fimea

Marketing Authorisation

Certificate No.[1]

Certificate of a Pharmaceutical Product

1	Certifying country **Finland**	Requesting country

2 Name and dosage form of the product

Additional information: *
According to the notification of the company applying for the Certificate of the Pharmaceutical Product the trade name for the product in the requesting country is:

2.1 Active substance(s) [2] and amount(s) per unit dose of unit volume [3]

2.2 Is this product authorised to be placed on the market for use in Finland?

☐ Yes ☐ No [4]

2.3 Is this product actually on the market in Finland?

☐ Yes ☐ No

3 Number of Marketing Authorisation and date of issue

[1] Finnish Medicines Agency fills.
[2] Use, whenever possible, International Nonproprietary Names (INNs) or names of the European Pharmacopoeia.
* There is an optional field where the applicant can add the trade name for the requesting country. In that case the applicant must also notify the trade name in the request for the Certificate, for example in the e-mail message.
[3] The formula (complete composition, including excipients) of the dosage form should be given on the certificate or to be appended.
[4] The Finnish Medicines Agency accords certificates only for the pharmaceutical products which have a Marketing Authorisation.

3.1 Marketing Authorisation Holder (name and address)

3.2 Manufacturer(s) of the Pharmaceutical Product (name(s) and address(es)

3.3 Manufacturer responsible for batch release (name and address)

3.4 The use of the product may be promoted in accordance with the

☐ **Summary of Product Characteristics (annex)** [5]

3.5 Applicant for certificate, it different from Marketing Authorisation Holder (name and address) [6]

[5] The official English translation of the approved Finnish Summary of Product Characteristics has to be included. The English Summary of Product Characteristics approved during the marketing authorization process by the Finnish Medicines Agency is also acceptable.

[6] In this circumstance, permission for issuing the certificate is required from the Marketing Authorization Holder. This permission has to be provided to the authority by the applicant.

This page is only used by authorities