

LETTERHEAD OF THE COMPANY

Proposal (doc.Nr.)

Prepared and submitted by

COMPANY NAME

ADDRESS

for

SIA Pharmidea

Rupnicu 4, Olaine, LV -2114

**Supply of ISAVUCONAZONIUM SULFATE Active Pharmaceutical Ingredient (API)
and set of working standards**

FINAL PROPOSAL

Date

General information on the Contractor:

Legal Form	
Commercial Register number	
VAT number	
Name, surname and title of the signatory person	

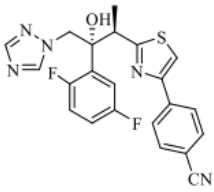
1. Price Quotation Subject

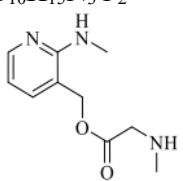
**Supply of ISAVUCONAZONIUM SULFATE Active Pharmaceutical Ingredient (API)
and set of working standards**

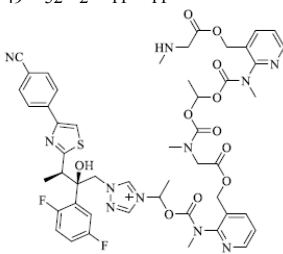
I SPECIFICATION OF required SUBSTANCES

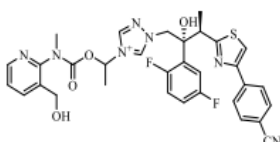
1. Specification of ISAVUCONAZONIUM SULFATE API (CAS: 946075-13-4)			PROPOSAL
Specification		Requirements	
1.1	Appearance	White to yellowish-white powder	
1.2	Identification by at least two methods, one of which is HPLC	HPLC RT: The major peak retention time of the sample should be consistent to that of the reference solution under assay item	
1.3	Water/LOD/TGA	NMT 2.0%	
1.4	Residual solvents:	NMT as per ICH Q3C guideline	
1.5	Assay	NLT 90%	
1.6	Microbial purity:		

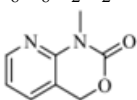
	-TAMC -TYMC	NMT 1000 CFU/g NMT 100 CFU/g	
1.7	Bacterial endotoxins	LT 0.9 IU/mg	
1.8	Remaining shelf life	NLT 15 months	
1.9	Amount of substance to be supplied	6.6 kg, of which preferably 4.6 kg from one batch and 2.0 kg from another batch. Other options can be discussed.	

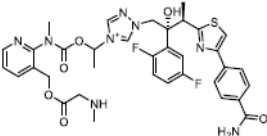
2. Specification of working standard of 4-(2-((2R,3R)-3-(2,5-difluorophenyl)-3-hydroxy-4-(1H-1,2,4-triazol-1-yl)butan-2-yl)thiazol-4-yl)benzonitrile Formula: C ₂₂ H ₁₇ F ₂ N ₅ OS  Structure: CAS: 241479-67-4			PROPOSAL
	Specification	Requirements	
2.1	Appearance	Powder or solid	
2.2	Purity/Assay	NLT 90%	
2.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
2.4	Amount of standard to be supplied	55 mg	

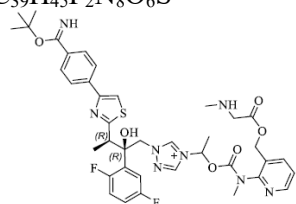
3. Specification of working standard of 4(2-(methylamino)pyridin-3-yl)methyl methylglycinate Formula: C ₁₀ H ₁₅ N ₃ O ₂  Structure: CAS: 2732924-98-8			PROPOSAL
	Specification	Requirements	
3.1	Appearance	Powder or solid	
3.2	Purity/Assay	NLT 65%	
3.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
3.4	Amount of standard to be supplied	150 mg	

4. Specification of working standard of 1-((2R,3R)-3-(4-(4-cyanophenyl)thiazol-2-yl)-2-(2,5-difluorophenyl)-2-hydroxybutyl)-4-(1-(((3-(5,8-dimethyl-2-(3-(((methylglycyl)oxy)methyl)pyridin-2-yl)-3,7,10-trioxo-4,6,11-trioxa-2,8-diazadodecan-12-yl)pyridin-2-yl)(methyl)carbamoyl)oxy)ethyl)-1H-1,2,4-triazol-4-ium Formula: C ₄₉ H ₅₂ F ₂ N ₁₁ O ₁₁ S ⁺ 			PROPOSAL
Structure: CAS: n/a			
Specification		Requirements	
4.1	Appearance	Powder or solid	
4.2	Purity/Assay	NLT 90%	
4.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
4.4	Amount of standard to be supplied	55 mg	

5. Specification of working standard of 1-((2R,3R)-3-(4-(4-cyanophenyl)thiazol-2-yl)-2-(2,5-difluorophenyl)-2-hydroxybutyl)-4-(1-(((3-(hydroxymethyl)pyridin-2-yl)(methyl)carbamoyl)oxy)ethyl)-1H-1,2,4-triazol-4-ium Formula: C ₃₂ H ₃₀ F ₂ N ₇ O ₄ S ⁺ 			PROPOSAL
Structure: CAS: 2761502-58-1 (cation form)			
Specification		Requirements	
5.1	Appearance	Powder or solid	
5.2	Purity/Assay	NLT 80%	
5.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
5.4	Amount of standard to be supplied	55 mg	

