



TECHNICAL SHEET OF THE MEDICAL DEVICE EASYAL 2 ml and 4 ml

Composition and characteristics

2.0 ml (4 ml) of the device contains:

- 40.0 mg (80.0 mg) of sodium hyaluronate with molecular weight in range 1.0-1.5 MDa;
- 16.0 mg (32.0 mg) of non-pyrogenic sodium chloride;
- 0.6 mg (1.2 mg) of sodium phosphate monobasic x 2 H₂O;
- 3.0 mg (6.0 mg) of sodium phosphate dibasic x 12 H₂O;
- Water for injection q.s. for 2 ml (4 ml).

The device has the following components apart from the sodium hyaluronate solution:

- 1 Vial syringe;
- needles of diameter size range 18 - 22 G.

The following analytical controls of the finished product are performed to measure the relevant characteristics:

- Appearance: clear and colourless gel
- pH: 6.50 - 7.50
- Extractable volume: 2.0 - 2.2 ml (4.0 - 4.4 ml)
- Osmolality: 270 - 330 mOsm/Kg
- Sodium hyaluronate identification (HPLC): Positive
- Sodium hyaluronate assay (HPLC): 18 - 22 mg/ml
- Sterility test (according to Ph.Eur.): pass the test, sterile
- Bacterial endotoxins (LAL test): < 10 EU/ml