

## **Technical Data Sheet**

Product: LORIS10% PVP-I Solution (Bottle 500 ml, E/F)

Product Code: 109-08 NPN 80008372 (Canada)

### **Product Packaging**

Solution content: 480 – 520 mL Number of bottles per corrugate: 12

### **Product Label**

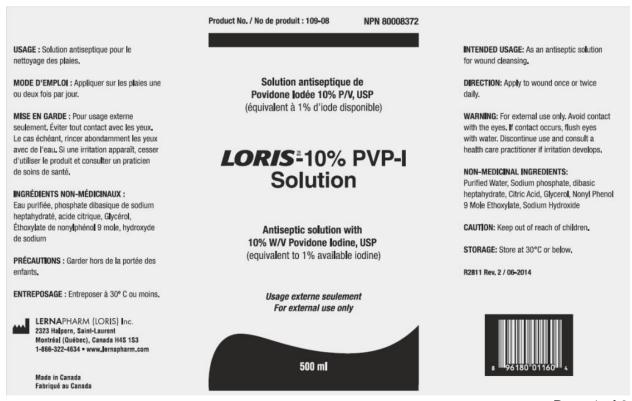
Intended use: Antiseptic solution for wound cleansing.

**Directions**: Apply to wound once or twice daily.

**Warnings**: For external use only. Avoid contact with the eyes. If contact occurs, flush eyes with water. Discontinue use and consult a health care practitioner if irritation develops.

Caution: Store at 30°C or below.

#### Label view



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# **In-Process Quality Controls on Finished Products**

Test	Method	Specification
Fill volume	S-MAN-003	Minimum 480 mL
Seal Integrity	Visual	No leaks found when a bottle is shaken upside down

# **Chemical / Biological Analysis**

Test	Method	Specification
Description	TL-S-QUA-012	Bottle containing brown liquid
Visual inspection	TL-S-QUA-012	The solution is free of dirt, hair, precipitates, and other foreign matter
рН	USP<791>	1.5 - 6.5
Available iodine	TL-S-QUA-012	0.85% w/v - 1.20% w/v
Identification (A)	TL-S-QUA-012	A deep blue color is produced
Identification (B)	TL-S-QUA-012	No blue color appears within 60 seconds
Total Aerobic Microbial Count (TAMC)	TL-S-QUA-028	Report < 10 cfu/mL
Total Combined Yeast and Molds Count (TYMC)	TL-S-QUA-028	Report < 2 cfu/mL
S.aureus	TL-S-QUA-053	Absence
P.aeruginosa	TL-S-QUA-053	Absence
B.cepacia	TL-S-QUA-053	Absence

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