NEXUS PHARMA

80 mg HYALURONIC ACID SODIUM SALT
40 mg (H-HA) + 40 mg (L-HA)
2.5 mL PREFILLED SYRINGE

PLENARIS

PRO **80**

High Quality and High Concentration HA

with PLENARIS PRO 80

High molecular weight

Low molecular weight

Hyaluronic Acid

PLENARIS PRO 80

High molecular weight Hyaluronic Acid

+

Low molecular weight Hyaluronic Acid

PLENARIS PRO 80 contains stabilized complexes of Low and High molecular weight Hyaluronic acid which is a product developed by the innovative team at Nexus Pharma Co., Ltd. The unique thermal to cooling manufacturing process enables to manufacture the product which contains stable interactions between different molecular weight of high-purity Hyaluronic acid.

The high and low molecular weight and non-cross-linked HA used in PLENARIS PRO 80 is obtained through a biological fermentation process without chemical modification, resulting in excellent tolerability.

Certified raw materials

High user convenience

International standard manufacturing site

This innovative formula counteracts the skin's physiological decline in HA, helping to restore moisture, elasticity, and skin tone.

Hydration

Lifting

Duration

PRODUCT SUMMARY

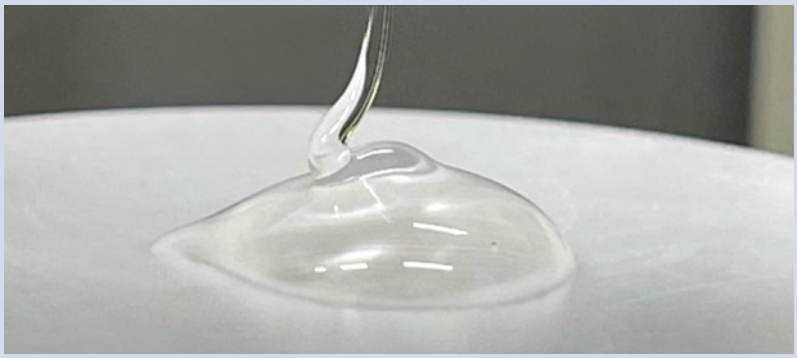
40mg of hyaluronic acid
(High molecular weight)

+

40mg of hyaluronic acid
(Low molecular weight)

=

80mg of Hyaluronic acid/2.5mL

	PLENARIS PRO 80
HA Concentration	40 mg/2.5 mL of High molecular weight HA (900 – 1400 kDa) 40 mg/2.5 mL of Low molecular weight HA (100 – 600 kDa)
Gel Type	
Volume	2.5 mL X 1 pre-filled syringe
Needle	Not included (Recommended needle: 29 Gauge)
Injection depth	Dermis and Subcutaneous tissue

PLENARIS PRO 80

Benefit of H-HA and L-HA complexes

High HA Concentration (80mg/2.5mL)
Slow and long lasting release of the natural HA
Increase elastin and collagen expression
Low inflammatory response
Can be used to treat entire face with small injection points

Treatment Cycle

An initial cycle of two treatment sessions at 1-month intervals is recommended.
Follow if necessary by maintenance treatments every 2 months.

NO Swelling

When PLENARIS PRO 80 is injected correctly in the suggested injection layer (not too superficial) and in the suggested area (malar-submalar area) there is no swelling.

Special follow-up

They are the same as for other injection treatments

Combined protocols with other fillers of treatments

Treated areas shouldn't be reinjected within 2 weeks of the initial procedure.

- Botulinum toxin: two weeks prior
- Microdermabrasion, chemical peel, IPL: 1-2 weeks pre or post treatment
- Fractional resurfacing 3-4 weeks distant
- Treatment should not be undertaken in the immediate period following other routine medical procedures (including vaccination)

INJECTION POINT GUIDELINE

Face

Identify the injection sites on each side of the face

Recommended use of needle (29G), inject 0.2 ml per bolus into the target layers

Target Layers: Dermis and Subcutaneous tissue

1 Zygomatic protrusion

Minimum distance of 2cm to the distal corner of the eye

2 Nasale Basis

At the intersection of a vertical line from the pupil and horizontal line from the nostril to the tragus

