

Starting material specification			SPS-KO-14-0028-03 (CIIC-KO-14-0028-03)
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Effective date: 16.04.2020	Supersede: SPS-KO-14-0028-02 (CIIC-KO-14-0028-02) dated 18.02.2019	Valid until: <u>unlimited</u>	Reason: actualization

Benzocaine BENZOCAINE Quality control according to Normative Documentation ND RB 1271S-2019 (НД РБ 1271C-2019)

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Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
1	Application			Heparin Plus, ointment for external use Menovazin, solution for external use
2	Quality parameter name: 2.1 Appearance (properties) 2.2 Identification A. IR spectrum 2.3 Related substances: - unspecified impurities - total impurities 2.4. Loss on drying 2.5 Sulphated ash 2.6 Assay 2.7 Microbial purity: - total aerobic microbial count (TAMC) and total yeast and mould count (TYMC), in total - bile-tolerant gram-negative bacteria or bacteria of the <i>Enterobacteriaceae</i> family	Visual, State Pharmacopoeia of the Republic of Belarus II, 1, 5.11 State Pharmacopoeia of the Republic of Belarus II, volume 1, 5.9 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.2.24 State Pharmacopoeia of the Republic of Belarus II, volume 2, 2.2.29 State Pharmacopoeia of the Republic of Belarus II, volume 2, 2.2.32 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.4.14 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.5.8 State Pharmacopoeia of the Republic of Belarus II, volume 1, 2.6.12, 2.6.13	SOP-KO-14-102 (COП-KO-14-102) Section “Identification A” of Normative Documentation ND RB 1271S-2019 (HД ПБ 1271C-2019) Section “Related substances” Normative Documentation ND RB 1271S-2019 (HД ПБ 1271C-2019) Section “Loss on drying” Normative Documentation ND RB 1271S-2019 (HД ПБ 1271C-2019) Section “Sulphate ash” Normative Documentation ND RB 1271S-2019 (HД ПБ 1271C-2019) Section “Assay” Normative Documentation ND RB 1271S-2019 (HД ПБ 1271C-2019) AM-12-0028 (AM-12-0028) MMU-MI-12-118 (MMY-MИ-12-118)	White or off-white crystalline powder or colourless crystals. Very slightly soluble in water, freely soluble in 96% alcohol. Possesses polymorphism. A. IR transmission spectrum of the test sample should correspond to the IR transmission spectrum of benzocaine RS (EP CRS) or the spectrum shown in Figure 1. Not more than 0.10 % Not more than 0.2% Not more than 0.5 % Not more than 0.1% Not less than 99.0% and not more than 101.0% calculated on an anhydrous basis State Pharmacopoeia of the Republic of Belarus II, volume 1, 5.1.4 Not more than 10 ² CFU/g Absence in 1 g

“BZMP” JSC

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Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
	- <i>Pseudomonas aeruginosa</i> - <i>Staphylococcus aureus</i>			Absence in 1 g Absence in 1 g
3	Sampling	—	In accordance with the Standard Operating Procedure: COП-KO-12-024 (SOP-KO-12-024); COП-KO-14-057(SOP-KO-14-057)	—
4	Control sampling volume	—	—	AL: 16.0g MBL: 30.0 g
5	Storage conditions	—	—	Store in a place protected from light at a temperature not exceeding 25 °C
6	Shelf life	—	—	2 years
7	Packaging	—	—	Polyethylene bags, multi-layer paper bags placed in cardboard drums, and other types of packaging that ensure the safety of raw materials throughout their shelf life.
8	Manufacturer	—	—	Hangzhou Famo Pharmtech Co., Ltd., China
9	Code	—	—	120224