

A look at Plastibase[®]

Hydrocarbon gel 50W and 55W



Plastibase (hydrocarbon gel) is a uniform, soft, glossy base used in the manufacturing of ointments around the world. It is manufactured under strict good manufacturing practice (GMP) conditions by Contract Pharmaceuticals Limited (CPL), Glasshouse Pharmaceutical's sister company and a leader in the development, manufacturing, and packaging of semi-solid prescription products.

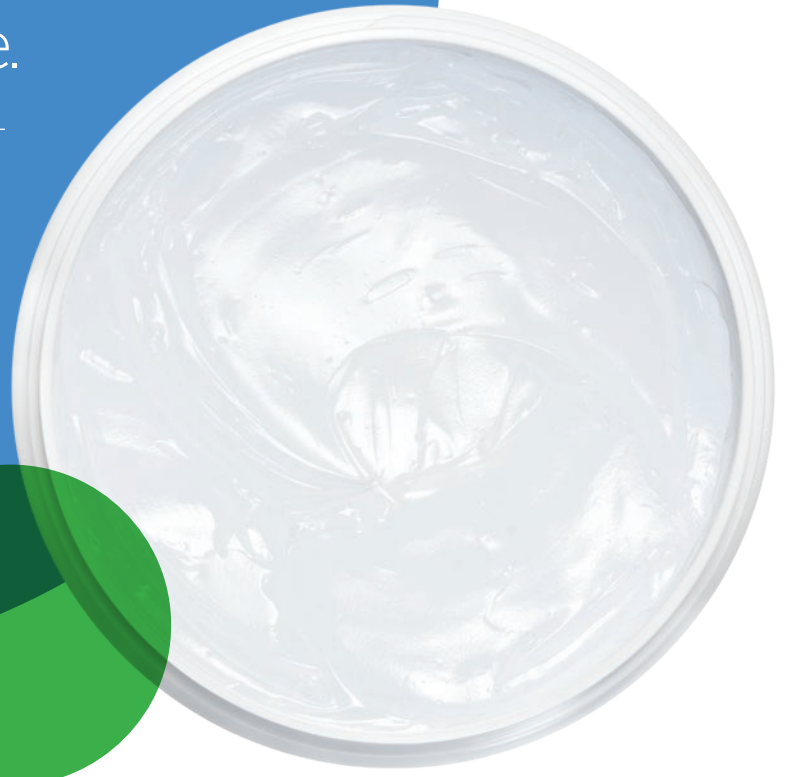
In May 2017, Glasshouse Pharmaceuticals Limited Canada purchased Plastibase 50W and 55W (hydrocarbon gel) from Bristol Myers Squibb (BMS). CPL manufactured Plastibase on behalf of BMS for more than a decade and will continue to manufacture Plastibase for Glasshouse Pharmaceuticals under strict GMP and in a site approved by the FDA, Health Canada, and the Japanese Health Authority.

It is important to note that while ownership of Plastibase has changed, the product itself has not. The raw materials, manufacturing process, manufacturing equipment, bulk and finished product testing specifications, and sites of manufacture and testing are all remaining the same.



The ideal ointment base.

Plastibase is made from a combination of polyethylene and mineral oil. Unlike white petrolatum, polyethylene contains both crystalline and amorphous fractions, which are prerequisites for the formation of optimal gel characteristics¹



Stability.

Plastibase contains a significant amount of mineral oil. Due to the insolubility of the macromolecules in the mineral oil, Plastibase has:

+ EXCELLENT STABILITY
across a wide temperature range
(-15°C to 60°C)¹

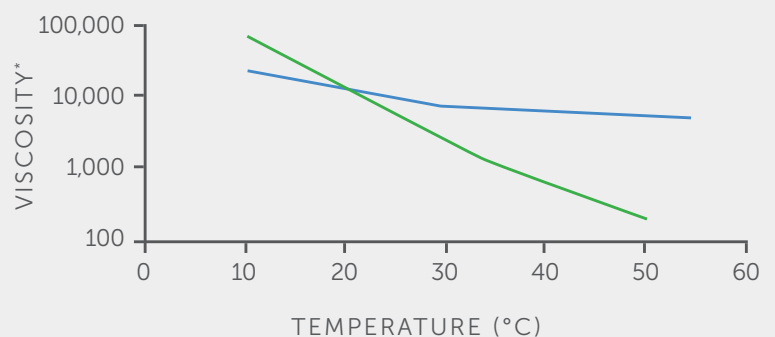
+ CONSISTENT VISCOSITY
across a wide temperature range
(5°C to 45°C)¹

Viscosity.