3 Tragus

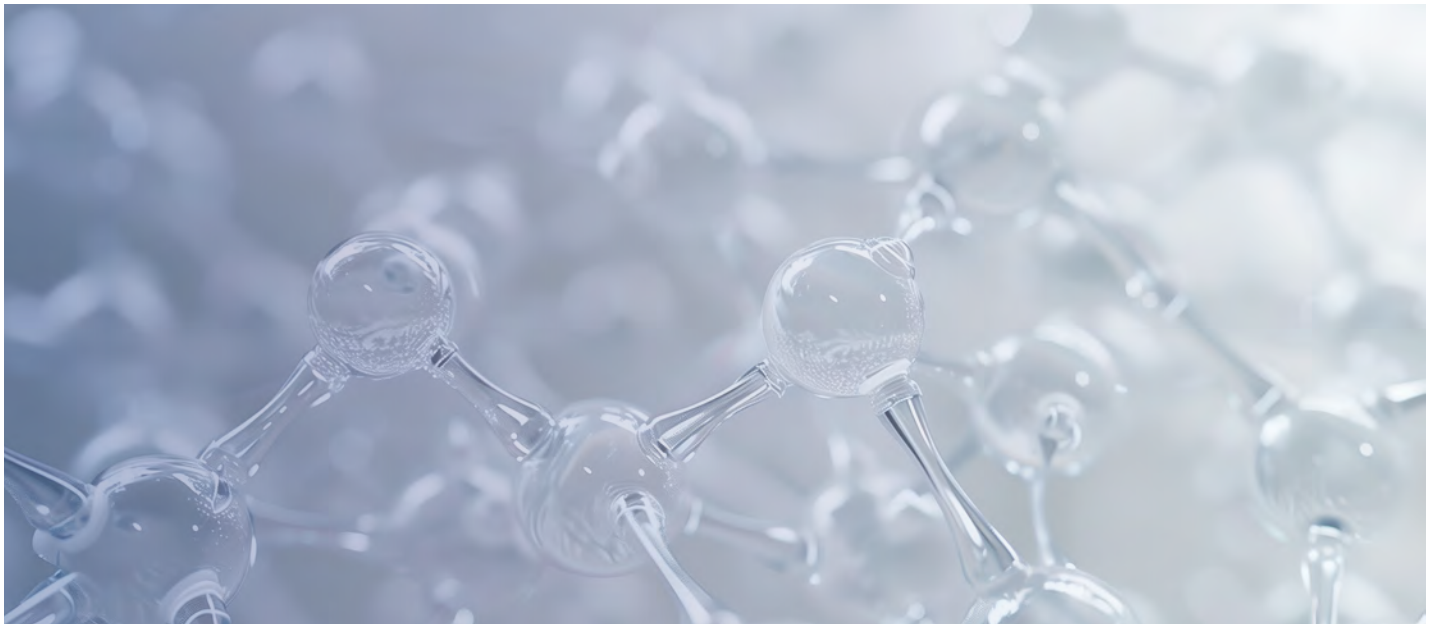
At least 1cm in front of the tragus

4 Chin

1.5cm from the intersection of a vertical line from the center of the chin and horizontal line intersecting the vertical line in the upper third

