
Proposed suppression of the monograph on Dextromoramide tartrate (0021)
from the Ph. Eur.

Q1-4 (3631)

NPA: (47705)

Type: (l/list-dropdown)

A10 - Estonia (EE)

Please choose: (47706)

Type: (L/list-radio)

In favour of the suppression of the monograph on Dextromoramide tartrate (0021) from the Ph. Eur.

A1

If you answered 'opposed', could you please justify your reply and/or provide details of any marketing authorisations for medicinal products containing substances covered by this monograph that may exist in your country.

(47707)

Type: (T/text-long)

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Can you approve the accompanying note outlining the reason for suppression, as reproduced below? This note will be used for the public consultation:

Dextromoramide is an opioid analgesic, structurally related to methadone, and indicated in the treatment of severe pain.

The monograph *Dextromoramide tartrate (0021)* was elaborated between 1974 and 1979 (first publication in the 2nd Edition) and since then only corrections have been made. The test for related substances in this monograph is not aligned with the current Ph. Eur. policy on impurities. A TLC procedure with a limit of maximum 1.0 per cent for any spot is prescribed. Therefore, this monograph requires a complete revision.

No approved product in Europe containing dextromoramide tartrate and no manufacturers of this active substance currently active on the European market could be identified. It is therefore proposed to suppress the monograph on *Dextromoramide tartrate (0021)* from the European Pharmacopoeia.

(47709)

Type: (L/list-radio)

Yes

A1

Remarks: (47708)

Type: (T/text-long)

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