

MGF-400105
Bemotrizinol (BEMT)

3.2.P.8.3 Stability data

Stability testing procedure for the investigational drug Oil-in-water (O/W) emulsion (batch and lot number SU-E-101413-87) 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:

- a) physical appearance by visual assessment
- b) color by visual assessment
- c) smell by olfactory assessment
- d) viscosity analysis (RV 5, 10rpm)
- e) pH
- f) phase separation and crystal formation by microscopy analysis

The results from stability testing are provided in the table below and are also representative for the production lots 22010OEV and 22011OEV as indicated in [section 3.2.P.8.3](#).

Table 1 in section 3.2.P.8.3: Oil-in-water (O/W) emulsion (SU-E-101413-87)

Manufacturing data: 03 August 2021; batch number: 001; program initiation date: 03 August 2021

Parameters / Occurrence		Physical appearance	Color	Smell	Viscosity [mPas]	pH	Microscopy
Start 03 August 2021	RT	Emulsion	White – off-white	characteristic	24'480	6.35	n.d.
	4°C	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	40°C	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	50°C	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
1 month 31 August 2021	RT	ok	ok	ok	34'800	6.34	ok
	4°C	ok	ok	ok	n.d.	n.d.	ok
	40°C	ok	ok	ok	n.d.	n.d.	ok
	50°C	ok	ok	ok	n.d.	n.d.	ok
2 months 28 September 2021	RT	ok	ok	ok	37'280	6.31	ok
	4°C	ok	ok	ok	n.d.	n.d.	ok
	40°C	ok	ok	ok	n.d.	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
3 months 26 October 2021	RT	ok	ok	ok	37'640	6.32	ok
	4°C	ok	ok	ok	n.d.	n.d.	ok
	40°C	ok	ok	ok	n.d.	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
6 months 26 October 2021	RT	ok	ok	ok	37'640	6.32	ok
	4°C	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	40°C	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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