTM D 445	4.0 – 8.0
6	Congealing point, °C	ASTM D 938	47 – 56
7	Specific gravity at 60 °C	USP	0.815 – 0.840

Remarks: The sample complies with prescribed standards as per Ph. Eur. / USP specifications and **USFDA requirements as per 21 CFR 172.880.**

This product complies as per ICH Q3C (R4) and USP <467> guidelines for Residual solvents.

PACKING: 190 kg Open mouth drums