5 Jaw angle

1cm above the jaw angle

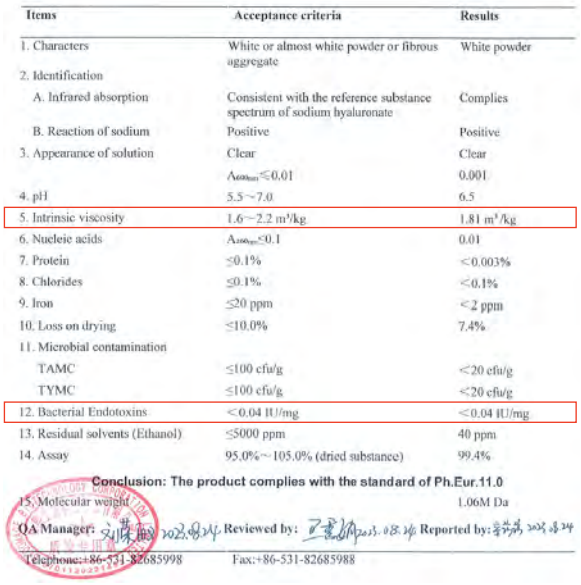


UNIQUE CHARACTERISTICS

Quality PLENARIS PRO 80 contains high quality and stabilized hyaluronic acid

Raw materials

High purity Hyaluronic acid used in ophthalmic pharmaceutical products

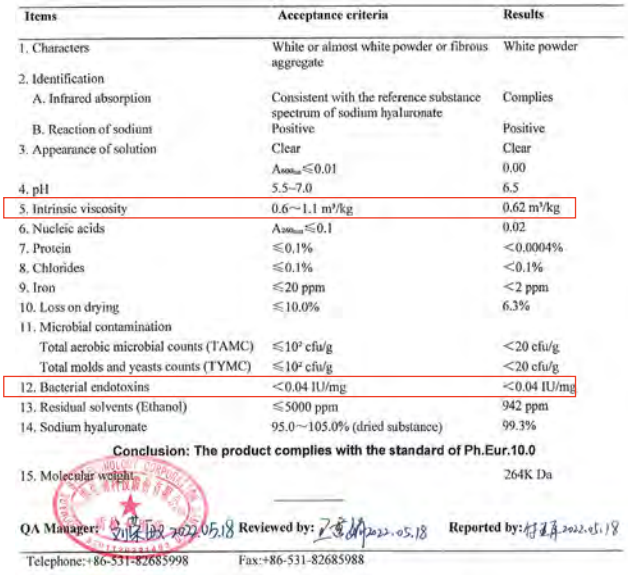


Items	Acceptance criteria	Results
1. Characters	White or almost white powder or fibrous aggregate	White powder
2. Identification		
A. Infrared absorption	Consistent with the reference substance spectrum of sodium hyaluronate	Complies
B. Reaction of sodium	Positive	Positive
3. Appearance of solution	Clear	Clear
	A_{600nm}≤0.01	0.001
4. pH	5.5~7.0	6.5
5. Intrinsic viscosity	1.6~2.2 m³/kg	1.81 m³/kg
6. Nucleic acids	A_{260nm}≤0.1	0.01
7. Protein	≤0.1%	<0.003%
8. Chlorides	≤0.1%	<0.1%
9. Iron	≤20 ppm	<2 ppm
10. Loss on drying	≤10.0%	7.4%
11. Microbial contamination		
TAMC	≤100 cfu/g	<20 cfu/g
TYMC	≤100 cfu/g	<20 cfu/g
12. Bacterial Endotoxins	<0.04 IU/mg	<0.04 IU/mg
13. Residual solvents (Ethanol)	≤5000 ppm	40 ppm
14. Assay	95.0%~105.0% (dried substance)	99.4%
Conclusion: The product complies with the standard of Ph.Eur.11.0		
15. Molecular weight		1.06M Da

QA Manager: Reviewed by: Reported by:

Telephone:+86-531-82685998 Fax:+86-531-82685988

CoA of H-HA



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B. Reaction of sodium	Positive	Positive
3. Appearance of solution	Clear	Clear
	A_{600nm}≤0.01	0.00
4. pH	5.5~7.0	6.5
5. Intrinsic viscosity	0.6~1.1 m³/kg	0.62 m³/kg
6. Nucleic acids	A_{260nm}≤0.1	0.02
7. Protein	≤0.1%	<0.0004%
8. Chlorides	≤0.1%	<0.1%
9. Iron	≤20 ppm	<2 ppm
10. Loss on drying	≤10.0%	6.3%
11. Microbial contamination		
Total aerobic microbial counts (TAMC)	≤10² cfu/g	<20 cfu/g
Total molds and yeasts counts (TYMC)	≤10² cfu/g	<20 cfu/g
12. Bacterial endotoxins	<0.04 IU/mg	<0.04 IU/mg
13. Residual solvents (Ethanol)	≤5000 ppm	942 ppm
14. Sodium hyaluronate	95.0~105.0% (dried substance)	99.3%
Conclusion: The product complies with the standard of Ph.Eur.10.0		
15. Molecular weight		264K Da

QA Manager: Reviewed by: Reported by:

Telephone:+86-531-82685998 Fax:+86-531-82685988

CoA of L-HA

Unparalleled Stability

PLENARIS PRO 80 features our groundbreaking thermally stabilized hyaluronate gel:

- Consistent Performance: Our innovative gel maintains its physicochemical properties over time, ensuring reliable results with every treatment.

Enhanced Safety

Experience peace of mind with our non-cross-linked hyaluronic acid gel:

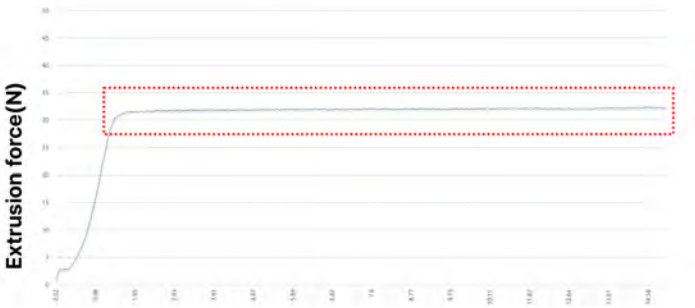
- BDDE-Free: Our formula contains no 1,4-butanediol diglycidyl ether (BDDE) or other chemical cross-linking agents.
- Minimized Side Effects: By eliminating cross-linking agents, we significantly reduce the risk of adverse reactions commonly associated with traditional dermal fillers.

