



JETEMA

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CERTIFICATE OF ANALYSIS


PRODUCT NAME	Implant Hyaluronic Acid Gel	BATCH NO.	YLC23017
TRADE NAME	STARFILL	MFG. DATE	June 21, 2023
MODEL	Implant Plus Lidocaine 1.1ml	EXP. DATE	June 20, 2025

TEST ITEMS	SPECIFICATIONS	RESULTS
1. Description	Colorless, transparent, high viscous aqueous gel without visible foreign substance.	Conform
2. HA Identification	1) Glucuronic acid: Red color 2) N-acetyl-glucosamine: Red purple color 3) Reaction of sodium 1: Yellow color 4) Reaction of sodium 2: White precipitate	Conform
3. HA Content	90.0~110.0% (21.6~26.4mg/mL)	100.04 %
4. Lidocaine HCl Identification	RT difference ≤ 0.2mins	Conform
5. Lidocaine HCl Content	90.0~110.0% (2.7~3.3mg/mL)	2.99 mg/mL
6. pH	6.0 ~ 7.5	6.79
7. Filling Volume	Not Less Than 100% (1.1 mL)	1.13 mL
8. Osmolality	200 ~ 400 mmol/kg	282.3 mmol/kg
9. Pushing Force	Not More Than 40 N	Tae-chang-9.0N(25G)/12.4N(27G)
10. BDDE Residue	Not More Than 2ppm	Not detected
11. Heavy Metals	<u>Not darker than the control</u> (<u>Not More Than 10ppm</u>)	Not darker than the control (Less Than 10ppm)
12. Bacterial Endotoxins	Less Than 12.5EU/mL	<0.1 EU/mL
13. Sterility	Sterile	Sterile
14. Complex Viscosity	<input checked="" type="checkbox"/> 370~500 Pa.s <input type="checkbox"/> 200~330 Pa.s <input type="checkbox"/> 30~100 Pa.s	482.2 Pa.s
ADJUDGEMENT: RELEASED		

Our product is tightly evaluated on the basis of specifications by Quality Control Department.

Approved by

Q.M.R.,


 date Jul. 12, 2023