

List of critical imports

No	Name of the pharmaceutical substance	INN in latin	HS code (10 signs)	Manufacturer, country	Demand in a year
1	Potassium orotat	Potassium orotat	2933599500	Noveon, USA	200 kg
2	Procainamide (Novocainamide)	Procainamide	2922498500	Organika a.s., Russian Federation	56 kg
3	Promedol	Trimeperidine	2933330009	State enterprise Chemical Technology Research, Ukraine	20 kg
4	Sufentanil citrate	Sufentanil	2933330009	Macfarlan Smith Limited, UK	15 g
5	Tetrahydrozoli hydrochloride	Tetrahydrozoline hydrochloride	2933499000	PCAS Finland Oy, Finland	0,5 kg
6	Fentanyl	Fentanyl	2933330009	Macfarlan Smith Limited, UK	65 g

F&V "BELMEDPREPARATY"	SP-0.2058.05-2-439
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POTASSIUM OROTATE	

Manufacturer : *Noveon , USA*

Provider:

According to the list of approved suppliers

Selection is carried out in accordance with: SOP-0.2200.00.00-2-001

Internal code

1	1	3	2	5
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Quantity (weight, volume) of sample for testing:

According to the approved
sampling plan


No p/p	The name of indicators	Permissible limits	Techniques control
1.	Description	White or almost white crystalline powder	Visual ND RB 0117C-2016
2.	Authenticity (identification)	A. The IR spectrum of the test substance must correspond to IR spectrum in Fig. 1 ND B. Qualitative reaction C. The UV spectrum of the solution should have a maximum absorption at a wavelength of 285 nm	State Fund of the Republic of Belarus II , vol. 1, 2.2.24 ND RB 0117C-2016 ND RB 0117C-2016 State Fund of the Republic of Belarus II , vol. 1, 2.2.25 ND RB 0117C-2016
3.	Transparency	The solution must be transparent	State Fund of the Republic of Belarus II , vol. 1, 2.2.1 ND RB 0117C-2016
4.	Chroma	The solution should be colorless	State Fund of the Republic of Belarus II , vol. 1, 2.2.2, method II , ND RB 0117C-2016
5.	Acidity or alkalinity	Must stand the test	ND RB 0117C-2016
6.	Amino acids	The solution should not turn blue-violet.	ND RB 0117C-2016
7.	Chlorides	No more than 100 ppm	State Fund of the Republic of Belarus II , vol. 1, 2.4.4 ND RB 0117C-2016
8.	Heavy metals	No more than 20 ppm	State Fund of the Republic of Belarus II , vol. 1, 2.4.8, method A,

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POTASSIUM OROTATE	

9.	Weight loss on drying	No more than 0.5%	ND RB 0117C-2016 State Fund of the Republic of Belarus II , vol. 2, 2.2.32 ND RB 0117C-2016
10.	Microbiological purity: - total number of aerobes in 1 g - total number of mushrooms in 1 g - Escherichia coli in 1 g	State Fund of the Republic of Belarus II , vol. 1, 5.1.4 - 10 ³ CFU - 10 ² CFU - absence	State Fund of the Republic of Belarus II , vol. 1, 2.6.12, 2.6.13 ND RB 0117C-2016
11.	Quantitation: - potassium orotate - potassium	98.5% - 100.5% (in terms of dry matter) 19.78% - 20.28%	State Fund of the Republic of Belarus II , vol. 2, 2.2.20 ND RB 0117C-2016
12.	Storage	In a tightly sealed container. In a place protected from moisture at a temperature of 15°C to 25°C	
13.	Best before date	3 years	

