

OJSC "BZMP"			
Starting materials Specification		AL	SPS-CO-14-0460-03
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Effective from: 03.03.2025	Introduced to replace: SPS-CO-14-0460-02 dated 01.03.2024	Valid until: <u>unlimited</u>	Reason: actualization

**ALLOPURINOL**  
**Allopurinolum**  
**ALLOPURINOL**  
**Quality control according to RD of the RB 2135C-2020**

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Sr. No.	Test parameters	Methods	Test methods	Acceptance criteria
1	Application	-	-	To develop manufacturing of Allopurinol, 100 mg and 300 mg tablets
2	Quality parameters:			
	2.1 Characteristics	Visual SPh of the RB II, 5.11	SOP-CO-14-102	White or almost white powder. Very slightly soluble in water and 96% alcohol. Soluble in dilute solutions of alkali metal hydroxides.
	2.2 *Identification			
	A. Ultraviolet and visible spectroscopy	SPh of the RB II, 2.2.25	Section Identification A RD of the RB 2135C-2020	A. The UV spectrum of the test solution from 220 nm to 350 nm have a maximum at 250 nm, minimum at 231 nm. $A_{231}/A_{250}$ is from 0.52 to 0.62
	B. Infrared spectroscopy	SPh of the RB II, 2.2.24	Section Identification B RD of the RB 2135C-2020	B. The transmission infrared spectrum of the test sample corresponds to the transmission infrared spectrum of allopurinol CRS (EP CRS)
	C. Qualitative test	SPh of the RB II, 2.3.1	Section Identification C RD of the RB 2135C-2020	C. It produces a white precipitate that does not dissolve when 5 mL of ammonia is added
	D. Thin layer chromatography (TLC)	SPh of the RB II, 2.2.27	Section Identification D RD of the RB 2135C-2020	D. The main spot on the chromatogram obtained from test solution corresponds in location and size to the main spot on the chromatogram obtained from reference solution
	2.3 Related substances:	SPh of the RB II, 2.2.29	Section Related substances RD of the RB 2135C-2020	NMT 0.2% NMT 0.1% NMT 0.1% NMT 0.10%
	- impurity A			
	- impurity B			
	- impurity C			
	- unspecified impurities			
	- total impurities, except impurities A, B, C			NMT 0.3%
	2.4 Impurities D and E	SPh of the RB II, 2.2.29	Section Impurities D and E RD of the RB 2135C-2020	NMT 0.1% NMT 0.1%
	- impurity D			
	- impurity E			
	2.5 Impurity F	SPh of the RB II, 2.2.29	Section Impurity F RD of the RB 2135C-2020	NMT 2.5 ppm

Sr. No.	Test parameters	Methods	Test methods	Acceptance criteria
	2.6 Loss on drying	SPh of the RB II, 2.2.32	Section Loss on drying RD of the RB 2135C-2020	NMT 0.5%
	2.7 Sulfated ash	SPh of the RB II, 2.4.14	Section Sulfated ash RD of the RB 2135C-2020	NMT 0.1%
	2.8 Residue organic solvents: - formamide	SPh of the RB II, 2.4.24, 2.2.28	Section Residue organic solvents RD of the RB 2135C-2020	SPh of the RB II, 5.4 NMT 220 ppm
	2.9 * Particle size: - d <sub>10</sub> - d <sub>50</sub> - d <sub>90</sub>	SPh of the RB II, 2.9.31	Manufacturer's method	MNT 20 µm MNT 30 µm MNT 40 µm
	2.10 Assay	SPh of the RB II, 2.2.29	Section Assay RD of the RB 2135C-2020	From 97.0% to 102.0% on the dried basis
	2.11 Microbiological Purity: - total amount of aerobes (TAA) - total amount of fungi (TAF) - <i>Escherichia coli</i>	SPh of the RB II, 2.6.12, 2.6.13	Test method AM-12-0460 SOP-CO-12-197	SPh of the RB II, 5.1.4 10 <sup>3</sup> CFU/g 10 <sup>2</sup> CFU/g Absence in 1 g
3	Sampling	-	According to the standard operational procedure: SOP-CO-14-057, SOP-CO-12-024	-
4	Control sample volume	-	-	AL: 30.0 g MBL: 20.0 g
5	Storage conditions	-	-	In a tightly closed container in a well-ventilated area
6	Self-life	-	-	5 years
7	Packing	-	-	Double polyethylene bags inserted in cardboard drums
8	Manufacturing	-	-	Union Quimico Farmaceutica, S.A., Spain
9	Code	-	-	900120 900121

\* Identification tests from each packaging unit before release for production shall be carried out in accordance with SOP-KO-14-056 by the method of SPh RB 2, 2.2.40 Near infrared spectrophotometry or SPh RB 2 2.2.48 Raman spectrometry. Acceptance criteria: «The spectrum of the test sample must correspond to the spectrum of allopurinol entered into the library of spectra of the NIR analyzer or vibrational (Raman) scattering spectrometer».

\*\* Additional requirement of OJSC "BZMP"