

MGF-400105
Bemotrizinol (BEMT)

3.2.P.8.3 Stability data

Stability testing procedure for the investigational drug sunscreen oil vehicle (batch and lot number SU-E-101413-91) is performed at four different temperatures: 4°C – 23°C - 40°C – 50°C. Relative humidity is not controlled as the samples are stored in closed and airtight containers. Relevant endpoints for assessing the stability of a sunscreen are:

- physical appearance by visual assessment
- color by visual assessment
- smell by olfactory assessment
- viscosity analysis by Brookfield
- phase separation and crystal formation by microscopy analysis

The results from stability testing are provided in the table below.

Table 1 in section 3.2.P.8.3: Sunscreen oil vehicle (SU-E-101413-91)

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

Parameters /Occurrence		Physical appearance	Color	Smell	Viscosity [mPas]	Microscopy
Start 07 December 2021	RT	Transparent	Yellow	characteristic	<100	n.d.
	4°C	n.d.	n.d.	n.d.	n.d.	n.d.
	40°C	n.d.	n.d.	n.d.	n.d.	n.d.
	50°C	n.d.	n.d.	n.d.	n.d.	n.d.
1 month 04 January 2022	RT	ok	ok	ok	<100	ok
	4°C	ok	ok	ok	n.d.	ok
	40°C	ok	ok	ok	n.d.	ok
	50°C	ok	ok	ok	n.d.	ok
2 months 01 February 2022	RT	ok	ok	ok	<100	ok
	4°C	ok	ok	ok	n.d.	ok
	40°C	ok	ok	ok	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.
3 months 04 March 2022	RT	ok	ok	ok	<100	ok
	4°C	ok	ok	ok	n.d.	ok
	40°C	ok	ok	ok	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.
6 months 03 June 2022	RT	ok	ok	ok	<100	ok
	4°C	n.a.	n.a.	n.a.	n.a.	n.a.
	40°C	n.a.	n.a.	n.a.	n.a.	n.a.
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.

n.d.: not determined; n.a.: not applicable