As pictured in the chart, in contrast to white petrolatum, the viscosity of Plastibase hardly changes with the temperature² Plastibase may be heated or cooled without affecting viscosity, while white petrolatum-based ointments' viscosity is seriously altered.

— HYDROCARBON GEL
— WHITE PETROLATUM

CHANGES IN VISCOSITY DUE TO TEMPERATURE



*(mPa•s) @50 1/s

Pharmaceutical characteristics.

The most important role of an ointment base is to allow the release of the active ingredient.³ In a test studying the release properties of antibiotics, researchers compared the results of using hydrocarbon gel versus white petrolatum. The test measured the inhibition of the growth of bacteria (known as the inhibition ring diameter and measured in millimeters [mm]) as an estimate of how much antibiotic is released.

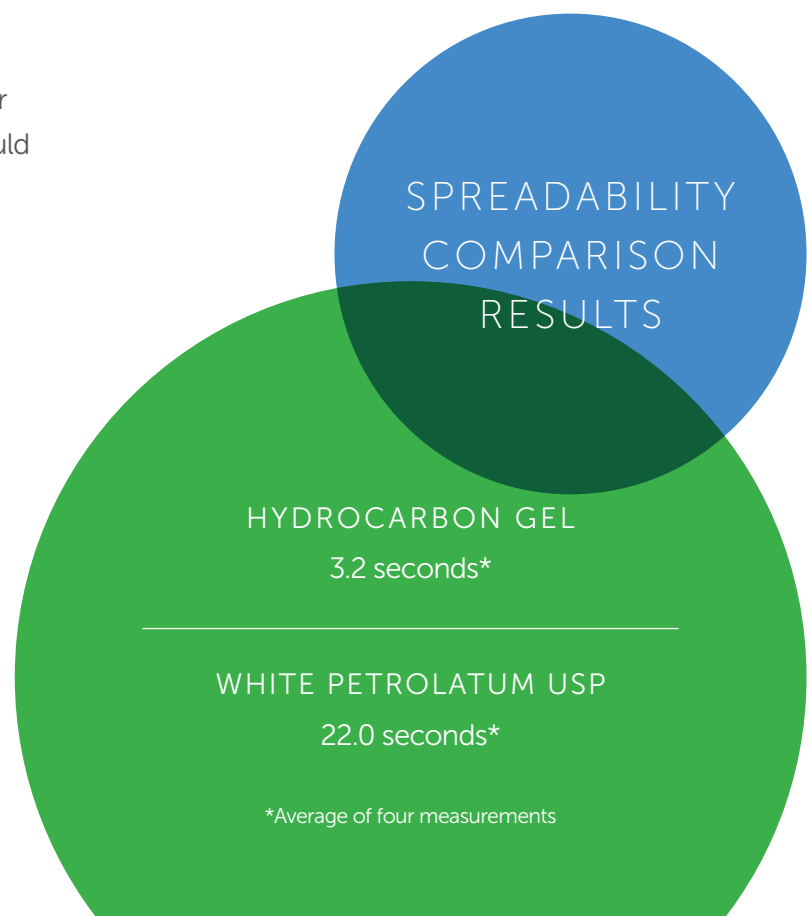
	PENICILLIN (10,000 U/mg)	STREPTOMYCIN (10mg/g)	TETRACYCLINE (30mg/g)	1% ACRINOL
Hydrocarbon gel	37.0 mm	6.0 mm	14.5 mm	4.5 mm
White petrolatum	34.5 mm	5.5 mm	10.0 mm	2.5 mm

The results demonstrated that hydrocarbon gel releases more antibiotic when compared to white petrolatum because the inhibition ring diameters are larger for hydrocarbon gel. Unlike white petrolatum, the movement of mineral oil in Plastibase brings a continually changing interface of medication to the skin, thereby permitting the release of API that is far superior to white petrolatum.¹

Spreadability.

An ointment needs to be easily spreadable to cover the affected area. To spread well, an ointment should behave like a good lubricant exhibiting maximum "slip" and minimum drag or resistance.³

To determine the spreadability of Plastibase and white petrolatum, a thin layer of each ointment was sandwiched between two slide glasses. The upper slide glass was pulled using 80g of force. The time required until the slide glass started to slip was measured.³ As the results on the right show, Plastibase is much easier to spread than white petrolatum.



