Dossier quality improvement ABIM 2019

Ctgb & HSE CRD

October 2019

Improving quality of active substance dossier
Part I: general issues

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Volkswagen e-Up!

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Biopesticides

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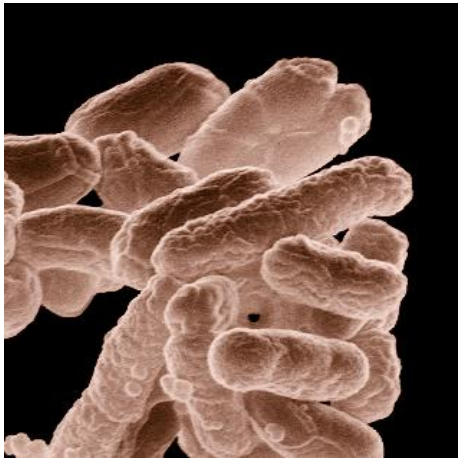
Active substance dossier

Botanical



Microorganism

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Botanical general issues

- Salvia elegans extract

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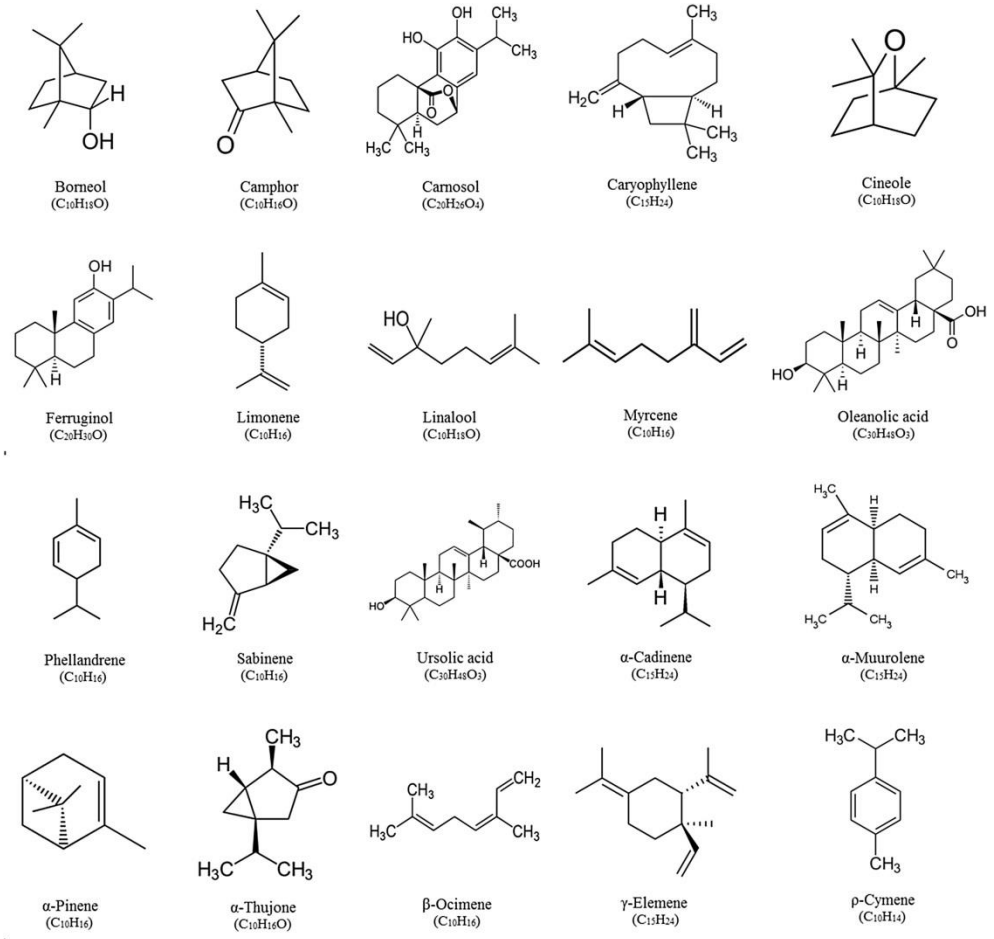
Botanical general issues



