

MGF-400105
Bemotrizinol (BEMT)

3.2.P.8.3 Stability data

Stability testing procedure for the investigational drug Water-in-oil (W/O) emulsion (batch and lot number SU-E-101413-89) 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 by Brookfield
- e) 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 22017OEV and 22018OEV as indicated in [section 3.2.P.8.3](#).

Table 1 in section 3.2.P.8.3: Water-in-oil (W/O) emulsion (SU-E-101413-89)

Manufacturing data: 04 August 2021; batch number: 001; program initiation date: 04 August 2021

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Parameters /Occurrence		Physical appearance	Color	Smell	Viscosity [mPas]	Microscopy
Start 04 August 2021	RT	Emulsion	White to off-white	Characteristic	11'200	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 01 September 2021	RT	ok, slight oil release	ok	ok	12'360	ok
	4°C	ok	ok	ok	n.d.	Few, small crystals visible
	40°C	ok	ok	ok	n.d.	ok
	50°C	ok	ok	ok	n.d.	ok
2 months 29 September 2021	RT	ok, slight oil release	ok	ok	14'680	ok
	4°C	ok	ok	ok	n.d.	Few, small crystals visible
	40°C	ok	ok	ok	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.
3 months 27 October 2021	RT	ok, slight oil release	ok	ok	15'640	ok
	4°C	ok	ok	ok	n.d.	Few, small crystals visible
	40°C	ok	ok	ok	n.d.	ok
	50°C	n.a.	n.a.	n.a.	n.a.	n.a.
6 months 13 January 2022	RT	ok, slight oil release	ok	ok	15'580	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 determind; n.a.: not applicable