Manufacturing.

Manufacturing and packaging are crucial to ointment development. If an ointment is too soft when packaged into a tube, there is a risk of leaking when the cap is opened. Conversely, if an ointment is too thick or stiff, it will be difficult to get the ointment out of the tube, and it will take longer to fill the ointment during the packaging process. Because Plastibase hardly changes in consistency with varying temperatures, it is the most user-friendly ointment base.

HYDROCARBON GEL²

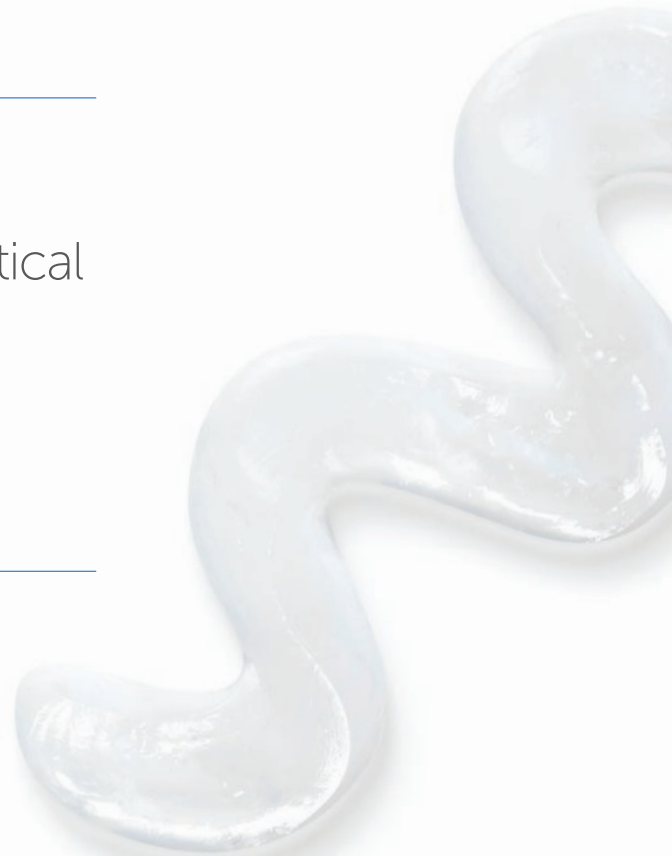


WHITE PETROLATUM²



Plastibase's qualities are superior in terms of stability, viscosity, pharmaceutical characteristics, spreadability, and manufacturing, all of which make it the ideal ointment base.

For more information about Plastibase, visit our website, glasshousepharma.com, or reach out to our general manager [Jan Sahai at jsahai@glasshousepharma.com](mailto:jsahai@glasshousepharma.com).



Product specifications.

Proprietary name: Plastibase

Non-proprietary name: Hydrocarbon gel 50W; hydrocarbon gel 55W

Manufacturer: Contract Pharmaceuticals Limited Canada

Intended usage: Ointment base

Regulatory standards: US FDA; Japanese Pharmaceutical Excipients; Health Canada (mutual recognition agreement with the EU/MHRA)

Shipping method: 50Kg/fiber drum

Storage method: Room temperature, airtight container

	PLASTIBASE Hydrocarbon gel 50W and 55W	WHITE PETROLATUM
MANUFACTURING	Manufactured by CPL under cGMP conditions (approved by US FDA, Canadian authorities, and Japanese Health Authority)	—
CHEMICAL PROPERTIES	An ideal ointment base with little interaction with the active ingredient	Suboptimal gel characteristics
VISCOSITY	A soft, glossy ointment base that maintains a consistent degree of softness over a wide temperature range	Stiff; likely to change in viscosity easily, depending on the temperature
STABILITY	Stable over a wide temperature range	Viscosity and appearance are subject to change, depending on the temperature range
USABILITY	Spreads well; easy to push out even at low temperatures (5°C)	Stiff texture; hard to push out of tube at low temperatures

1. Mutimer MN et al. Modern ointment base technology. I. Properties of hydrocarbon gels. *J Am Pharm Assoc*, 1956; 45(2 Part 1):101-105.

2. Data on File. Summit Pharmaceuticals International.

3. Mutimer MN et al. Modern ointment base technology. II. Comparative evaluation of bases. *J Am Pharm Assoc*, 1956; 45(4):212-218.