

Starting material specification			SPS-KO-14-0241/1-02 (CTIC-KO-14-0241/1-02)
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Effective date: 20.03.2024	Supersede: SPS-KO-14-0241/1-01 (CTIC-KO-14-0241/1-01) dated 28.10.2016	Valid until: <u>unlimited</u>	Reason: actualization

## Articaini hydrochloridum ARTICAINE HYDROCHLORIDE

### Quality control according to Normative Documentation ND RB 1663S-2016 (НД РБ 1663C-2016)

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Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
1	Application	—	—	Articaine with epinephrine, injection solution (40 mg + 0.005 mg)/ 1 ml for RB
2	Quality parameter name: 2.1 Appearance (properties)  2.2 Identification: C. UV spectrophotometry  B. Infrared absorption spectrophotometry  C. Thin layer chromatography  D. Reaction (a) to chlorides  2.3 Solution clarity  2.4 Solution colour  2.5 pH  2.6 Related substances: - impurity A - unspecified impurities - total of unspecified impurities	Visual, State Pharmacopoeia of Republic of Belarus II, 5.11  State Pharmacopoeia of the Republic of Belarus II, 2.2.25  State Pharmacopoeia of the Republic of Belarus II, 2.2.24  State Pharmacopoeia of the Republic of Belarus II, 2.2.27  State Pharmacopoeia of the Republic of Belarus II, 2.3.1  State Pharmacopoeia of the Republic of Belarus II, 2.2.1.  State Pharmacopoeia of the Republic of Belarus II, 2.2.2, method II State Pharmacopoeia of the Republic of Belarus II, 2.2.3  State Pharmacopoeia of the Republic of Belarus II, 2.2.29	SOP-KO-14-102 (COII-KO-14-102)  Section “Identification A” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Identification B” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Identification C” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Identification D” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Solution clarity” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Solution colour” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “pH” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)  Section “Related substances” of Normative Documentation ND RB 1663S-2016 (HД PБ 1663C-2016)	White or off-white crystal powder. Freely soluble in water and 96% alcohol  A. In the wavelength range from 200 nm to 350 nm, the solution has an absorption maximum at 272 nm. The specific absorption index at maximum is from 290 to 320 B. The infrared transmission spectrum of the test sample should correspond to the transmission spectrum of articaine hydrochloride RS (EP CRS) or the spectrum shown in Figure 1 B. Chromatogram of the test solution show a main spot, corresponding to the main spot in the chromatogram of the reference solution in position and size. D. The test sample gives reaction (a) to chlorides  Solution S should be clear  Solution S should be coloured not more intensely than the reference standard BY(КЖ) <sub>6</sub> 4.2 to 5.2  Not more than 0.2% Not more than 0.10 % Not more than 0.5 %

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## “BZMP” JSC

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Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
	2.7 Heavy metals	State Pharmacopoeia of the Republic of Belarus II, 2.4.8, method A	Section “Heavy metals” Normative Documentation ND RB 1663S-2016 (HД РБ 1663C-2016)	Not more than 0.0005% (5 ppm)
	2.8 Loss on drying	State Pharmacopoeia of the Republic of Belarus II, 2.2.32	Section “Loss on drying” Normative Documentation ND RB 1663S-2016 (HД РБ 1663C-2016)	Not more than 0.5 %
	2.9 Sulphated Ash	State Pharmacopoeia of the Republic of Belarus II, 2.4.14	Section “Sulphate ash” Normative Documentation ND RB 1663S-2016 (HД РБ 1663C-2016)	Not more than 0.1%
	2.10 Assay	State Pharmacopoeia of the Republic of Belarus II, 2.2.20.	Section “Assay” Normative Documentation ND RB 1663S - 2016 (HД РБ 1663C - 2016)	Not less than 98.5% and not more than 101.0% on a dry substance basis
	2.11 Bacterial endotoxins	State Pharmacopoeia of the Republic of Belarus II, 2.6.14	Test Method AMBE-12-0241/1 SOP-KO-12-059 (COП-KO-12-059)	Not more than 0.7 EU per 1 mg of articaine hydrochloride
	2.12 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 - <i>Pseudomonas aeruginosa</i> - <i>Staphylococcus aureus</i>	State Pharmacopoeia of the Republic of Belarus II, 2.6.12, 2.6.13	Test method AM-12-0241/1 SOP-KO-12-197 (COП-KO-12-197)	State Pharmacopoeia of the Republic of Belarus II, 5.1.4  Not more than 10 <sup>2</sup> CFU/g  Absence in 1 g  Absence in 1 g Absence in 1 g
3	Sampling		In accordance with the Standard Operating Procedure: SOP-KO-14-057 (COП-KO-14-057), SOP-KO-12-024 (COП-KO-12-024)	
4	Control sampling volume	—	—	AL: 38.0 g MBL: 31.0 g
5	Storage conditions	—	—	In a place protected from light
6	Shelf life	—	—	5 years
7	Packaging	—	—	Double polyethylene bags placed in cardboard drums
8	Manufacturer	-	—	S.I.M.S.S.r.l. (Societa Italiana Medicinali Scandicci), Italy
9	Code	—	—	120173