UNIQUE CHARACTERISTICS

Satisfying PLENARIS PRO 80 has an ergonomic design that enhances user convenience and enables stable injection

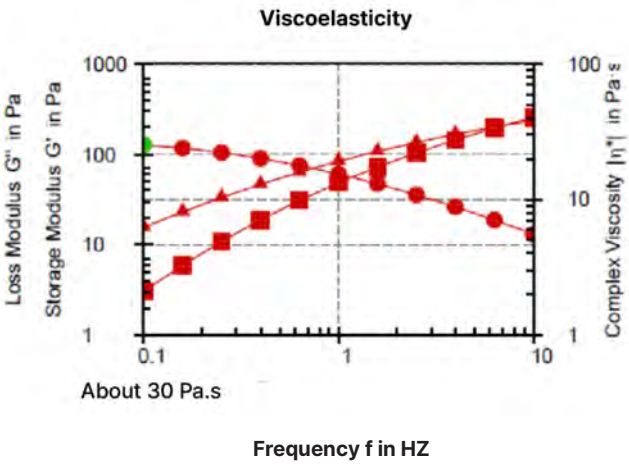
Extrusion force *(Injection force)*

Easy to inject stably due to maintenance of uniformal injection force



Viscoelasticity

Low viscosity hyaluronic acid filler with high spreadability



Ref. 1) Measurement results from NEXUS PHARMA R&D center

UNIQUE CHARACTERISTICS

End-user satisfaction

PLENARIS PRO 80 demonstrates potential satisfaction over alternative skin boosters, including a reduced frequency of treatments, comparable or lower pain levels during administration, and similar or extended duration of effects.

In the case of complexes of high- and low-molecular-weight Hyaluronic acid, patient satisfaction appears to be higher compared to skin boosters or fillers with other ingredients, such as PN or HA, in terms of pain level, treatment frequency, and duration.

Comparison of Dermal products

	PLENARIS PRO 80	PN Filler	Skin Booster
Ingredients	**H-HA & L-HA**	Polynucleotide	HA
Pain Level	**++**	+++	++
Treatment Frequency	**2 sessions, 1 month apart**	3 sessions, 1 month apart	3 sessions, 1 month apart
Duration	**6-9 months**	6 months	3-6 months

The PLENARIS PRO 80 Advantage

- Natural-Looking Results: Achieve a youthful appearance without compromising on safety.
- Biocompatibility: Our pure hyaluronic acid formulation integrates seamlessly with your skin's natural structure.
- Versatile Application: Ideal for various aesthetic treatments for fine lines and stimulation of elastin and collagen formation.

UNIQUE CHARACTERISTICS

Satisfying PLENARIS PRO 80 is manufactured a facility that meets international standards

Quality Management System

The Quality Management System for Medical Devices is compliance with the Standard EN ISO 13485:2016


CERTIFICATE

No. 820618

Nexus Pharma Co., Ltd.

EN ISO 13485:2016

Design and Development, Production, Distribution and Sales of Medical Device (Graft/prosthesis, biomaterial and Dressing, fluid-impermeable film) and Provision of Steam sterilization service and validation as per ISO 17665-1

Manufacturing process

- Manufactured in clean room strictly controlled by Global standards, ISO 14644
- Sterile and pyrogen-free through closing system using auto filling equipment
- Increased sterility of product sterilized by a moist heat sterilize

PRODUCT INFORMATION

PLENARIS PRO 80

Manufacturer

NEXUS PHARMA Co., Ltd.

Product name

PLENARIS PRO 80

Packaging unit

1 pre-filled syringe(2.5 mL) / 1 Box

Medical device

Single-use medical device, Do not re-use

Indication

Used to temporarily improve facial wrinkles through a physical graft by injecting sodium hyaluronate gel subcutaneously

Storage conditions

2℃~25℃, avoid light and freezing

PLENARIS PRO 80

NEXUS PHARMA

www.nexus-pharma.com

CH BUILDING, 71, GONGHANGDAERO 45GIL
GANGSEOGU, SEOUL, KOREA
(T) +82 2 6406 2405
info@nexus-pharma.com