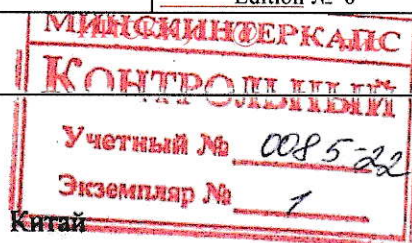


UE "Minskintercaps"		
Specification for substance	SPF-S-70	p 1/2
Allocation: PO (1), OMTC (1), HML (2+1 in electronic form), TB (1),a		Edition № 6
Substance name МНН	Indapamide	



Inner code: 66 - C

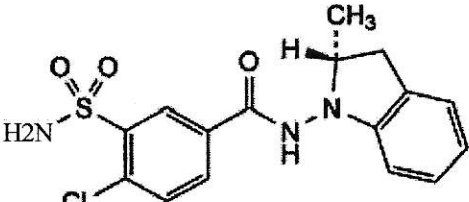
Name ND for substance:

НД RB 0576C-2021 Substance

manufacturer: Suzhou Lixin Pharmaceutical Co., Ltd., Sampling method

Китай

SOP MIC 088; EP II, т.1, п. # 1.7

№ п/п	Test	Requirements	Method	Note
1	Formula Chemical name M.m.	 C₁₆H₁₆ClN₃O₃S 4-chloro-N-[(2RS)-2-methyl-2,3-dihydro-1H-indol-1-yl]-3-sulfamoylbenzamide 365,8 and enantiomer		
2	Description (properties)	White or off-white powder. Practically insoluble in water, soluble in alcohol, slightly soluble in ether.	Visual	
3	Particle size	D90: 10-30 mkm.	Laser diffraction radiation PH Belarus II, 2.9.31	Manufacturer certificate
4	Authenticity (identification) First identification: B Second identification: A,C,D A. UV spectrum	The UV spectrum taken in the range 220-350 nm should have a maximum at a wavelength of 242 ± 2 nm and two additional peaks at wavelengths of 279 nm and 287 nm. The specific absorption rate at the maximum is 590-630	Absorption spectrophotometry in the ultraviolet and visible areas PH Belarus II, 2.2.25	
	B. IR-spectrum	corresponds to IR spectrum of the IR spectrum of the PRS indapamide a	Absorption spectrophotometry PH Belarus II, 2.2.24	
	C. TLC	The main spot on the chromatogram the test solution should be similar in location and size to the main spot on the chromatogram of the reference solution (a)	TLC PH Belarus II, 2.2.27	
	#D. LC	- the retention time of the main peak in the Chromatogram of the test solution obtained, During the test "Assey" should correspond	LC, PH Belarus II, 2.2.29	
Разработал Матейко Ю.Б. Томко Л.А.		Согласовал Дударева И.В. Зайковский В.М.	Утвердил Слесарева Н.А. т. « 01 » 2022 г.	

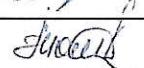
UE "Minskintercaps"		
Specification for substance		SPF-S-70
Allocation: PO (1), OMTC (1), HML (2+1 in electronic form), TB (1) OKK (1)		p. 2 /2 Edition N• 6
Substance name	Indapamide	
MHH		

№ nln	Test	Requirements	Method	Note
		to the retention time of the indapamide peak in the chromatogram of the reference solution (s)		
5	Angle of optical rotation, °	From -0,02 to +0,02	Polarimetry, <i>PH Belarus II, 2.2.7</i>	
6	Related impurities, %: - impurity of indapamide B ; - any other impurity; - total impurities	Not more 0,3; Not more 0,1; Not more 0,5.	<i>PH Belarus II, 2.2.29</i>	
7	Methylnitrosoindoline (Impurity A), ppm	Not more 5	<i>PH Belarus II, 2.2.29</i>	
8	Impurity C, ppm	Not more 600	<i>PH Belarus II, 2.2.29</i>	
9	Water, %	Not more 3,0	Titrimetric semimicromethod, <i>PH Belarus II, 2.5.12</i>	
10	Sulphated ash, %	Not more 0,1	Chemical gravimetric, <i>PH Belarus II, 2.4.14</i>	
11	Residual amounts of organic solvents, ppm: A. - methanol; - 2-propanol; - toluene.	Not more 3 000; Not more 5 000; Not more 890.	<i>PH Belarus II, 2.2.28, 5.4</i>	
	B. - dimethylformamide	Not more 880.	<i>PH Belarus II, 2.2.28, 5.4</i>	
	c - chloroform; - tetrahydrofuran.	Not more 60; Not more 720.	<i>PH Belarus II, 2.2.28, 5.4</i>	
12	Assay, %	98,0 - 102,0 (on anhydrous basis).	<i>PH Belarus II, 2.2.29</i>	
13	Microbial purity: CFU/g - - total number of aerobs; - total number of fungi; - Escherichia coli, in 1 g.	Not more 10 ³ ; Not more 10 ² ; Absent	<i>PH Belarus II, 2.6.12, 2.6.13, 5.1.4.</i>	
14	Storage	In protected from light place at a temperature below 25 °C.		
15	Expiration date	4 years		From the certificate of the manufacturer

REVISION NOTICE

SPF-S-70, RED. № 5

INDAPAMIDE SUBSTANCE SPECIFICATION

Post	Date	Signature	Name
Issued:			
Начальник РО			Матейко Ю.Б.
Провизор РО	26.01.22		Томко Л.А.

№	Change
П. 2. Particle size	Section added.