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FENTANYL		

			amended. 1
7.	Heavy metals	No more than 20 ppm	State Fund of the Republic of Belarus II , vol. 1, 2.4.8, <i>method C</i> , ND RB 0935C-2015, amended. 1
8.	Sulfated ash	No more than 0.1%	State Fund of the Republic of Belarus II , vol. 1, 2.4.14 ND RB 0935C-2015, amended. 1
9.	Bacterial endotoxins	Less than 50 EU/mg	State Fund of the Republic of Belarus II , vol. 1, 2.6.14 ND RB 0935C-2015, amended. 1
10 .	Residual quantities of organic solvents: - ethanol - methanol	- no more than 2000 ppm - no more than 1000 ppm	State Fund of the Republic of Belarus II , vol. 2, 5.4, vol.1, 2.4.24 ND RB 0935C-2015, amended. 1
ele ven .	Microbiological purity: - total number of aerobes and total number of fungi (total) in 1g - gram-negative bacteria tolerant to bile, or bacteria of the Enterobacteriaceae family in 1g - Pseudomonas aeruginosa in 1g - Staphylococcus aureus in 1g	State Fund of the Republic of Belarus II , vol. 1, 5.1.4 - no more than 10 ² CFU - absence - absence - absence	State Fund of the Republic of Belarus II , vol. 1, 2.6.12, 2.6.13 ND RB 0935C-2015, amended. 1
12.	quantitation	Not less than 99.0% and not more than 101.0%, in terms of dry matter	ND RB 0935C-2015, amended. 1
13.	Storage	In a place protected from light at a temperature not exceeding 25°C	
14.	Best before date	4 years	

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FENTANYL	

Manufacturer : **Johnson Matthey Macfarlan Smith , UK**

Provider:

According to the list of approved suppliers

Selection is carried out in accordance with: SOP-0.2200.00.00-2-001


Internal code

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Quantity (weight, volume) of sample for testing:

According to the approved
sampling plan

No. p/p	The name of indicators	Permissible limits	Techniques control
1.	Description (properties)	White or almost white powder. Shows polymorphism. Practically insoluble in <i>water R</i> , easily soluble in <i>96% alcohol R</i> and <i>methanol R</i>	Visual State Fund of the Republic of Belarus II, vol. 1, 5.9 State Fund of the Republic of Belarus II, vol. 2, 1.4 ND RB 0935C-2015, amended. 1
2.	Authenticity (Identification)	The IR spectrum of the test substance must correspond to the IR spectrum of the fentanyl standard for the reference spectrum (Fig. 1 ND)	State Fund of the Republic of Belarus II, vol. 1, 2.2.24 ND RB 0935C-2015, amended. 1
3.	Transparency	The solution of the test substance must be transparent	State Fund of the Republic of Belarus II, vol. 1, 2.2.1 ND RB 0935C-2015, amended. 1
4.	Chroma	The color of the solution should be no more intense than the color of standard B(K) ₇	State Fund of the Republic of Belarus II, vol. 1, 2.2.2, <i>method II</i> , ND RB 0935C-2015, amended. 1
5.	Related impurities: - impurity A - impurity B - impurity C - impurity D - unspecified impurities - amount of impurities	- no more than 0.25% - no more than 0.25% - no more than 0.25% - no more than 0.25% - no more than 0.10% - no more than 0.5%	State Fund of the Republic of Belarus II, vol. 2, 2.2.29 ND RB 0935C-2015, amended. 1
6.	Weight loss on drying	No more than 0.5%	State Fund of the Republic of Belarus II, vol. 2, 2.2.32 ND RB 0935C-2015,

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TETRAHYDROZOLINE HYDROCHLORIDE	

			Republic of Belarus II , 2.4.14 ND RB 2069C-2020
8.	Heavy metals	No more than 0.005% (50 ppm)	State Fund of the Republic of Belarus II , 2.4.8, <i>method A</i> ND RB 2069C-2020
9.	Residual amounts of organic solvents: 2-propanol	No more than 5000 ppm	State Fund of the Republic of Belarus II , 2.2.28, 2.4.24, 5.4 ND RB 2069C-2020
10.	Related impurities: -impurity A - any other impurity -sum of impurities	-no more than 0.1% -no more than 0.1% -no more than 0.2%	State Fund of the Republic of Belarus II , 2.2.28 ND RB 2069C-2020
11.	Related impurities: - N -(2-aminoethyl)- tetrahydronaphthalen-1-yl amide (impurity 7) -1,2,3,4-tetrahydro-1- naphthoic acid (impurity 13)	-no more than 0.10% -no more than 0.10%	State Fund of the Republic of Belarus II , 2.2.29 ND RB 2069C-2020
12.	Microbiological purity: -total number of aerobes and total number of fungi (total) in 1 g - gram-negative bacteria tolerant to bile, or bacteria of the Enterobacteriaceae family in 1g - Pseudomonas aeruginosa in 1g - Staphylococcus aureus in 1g	State Fund of the Republic of Belarus II , 5.1.4 No more than 10 ² CFU Absence Absence Absence	State Fund of the Republic of Belarus II , 2.6.12, 2.6.13 ND RB 2069C-2020
13.	quantitation	From 98.0% to 101.0% in terms of dry matter	State Fund of the Republic of Belarus II , 2.2.20 ND RB 2069C-2020
14.	Storage	In an airtight container, protected from light, at a temperature not exceeding 25°C	
15.	Best before date	3 years	

