

MGF-400105
Bemotrizinol (BEMT)

3.2.P.8.3 Stability data

Stability testing procedure for the investigational drug Petrolatum formulation (batch and lot number SU-E-101413-82) is performed at two different temperatures: 4°C and 23°C. Relative humidity is not controlled as the samples are stored in closed and airtight containers. Relevant endpoints for assessing the stability of a Petrolatum formulation are:

- a) physical appearance by visual assessment
- b) color by visual assessment
- c) smell by olfactory assessment
- d) phase separation and homogenous dispersion by microscopy analysis

The results from stability testing are provided in the table below and are also representative for the production lot 004 as indicated in [section 3.2.P.8.3](#).

Table 1 in section 3.2.P.8.3: Petrolatum formulation (SU-E-101413-82)

Manufacturing data: 07 October 2021; batch number: 001; program initiation date: 07 October 2021

Parameters /Occurrence		Physical appearance	Color	Smell	Microscopy
Start 07 October 2020	RT	Opaque dispersion	Yellowish	characteristic	n.d.
	4°C	n.d.	n.d.	n.d.	n.d.
1 month 04 November 2020	RT	ok	ok	ok	ok
	4°C	ok	ok	ok	ok
2 months 02 December 2020	RT	ok	ok	ok	ok
	4°C	ok	ok	ok	ok
3 months 04 January 2021	RT	ok	ok	ok	ok
	4°C	ok	ok	ok	ok
6 months 29 March 2021	RT	ok	ok	ok	ok
	4°C	n.d.	n.d.	n.d.	n.d.

n.d.:
not

determind; n.a.: not applicable