We see that we get somwehat different results in the parameter space. The acceptable region with blue dots (design space) get a more rounded corner. The vertical left line is also more rugged.

With much more simulations we could get a better idea of the probablity that a batch is accepted and determine the design space in proabilistic sense.

3 Summary

We have worked through a simple example of evaluation of batch cuöture with given acceptance criteria and how that criteria can be translated to acceptable variation in process parameters, i.e. the design space.

In the deterministic case we get a rather clear cut design space.

In the more realistic case with subsrate measurment noise included we get a more complicated design space, but still similar.

The stochastic model introduce erorrs both due to the added normal noise in the substrate concentration, and due to the fact that we use time discrete system for the noise. The impact of the time discrete check when batch has ended can be made smaller by chosing a smaller sample intervall. This was not studied here and is left for the interested reader.

Note...

References

[1] Axelsson J.P. and A. Elsheikh: “An example of sensitivity analysis of a bioprocess using Bioprocess Library for Modelica”, Proceedings MODPROD, Linköping, Sweden 2019, see presentation here.

Appendix

```
describe('parts')
```

```
['bioreactor', 'bioreactor.culture', 'monitor', 'sensor']
```