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saypha® VOLUME Lidocaine

Technical factsheet

saypha® VOLUME Lidocaine [1]	
Intended purpose	To create volume in order to correct wrinkles and folds in order to treat signs of ageing.
Indication	The device is indicated to correct moderate to severe nasolabial folds.
Injection area	Deep dermis or subcutis
Ingredients	
Concentration HA	2.3% (23 mg/mL) High molecular weight hyaluronic acid of non-animal origin
Crosslinking agent	BDDE (concentration ≤ 2 ppm)
Additional ingredients	Phosphate buffer, NaCl, 0.3% lidocaine hydrochloride
Packaging	
Packaging unit	1 box of 1 mL syringe
Needle	2 x 27G ½" thin wall Terumo™ needles (CE 0197)
Duration	
Est. duration in the skin	Anticipated at least 9 months [2]

Crosslinking

The product is a biphasic gel containing a crosslinked and a non-crosslinked phase mixed in a defined ratio (crosslinked phase 95%, non-crosslinked phase 5%). These specifications are not to be confused with the crosslinking degree of the products, since a crosslinked phase contains non-crosslinked HA as well.

Rheology

Purpose of rheological measurements is to evaluate the physical characteristics of HA fillers. The storage modulus G' represents a suitable parameter to determine the stiffness of HA-based, crosslinked products like saypha® VOLUME, where the elasticity is more pronounced than the viscosity.

Test method: G' ($\omega = 1 s^{-1}$, f=0.16 Hz, T=25°C)
Result: 257,183 mPa [3]

Extrusion force

Extrusion force measurements are conducted to determine the force [N] needed to eject the gel from the syringe. The tests are always performed with the enclosed needle. A low and constant extrusion force is beneficial for smooth and predictable results.

Needle: 27G ½" thin wall Terumo™ (CE 0197)
Result: 13 N [4]

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Microbiological parameters

Endotoxins

Endotoxins are components of gram-negative bacteria membranes and are released when the bacterial cells are disrupted (e.g. during sterilization). Therefore, the products are tested to assure that the endotoxin concentration lies below the predefined specification limits.

Test method: According to Ph.Eur.[5]
Result: Virtually free on endotoxins[6]

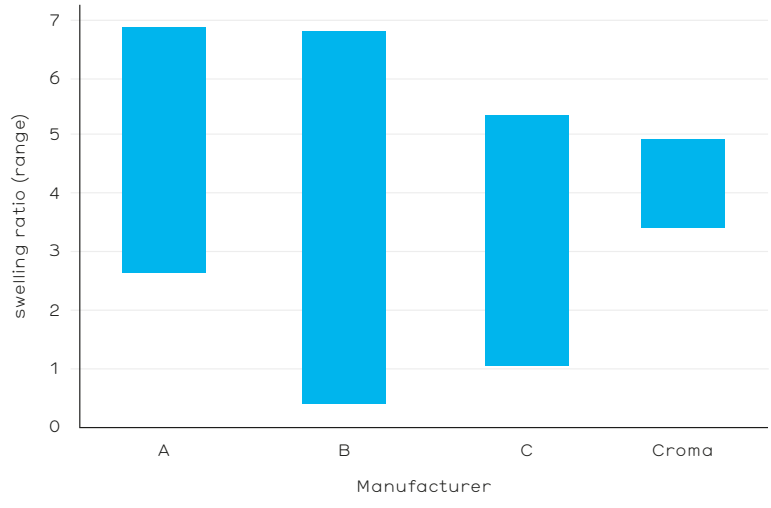
Sterility

Croma HA fillers are steam sterilized within the syringe.

Swelling ratio

Water uptake influences the volumising effect of HA fillers. Therefore, the in vitro swelling behaviour is a useful parameter. Croma HA fillers show a reproducible swelling in vitro within the entire product range (compared to the competitor product ranges A, B, C in the table). Furthermore, Croma HA fillers have a very low batch to batch variability, which contributes to the predictability of the results.[7]

Test method: Gravimetric measurement to determine the ability of a gel to take-up PBS (phosphate buffered saline)



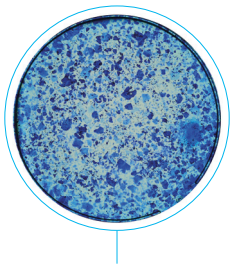
Croma data on file

Gel particles

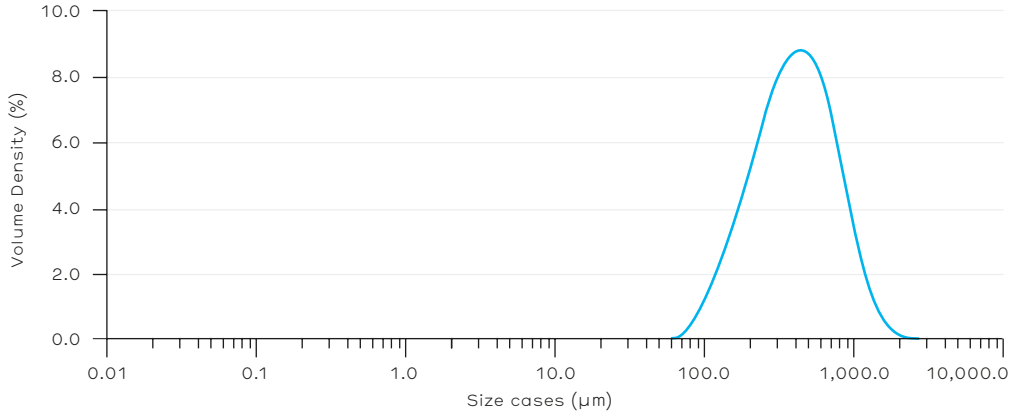
Croma's crosslinked hyaluronic acid fillers are characterized by smooth HA gel-particles with a typical diameter around 0.5 mm. Particle staining is useful to illustrate the structure of HA fillers: a homogeneous composition of smooth gel particles made of crosslinked hyaluronic acid.[8]

Test method: Crosslinked gels are placed on petri dishes and treated with a methylene blue solution, leading to particle staining which is then photographed

An exemplary picture and particle size distribution of saypha® VOLUME PLUS are shown below



saypha®
VOLUME PLUS
with lidocaine



Croma data on file

[1]CE 0123 [2]CPH-401-201258 [3]Batch: 904028, specification limits: 200,000-400,000 mPa [4]Batch: 904028, specification limits: 8-25 N, [5]Ph.Eur. = European Pharmacopoeia
[6]EU = Endotoxin Unit according to Ph.Eur., specification limits saypha® VOLUME Lidocaine ≤ 2 EU/mL [7]A_RD_TRIR_051, [8] A_RD_TRIR_089ext

The medical practitioner confirms having informed the patient of a likely risk associated with the use of the medical device in line with its intended use.
For risks and adverse events associated with the use of the product consult the instructions of use.

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