

Raw material specification			SPS-KO-14-0462-05 (CПC-KO-14-0462-05)
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Effective date: 07.03.2024	Supersede: SPS-KO-14-0462-04 (CПC-KO-14-0462-04) dated 22.08.2022	Valid until: <u>unlimited</u>	Reason: update

IRON (III) HYDROXIDE POLYMALTOSE COMPLEX, Ferric hydroxide polymaltose complex, quality control according to Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1

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Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
1	Use	—	—	CompliFer® 50 mg/ml, drops for internal use
2	Quality parameter name: 2.1 Appearance (properties) 2.2 Identification: A. Combined iron (III) B. Polymaltose 2.3 pH 2.4 Loss on drying 2.5 Sodium chloride 2.6 Free iron (III) 2.7 Molecular weight distribution 2.8 Assay: - iron (III)	Visual, State Pharmacopoeia of Republic of Belarus II, 5.11 In accordance with the Normative Documentation In accordance with the Normative Documentation State Pharmacopoeia of the Republic of Belarus II, 2.2.3 State Pharmacopoeia of the Republic of Belarus II, 2.2.32 In accordance with the Normative Documentation In accordance with the Normative Documentation State Pharmacopoeia of the Republic of Belarus II, 2.2.29, 2.2.30 In accordance with the Normative Documentation	SOP-KO-14-102 (COП-KO-14-102) Section "Identification A", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "Identification B", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "pH", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "Loss on drying", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "Sodium chloride", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "Free iron (III)", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section "Molecular mass distribution", Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1 Section “Assay”, Normative Documentation ND RB 2222S-2021 (HД ПБ 2222C-2021), amend. No. 1	Brown or dark brown powder, odourless. Soluble in water, practically insoluble in organic solvents. A. The solution turns an intense red colour. B. The test sample passes the Assay test as specified in the section “Purity”. 5.5 to 7.5 Not more than 8.0% Not more than 3.0%, calculated on an anhydrous basis Not more than 0.05% Mass-average molecular mass (Mw) of dextran in iron (III) hydroxide polymaltose complex should be in the range of 110,000 - 270,000 daltons Not less than 26.0% and not more than 36.0%, calculated on an anhydrous basis

Sr. No.	Control parameters	Methods	Test methods	Acceptance criteria
	- polymaltose 2.9 Microbiological purity: - total aerobic microbial count (TAMC) - total yeast and moulds count (TYMC) - <i>Escherichia coli</i>	In accordance with the Normative Documentation State Pharmacopoeia of the Republic of Belarus II, 2.6.12, 2.6.13	Section “Assay”, Normative Documentation ND RB 2222S-2021 (HД PБ 2222C-2021), amend. No. 1 Test procedure AM-12-0462 SOP-KO-12-197 (COП-KO-12-197)	Not less than 25.0% and not more than 50.0%, calculated on an anhydrous basis State Pharmacopoeia of the Republic of Belarus II, 5.1.4 10 ³ CFU/g 10 ² CFU/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	Sampling	—	—	Analytical laboratory: 115.0 g Microbiological laboratory 20.0 g
5	Storage conditions	—	—	In a tightly closed container at a temperature not exceeding 25 °C
6	Shelf life	—	—	5 years
7	Packaging	—	—	Double polyethylene bags placed in cardboard drums
8	Manufacturer	—	—	Biofer S.p.A., Italy
9	Code	—	—	120333