Components of Salvia officinalis; Ghorbani & Esmaeilizadeh 2017

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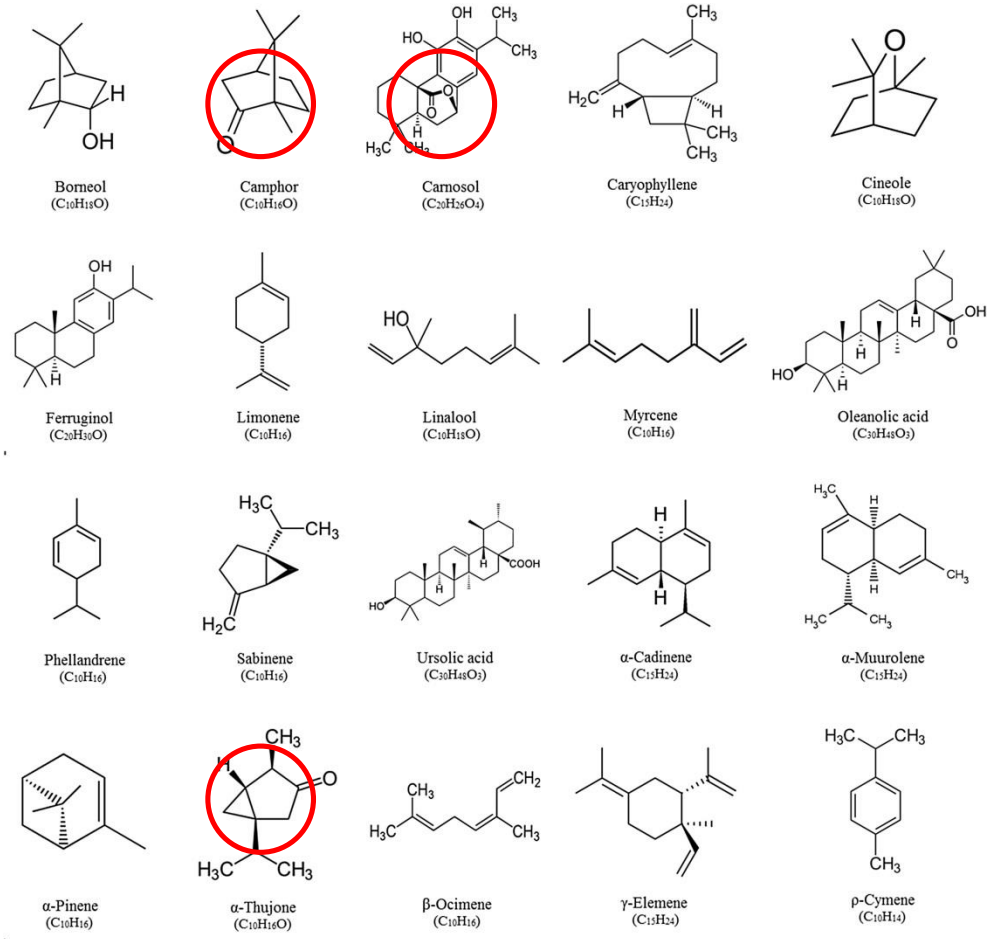
Botanical general issues



Components of Salvia officinalis; Ghorbani & Esmaeilizadeh 2017

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Botanical general issues

- make overview table for whole dossier
- address all issues, even if you know the compound is not in your active substance
- give information on all components; prevent loose ends

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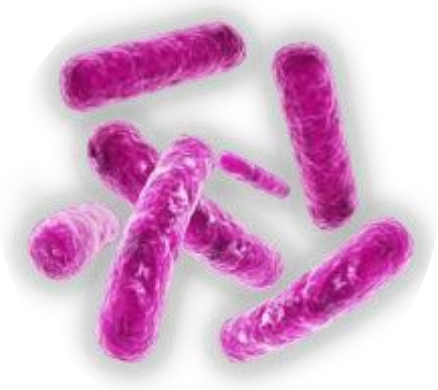
Microorganism general issues

