

Certificate of Analysis & Declaration of conformity

Our reference Maria Littorin Kjellgren	Product Apotekets Hypertonic Nasal spray	Batch no 24019567
Number of products 6432 cans = 134 boxes	Expire date 2027-01	Article no 301048

Characteristic	Test method	Specifications	Result
NaCl concentration	SOP 10102	2.0 – 2.2 % w/w	2,1 %
Net Weight	SOP 10057	98 – 102 g	Pass
Finished product Pressure	SOP 10055	5.3 – 6.3 Bar	5,8 Bar
Discharge weight	SOP 10056	Not less than 96 g	99 g
pH	SOP 10095	6.5 – 8.5	7,9
Appearance	Visual	Liquid is free of foreign particles. Clear	Pass
Color	Visual	Colourless	Pass
Terminal sterilization	ISO 11137	Sterile	Pass

Date of manufacture 2024-01-04	Date of irradiation 2024-03-05 / 2024-03-06	Customer Apotekernes A.m.b.a.
Date of filling 2024-01-04	Date of analysis 2024-01-04	

Declaration of Conformity

Aurena Laboratories AB certify that Apotekets Hypertonic Nasal, 100ml, 301048 REF # 1018-8, is in conformity with the applicable provisions of Council directive 93/42/EEC (Medical Device Directive) via the Swedish implementation of LVFS 2003:11, annex II as amended in LVFS 2009:18.

2024-03-07

Date

Maria Littorin Kjellgren

Signature

CE 0413

Version of history

Version	Change	Changed by/date
2	-	2019-06-17/KFL
3	Version history added. Product specification 301 048, version 3.0, 2022-03-30 COP 100091 version 1.0, 2019-03-26	2022-05-31/CC