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TETRAHYDROZOLINE HYDROCHLORIDE	

Manufacturer : PCAS Finland Oy , Finland

Supplier: **According to the list of approved suppliers**


Selection is carried out in accordance with **SOP-0.2200.00.00-2-001**

Internal code

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Quantity (weight, volume) of sample for testing: *According to the approved sampling plan*

No. p/p	The name of indicators	Permissible limits	Techniques control
1.	Description	White or almost white crystalline powder. Easily soluble in <i>water R</i> .	Visual, State Fund of the Republic of Belarus II , 1.4, ND RB 2069C-2020
2.	Authenticity (Identification)	A. The IR spectrum of the test substance must correspond to the IR spectrum of <i>FSO tetrizoline hydrochloride (EP CRS)</i> , or the IR spectrum presented in <i>Figure 1. ND RB 2069C-2020</i> B. In the chromatogram of the test solution, the retention time of the main peak should correspond to the retention time of the main peak in the chromatogram of the standard solution (a). C. Qualitative reaction(s) to chlorides	GF RB II . 2.2.24 ND RB 2069C-2020 State Fund of the Republic of Belarus II , 2.2.29 ND RB 2069C-2020 State Fund of the Republic of Belarus II , 2.3.1 ND RB 2069C-2020
3.	Transparency	Solution <i>S</i> must be transparent	State Fund of the Republic of Belarus II , 2.2.1 ND RB 2069C-2020
4.	Chroma	Solution <i>S</i> should be colorless	State Fund of the Republic of Belarus II , 2.2.2, <i>method II</i> ND RB 2069C-2020
5.	pH	pH of solution <i>S</i> from 4.5 to 6.5	State Fund of the Republic of Belarus II , 2.2.3 ND RB 2069C-2020
6.	Weight loss on drying	No more than 0.5%	State Fund of the Republic of Belarus II , 2.2.32 ND RB 2069C-2020
7.	Sulfated ash	No more than 0.1%	State Fund of the

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SUFENTANIL CITRATE	

	-impurity E -impurity F -impurity G -impurity H -impurity I - any unspecified impurity -sum of impurities	-no more than 0.5% -no more than 0.5% -no more than 0.5% -no more than 0.5% -no more than 0.5% -no more than 0.5% -no more than 0.10% -Not more than 1.0%	
10.	Bacterial endotoxins	Less than 100 EE/mg	State Fund of the Republic of Belarus II , vol. 1, 2.6.14 ND RB 2149C-2020
eleven.	Microbiological purity: - the total number of aerobes and the total number of fungi (total) in 1 g; - gram-negative bacteria tolerant to bile, or bacteria of the <i>Enterobacteriaceae</i> family in 1 g; - <i>Pseudomonas aeruginosa</i> in 1 g; - <i>Staphylococcus aureus</i> in 1 g	State Fund of the Republic of Belarus II , vol. 1 , 5.1.4 no more than 10 ² CFU absence absence absence	State Fund of the Republic of Belarus II , vol. 1, 2.6.12, 2.6.13, ND RB 2149C-2020
12.	quantitation	Not less than 99.0% and not more than 101.0%, calculated on dry matter	ND RB 2149C-2020
13.	Storage	In a place protected from light at a temperature not exceeding 25°C	
14 .	Best before date	5 years	