- *Bacillus amyloliquefaciens*



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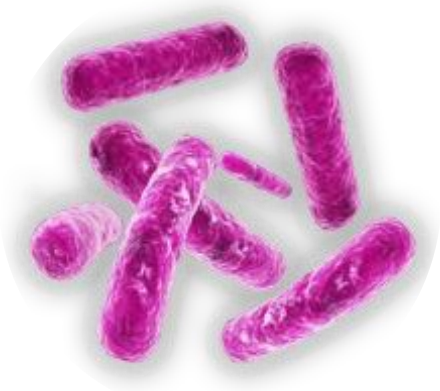
Microorganism general issues

- *Bacillus other name?*



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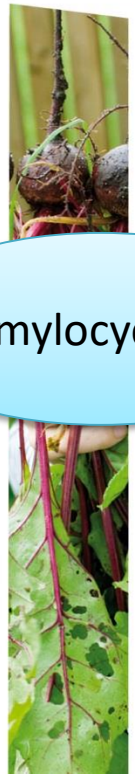
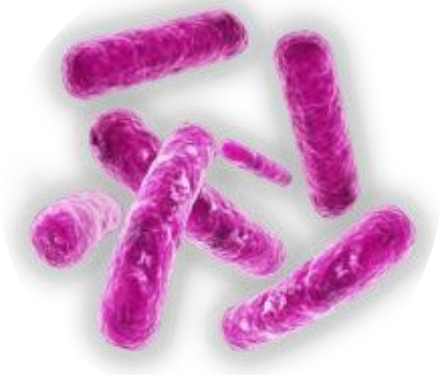
Microorganism general issues



macrolactin

bacillaene

bacilysin



bacillomycin D

bacillibactin

plantazolicin

amylocyclicin

difficin

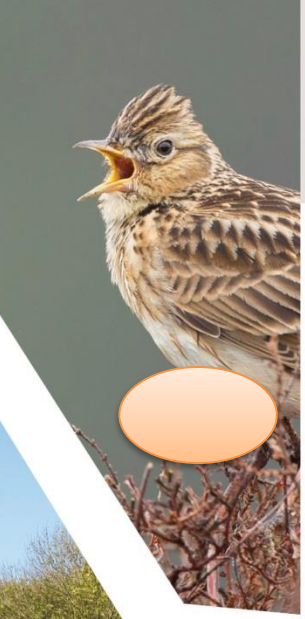
fengycin

Orphan nrps 1

T3pks

lci

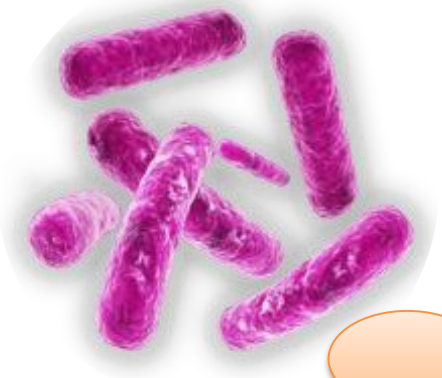
Microorganism general issues



macrolactin

bacillaene

bacilysin



bacillomycin D

bacillibactin

plantazolicin

amylocyclicin

difficin

fengycin

Orphan nrps 1

T3pks

lci



Microorganism general issues

- list all identified metabolites
- VFDF?
- WGS data: ‘no genes were found’
- only subset of metabolites is addressed

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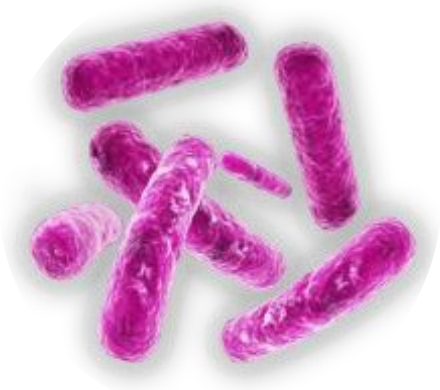
Microorganism general issues