6. Specification of working standard of 1-methyl-1,4-dihydro-2H-pyrido[2,3-d][1,3]oxazin-2-one Formula: C ₈ H ₈ N ₂ O ₂  Structure: CAS: 2734004-61-4			PROPOSAL
Specification		Requirements	
6.1	Appearance	Powder or solid	
6.2	Purity/Assay	NLT 90%	
6.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
6.4	Amount of standard to be supplied	55 mg	

7. Specification of working standard of 1-((2R,3R)-3-(4-(4-carbamoylphenyl)thiazol-2-yl)-2-(2,5-difluorophenyl)-2-hydroxybutyl)-4-(1-((methyl(3-((methylglycyl)oxy)methyl)pyridin-2-yl)carbamoyl)oxy)ethyl)-1H-1,2,4-triazol-4-ium Formula: C ₃₅ H ₃₇ F ₂ N ₈ O ₆ S ⁺  Structure: CAS: 2962831-01-0 (cation form)			PROPOSAL
Specification		Requirements	
7.1	Appearance	Powder or solid	
7.2	Purity/Assay	NLT 90%	
7.3	Remaining shelf life	NLT 9 months or retest to be performed to cover NLT 9 months	
7.4	Amount of standard to be supplied	55 mg	

8. Specification of working standard of 1-((2R,3R)-3-(4-(4-(tert-butoxy(imino)methyl)phenyl)thiazol-2-yl)-2-(2,5-difluorophenyl)-2-hydroxybutyl)-4-(1-((methyl(3-((methylglycyl)oxy)methyl)pyridin-2-yl)carbamoyl)oxy)ethyl)-1H-1,2,4-triazol-4-ium Formula: C ₃₉ H ₄₅ F ₂ N ₈ O ₆ S ⁺  Structure: CAS: n/a			PROPOSAL
Specification		Requirements	

8.1	<i>Appearance</i>	<i>Powder or solid</i>	
8.2	<i>Purity/Assay</i>	<i>NLT 90%</i>	
8.3	<i>Remaining shelf life</i>	<i>NLT 9 months or retest to be performed to cover NLT 9 months</i>	
8.4	<i>Amount of standard to be supplied</i>	<i>55 mg</i>	

II ADDITIONAL REQUIREMENTS for all named substances

1. For the supply of ISAVUCONAZONIUM SULFATE API			PROPOSAL
1.1	<i>Supplier should submit GMP Certificate or Confirmation signed by Supplier that API production unit have GMP certificate of the country of production</i>		
1.2.	<i>Certificate of Analyses confirming compliance to specification and/or Specification should be attached</i>		

2. For the supply of all working standards			PROPOSAL
2.1.	<i>Certificate of Analyses confirming compliance to specification and/or specification should be attached to all named working standards</i>		

III Qualification criteria (preferable)

1.	<i>Experience of Supplier</i>	<i>Not less than 3 years experience in supply of GMP compliant APIs and working standards</i>	PROPOSAL
2.	<i>Address for delivery:</i>	<i>SIA PHARMIDEA, 4 Rupnicu Str., Olaine, Olaine district, Latvia, LV-2114.</i>	
3.	<i>Terms of delivery</i>	<i>a. CIP (carriage and insurance paid to) as one shipment b. The following information should be indicated on the packing: name of the substance, batch number, amount, validity period, manufacturer.</i>	
4.	<i>Contract implementation period</i>	<i>Not later than by the 26th October, 2026.</i>	
5.	<i>Compliance</i>	<i>If there is an equivalent to the requirements indicated in the Technical Specification, but not provided by the beneficiary, tenderer may submit appropriate equivalent. Tender may submit also an offer compliant to higher requirements.</i>	
6.	<i>Terms of payment:</i>	<i>Tenderer accepts, that payment conditions will be agreed under</i>	

		<i>the contract, but payment will be made after dispatch of substance and not earlier as Net 30.</i>	
7.	<i>Price:</i>	<i>Shall be indicated in EUR (without VAT) or USD (without VAT);</i> <i>If the price will not be indicated in EUR, the Customer will use the currency exchange rate set by the Bank of Latvia on the day of Offer evaluation and selection, in order to compare the prices of different offers.</i>	
	<i>Requirements for layout of the proposal:</i>	- <i>Proposal should be prepared in Latvian or in English, signed and submitted electronically (as scanned doc),</i> - <i>Letterhead of the company should be used (if available) for preparation of the Quotation.</i> - <i>Date, number of the quotation and name of contact person should be indicated.</i> - <i>Please indicate that the submitted proposal is the final proposal.</i>	-

TOTAL Price for the whole set	EUR (without VAT) or USD (without VAT)
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Signature, Name, Surname of the signatory person