* For the Platinoids* (palladium) test, data is accepted from the certificate of the manufacturer of the pharmaceutical substance - Macfarlan Smith Limited, UK

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	SUFENTANIL CITRATE


Manufacturer : **Macfarlan Smith Limited , UK**
Supplier: **According to the list of approved suppliers**
The selection is made according to : **SOP-0.2200.00.00-2-001**

Internal code


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Quantity (weight, volume) of sample for testing: *According to the approved sampling plan*


No. p/p	Name indicators	Permissible limits	Control methods
1.	Description	White or almost white powder. Soluble in <i>water R</i> , readily soluble in <i>methanol R</i> , soluble in <i>96% alcohol R</i> .	Visual, State Fund of the Republic of Belarus II, vol. 2, 1.4 ND RB 2149C-2020
2.	Authenticity (Identification)	The IR spectrum of the test substance should correspond to the standard <i>IR spectrum of sufentanil citrate (EP CRS)</i> presented in Figure 1 ND RB 2149C-2020	State Fund of the Republic of Belarus II, vol. 1, 2.2.24 ND RB 2149C-2020
3.	Transparency	<i>Solution S</i> must be transparent	State Fund of the Republic of Belarus II, vol. 1 2.2.1, ND RB 2149C-2020
4.	Chroma	<i>Solution S</i> should be colorless or the color of the <i>solution S</i> should be no more intense than standard B(K) 9	State Fund of the Republic of Belarus II, vol. 1, 2.2.2 ND RB 2149C-2020
5.	Weight loss on drying	No more than 0.5%	State Fund of the Republic of Belarus II, vol. 1, 2.2.32, ND RB 2149C-2020
6.	Residual amounts of organic solvents: - acetone	No more than 0.3%	State Fund of the Republic of Belarus II, vol. 1, 2.2.28, 2.4.24, vol. 2, 5.4. ND RB 2149C-2020
7.	Heavy metals	No more than 20 ppm	ND RB 2149C-2020
8.	Platinoids* (palladium)	No more than 1 ppm	State Fund of the Republic of Belarus II, vol. 1, 2.2.23, <i>method I</i> , ND RB 2149C-2020
9.	Related impurities: -impurity A -impurity B -impurity C -impurity D	-no more than 0.5% -no more than 0.5% -no more than 0.5%	State Fund of the Republic of Belarus II, vol. 2, 2.2.29 ND RB 2149C-2020

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PROMEDOL	

12.	Residual quantities of organic solvents: - isopropyl alcohol - diethyl ether	- no more than 1000 ppm - no more than 1000 ppm	State Fund of the Republic of Belarus II , vol. 2, 5.4, vol.1, 2.4.24 ND RB 1544 C - 2015, change 1
13.	Propionic acid	No more than 1000 ppm	ND RB 1544 C - 2015, change 1
14.	Bacterial endotoxins	Less than 7.04 EU/mg	State Fund of the Republic of Belarus II , vol. 1, 2.6.14 ND RB 1544 C - 2015, change 1
15.	Microbiological purity: - total number of aerobes and total number of fungi (total) in 1g - gram-negative bacteria tolerant to bile, or bacteria of the Enterobacteriaceae family in 1g - Pseudomonas aeruginosa in 1g - Staphylococcus aureus in 1g	State Fund of the Republic of Belarus II , vol. 1, 5.1.4 - no more than 10 ² CFU - absence - absence - absence	State Fund of the Republic of Belarus II , vol. 1, 2.6.12, 2.6.13 ND RB 1544 C - 2015, change 1
16.	quantitation	Not less than 99.0% and not more than 101.0%, in terms of dry matter	ND RB 1544 C - 2015, change 1
17.	Storage	In a place protected from light and moisture at a temperature of 15°C to 25°C	
18.	Best before date	2 years	