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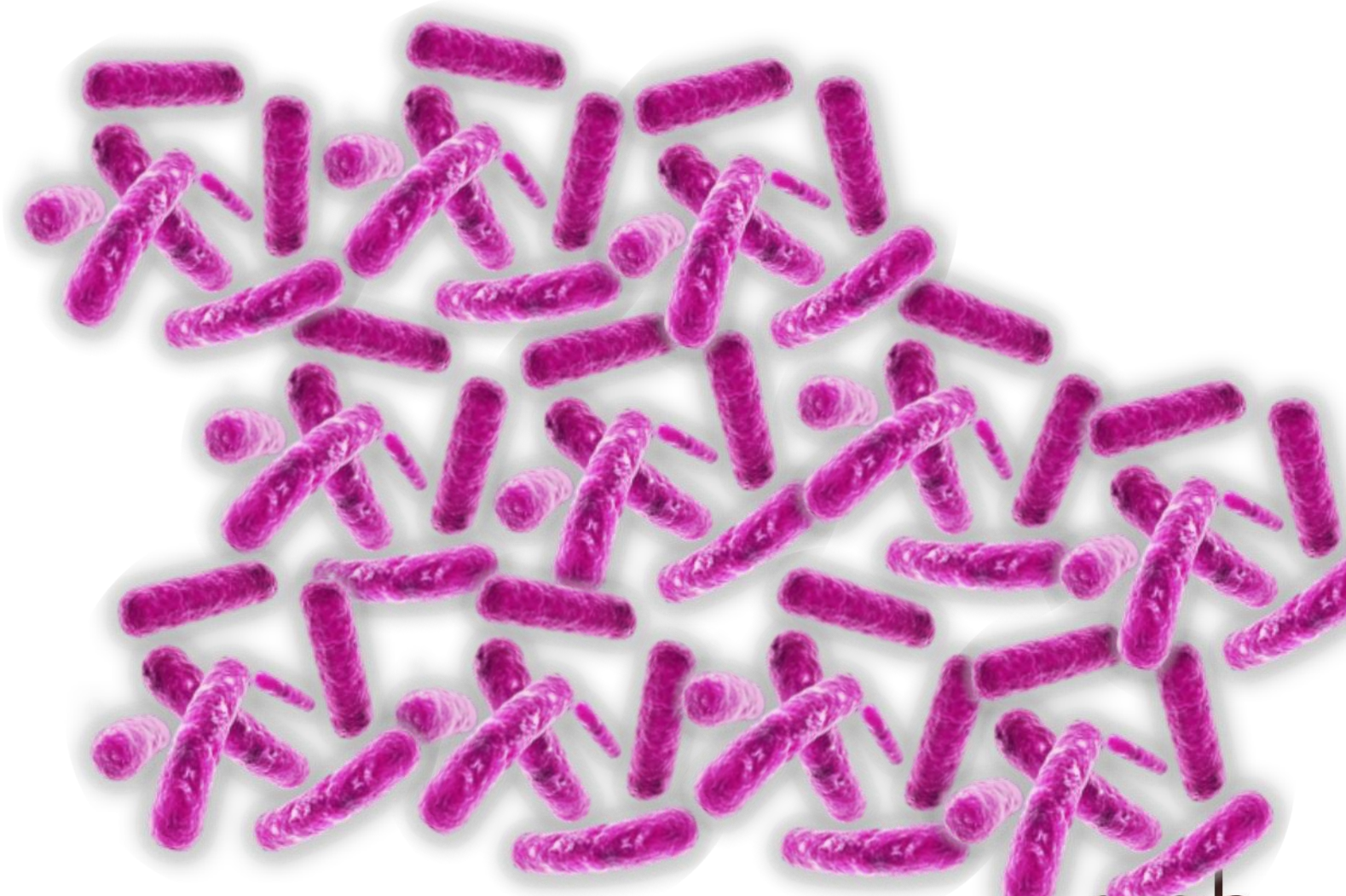
Microorganism general issues



Efficacy trials (field/greenhouse)

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Microorganism general issues

- Use taxonomy; explain bridging for every study
- Overview table for metabolites
- Get most out of efficacy trials

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Data requirements

- Should ensure that all information is submitted in dossier to demonstrate safe use
- If not, add information at the best matching data requirement
- prepare overview tables and use cross references to avoid contradictions

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