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PROMEDOL	

5.	Chroma	The color of solution S should be no more intense than the color of standard B(K) ₇	State Fund of the Republic of Belarus II , vol. 1, 2.2.2, <i>method II</i> , ND RB 1544 C - 2015, change 1
6.	pH	From 4.5 to 6.0. Determine the pH of the solution S.	State Fund of the Republic of Belarus II , vol. 1, 2.2.3 ND RB 1544 C - 2015, change 1
7.	Related impurities: -1,2,5-trimethyl-4-phenylpiperidol-4 - any other impurity - amount of any other impurities	- no more than 0.3% - no more than 0.1% - no more than 2	State Fund of the Republic of Belarus II , vol. 1, 2.2.27 ND RB 1544 C - 2015, change 1
8.	Sulfates	No more than 0.05%	State Fund of the Republic of Belarus II , vol. 1, 2.4.13 ND RB 1544 C - 2015, change 1
9.	Weight loss on drying	No more than 0.5%	State Fund of the Republic of Belarus II , vol. 2, 2.2.32 ND RB 1544 C - 2015, change 1
10.	Sulfated ash	No more than 0.1%	State Fund of the Republic of Belarus II , vol. 1, 2.4.14 ND RB 1544 C - 2015, change 1
level n.	Heavy metals	No more than 0.001%	State Fund of the Republic of Belarus II , vol. 1, 2.4.8, <i>method A</i> , ND RB 1544 C - 2015, change 1

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PROMEDOL	

Manufacturer : State enterprise Research and design

Institute of Chemical Technologies Khimtekhlogiya, Ukraine

Provider:

According to the list of approved suppliers

Selection is carried out in accordance with: SOP-0.2200.00.00-2-001


Internal code

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Quantity (weight, volume) of sample for testing:


According to the approved
sampling plan

No. p/p	The name of indicators	Permissible limits	Techniques control
1.	Description	White or white with a creamy tint, finely crystalline powder, odorless or with a slight specific odor	Visual ND RB 1544 C - 2015, change 1
2.	Solubility	Easily soluble in <i>water R</i> and <i>chloroform R</i> , soluble in <i>95% alcohol R</i> , practically insoluble in <i>ether R</i> and <i>benzene R</i>	State Fund of the Republic of Belarus II, vol. 2, 1.4 ND RB 1544 C - 2015, change 1
3.	Authenticity (Identification)	A. Qualitative reaction to promedol (appearance of a red ring at the border of contact of two media) B. A yellow precipitate (promedol) appears C. Characteristic reaction (a) to chlorides D. The UV spectrum of the solution in the region from 245 nm to 290 nm has maxima at wavelengths of 251 nm, 257 nm and 263 nm (Fig. 1 ND)	ND RB 1544 C - 2015, change 1 ND RB 1544 C - 2015, change 1 State Fund of the Republic of Belarus II, vol. 2, 2.3.1 ND RB 1544 C - 2015, change 1 State Fund of the Republic of Belarus II, vol. 1, 2.2.25 ND RB 1544 C - 2015, change 1
4.	Solution transparency	Solution S must be transparent	State Fund of the Republic of Belarus II, vol. 1, 2.2.1 ND RB 1544 C - 2015, change 1


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NOVOCAINAMIDE	

No.	The name of indicators	Permissible limits	Control methods/ control methods
	<ul style="list-style-type: none"> - total number of aerobes and total number of fungi (total) - gram-negative bacteria tolerant to bile, or bacteria of the <i>Enterobacteriaceae</i> family - <i>Pseudomonas aeruginosa</i> - <i>Staphylococcus aureus</i> 	<p>5.1.4</p> <ul style="list-style-type: none"> - no more than 10² CFU/g - absence (in 1 g) - absence (in 1 g) - absence (in 1 g) 	<p><i>Republic of Belarus II, 2.6.12, 2.6.13, (ND RB 0067C-2022, amendment 1)</i></p>
14.	Bacterial endotoxins	No more than 0.175 EU/mg	<i>State Fund of the Republic of Belarus II, 2.6.14, (ND RB 0067C-2022, amendment 1)</i>
15.	quantitation	98.0% - 101.0% in terms of dry matter	<i>State Fund of the Republic of Belarus II, 2.5.8, (ND RB 0067C-2022, amendment 1)</i>
16.	Storage	In a place protected from light at a temperature not exceeding 30°C	
17.	Best before date	3 years	

Note: All regulatory documents given in this specification must be viewed with changes current as of the date of testing.

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NOVOCAINAMIDE	

No.	The name of indicators	Permissible limits	Control methods/ control methods
4.	Melting temperature	From 166°C to 170°C	<i>State Fund of the Republic of Belarus II, 2.2.14, (ND RB 0067C-2022, amendment 1)</i>
5.	Transparency	The test solution must be transparent	<i>GF RB II, 2.2.1, (ND RB 0067C-2022, amendment 1)</i>
6.	Chroma	The test solution should be colorless or the color of the solution should be no more intense than the color of standard B(K) ₆	<i>State Fund of the Republic of Belarus II, 2.2.2, method II, (ND RB 0067C-2022, amendment 1)</i>
7.	pH	From 5.6 to 6.3	<i>GF RB II, 2.2.3, (ND RB 0067C-2022, amendment 1)</i>
8.	Related impurities: - any single impurity - amount of impurities	 - no more than 0.2% - no more than 0.5%	<i>State Fund of the Republic of Belarus II, 2.2.27, (ND RB 0067C-2022, amendment 1)</i>
9.	Residual amounts of organic solvents: - 2-propanol - methanol - 1,2-dichloroethane	 - no more than 1000 ppm - no more than 500 ppm - no more than 5 ppm	<i>State Fund of the Republic of Belarus II, 2.2.28, 5.4, (ND RB 0067C-2022, amendment 1)</i>
10.	Weight loss on drying	No more than 0.5%	<i>State Fund of the Republic of Belarus II, 2.2.32, (ND RB 0067C-2022, amendment 1)</i>
11.	Sulfated ash	No more than 0.1%	<i>State Fund of the Republic of Belarus II, 2.4.14, (ND RB 0067C-2022, amendment 1)</i>
12.	Heavy metals	No more than 20 ppm	<i>State Fund of the Republic of Belarus II, 2.4.8, method C, (ND RB 0067C-2022, amendment 1)</i>
13.	Microbiological purity:	<i>State Fund of the Republic of Belarus II,</i>	<i>State Fund of the</i>

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NOVOCAINAMIDE	

Manufacturer: JSC "Organika" Russian Federation, Novokuznetsk

Provider: according to the approved "List of suppliers / manufacturers of starting and packaging materials"

The selection is made according to: SOP-0.2200.00.00-2-001

Internal code:

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Quantity (weight, volume) of sample for testing:

according to the approved "Sampling Plan"

No.	The name of indicators	Permissible limits	Control methods/ control methods
1.	Description	Crystalline powder of white or white with a slight yellowish tint. Hygroscopic.	Visual (ND RB 0067C-2022, amendment 1)
2.	Solubility	Very easily soluble in <i>water R</i> , easily soluble in <i>alcohol R 96%</i> , slightly soluble in <i>chloroform R</i> and <i>acetone R</i>	<i>State Fund of the Republic of Belarus II</i> , 1.4, (ND RB 0067C-2022, amendment 1)
3.	Authenticity (Identification)	A. The IR spectrum of the test substance in the region from 4000 cm ⁻¹ to 650 cm ⁻¹ must correspond to the IR spectrum of the procainamide hydrochloride sample standard (EP CRS) or IR spectrum shown in Fig. 1 ND B. The ultraviolet absorption spectrum of the test solution in the region from 220 to 350 nm should have an absorption maximum at a wavelength of 273 ± 2 nm. The specific absorption rate at the absorption maximum should be in the range of 580 up to 610. C. Characteristic reaction to primary aromatic amines. D. Characteristic reaction (a) to chlorides. E. A cherry red color should appear.	<i>State Fund of the Republic of Belarus II</i> , 2.2.24, (ND RB 0067C-2022, amendment 1) <i>State Fund of the Republic of Belarus II</i> , 2.2.25, (ND RB 0067C-2022, amendment 1) <i>GF RB II</i> , 2.3.1, (ND RB 0067C-2022, amendment 1) <i>GF RB II</i> , 2.3.1, (ND RB 0067C-2022, amendment 1) ND RB 0067C-2022, amendment 1