



Zakroczym, on 27 April 2023 place and date

## MARKET INSIGHT FORM

## I. Purpose of the form:

In relation to the execution of the project entitled "Development of a novel combination medicinal product for use in the treatment of type 2 diabetes mellitus", co-financed from the national budget funds as part of the competitions organized by the Medical Research Agency, we would like to ask you to provide the value of the planned order described in detail under item II below and to provide information listed in Appendix no. 1 to this Form and the price.

Please sign this Market Insight Form and send a scan (in the pdf format) by e-mail to: zapytaniaofertowe@lekam.pl by: 17 May 2023.

If you need additional information, please contact us by e-mail: <u>zapytaniaofertowe@lekam.pl</u>

## **II.** Order specification:

- 1. The planned partial order concerns the non-pharmacopeial standards described in detail below in point II.5.
- 2. The Ordering Party allows for the placement of partial offers for the individual items defined in the Detailed Order Specification.
- 3. CPV CODE: 33696300-8 Chemical reagents
- 4. Deadline for completion of the order: all items listed in p. II.5 are planned to be ordered by 31 December 2023 and shall be delivered to the Ordering Party within the period of maximum 8 weeks from the day of conclusion of the contract/placement of the order. The Ordering Party reserves the right to place partial orders by 31 December 2023.

## 5. Detailed order specification:

Requirements								
Dont of the								
Part of the	Specification							
order								
	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-hydroxybenzyl)phenyl)-6-(hydroxymethyl tetra-hydro-2H-pyran-3,4,5-triol  quantity: 20 mg (preferred 2 x 10 mg)							
Part 1	<ul> <li>quality requirements: <ol> <li>Quality certificate containing at least the following data:</li> <li>standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA</li> <li>standard storage conditions</li> <li>for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate</li> <li>for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard</li> <li>expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))</li> </ol> </li> <li>Offer valid until 31 December 2023 with a price guarantee</li> </ul>							





	name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-hydroxybenzyl)phenyl)-6-							
	(hydroxymethyl tetra-hydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	1							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• purity by HPLC ≥ 90%							
Part 2	standard storage conditions							
	• for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate							
	for a secondary standard, please provide the results of identity testing							
	against the primary standard, along with the quality certificate for the							
	primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							
	<b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R)-1-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)							
	benzyl)phenyl)hexane-1,2,3,4,5,6-hexaol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
Part 3	<ul> <li>standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA</li> <li>standard storage conditions</li> </ul>							
Tarts	<ul> <li>for a primary standard, identity (using at least 2 methods) confirming the</li> </ul>							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	identity in the certificate or attached to the certificate							
	<ul> <li>for a secondary standard, please provide the results of identity testing</li> </ul>							
	against the primary standard, along with the quality certificate for the							
	primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee							
	name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2S,3R,4R)-1-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)							
	benzyl)phenyl)hexane-1,2,3,4,5,6-hexaol							
	44. 20. ( 6. 10. 12. )							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	<ul> <li>purity by HPLC ≥ 90%</li> </ul>							
Part 4	<ul> <li>standard storage conditions</li> </ul>							
	• for a primary standard, identity (using at least 2 methods) confirming the							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	identity in the certificate or attached to the certificate							
	• for a secondary standard, please provide the results of identity testing							
	against the primary standard, along with the quality certificate for the primary standard							
	<ul> <li>expiration/retest date – a minimum of 12 months preferred (for retest,</li> </ul>							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							





_	,							
	name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-methoxybenzyl)phenyl)-6-							
	(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	Tamana and angles							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• standard potency $\geq$ 90% or purity by HPLC $\geq$ 90% + water content or TGA							
Part 5	standard storage conditions							
	• for a primary standard, identity (using at least 2 methods) confirming the							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	<ul> <li>identity in the certificate or attached to the certificate</li> <li>for a secondary standard, please provide the results of identity testing</li> </ul>							
	against the primary standard, along with the quality certificate for the							
	primary standard							
	<ul> <li>expiration/retest date – a minimum of 12 months preferred (for retest,</li> </ul>							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							
	<b>name:</b> Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-methoxybenzyl)phenyl)-6-							
	(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 v 10 mg)							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• purity by HPLC ≥ 90%							
Part 6	standard storage conditions							
	• for a primary standard, identity (using at least 2 methods) confirming the							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	<ul> <li>identity in the certificate or attached to the certificate</li> <li>for a secondary standard, please provide the results of identity testing</li> </ul>							
	against the primary standard, along with the quality certificate for the							
	primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							
	name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2S,3R,4R,5S,6R)-2-(4-bromo-3-(4-(((S)-tetrahydrofuran-3-							
	yl)oxy)benzyl)phenyl)-6(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
<b>.</b>	• standard potency $\geq$ 90% or purity by HPLC $\geq$ 90% + water content or TGA							
Part 7	standard storage conditions    Same and interest and interest (and in a standard 2 mostles de) and interest (							
	• for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the							
	identity in the certificate or attached to the certificate							
	<ul> <li>for a secondary standard, please provide the results of identity testing</li> </ul>							
	against the primary standard, along with the quality certificate for the							
	primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							





name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-bromo-3-(4-(((S)-tetrahydrofuran-yl)oxy)benzyl)phenyl)-6(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol	,						
John Soft and Soft an	<b>3-</b>						
quantity: 20 mg (preferred 2 x 10 mg)							
quality requirements:							
1. Quality certificate containing at least the following data:							
• purity by HPLC ≥ 90%							
• standard storage conditions							
<ul> <li>for a primary standard, identity (using at least 2 methods) confirms structure of the compound (e.g. NMR, MS, IR), data confirming th identity in the certificate or attached to the certificate</li> </ul>							
<ul> <li>for a secondary standard, please provide the results of identity test</li> </ul>	•						
against the primary standard, along with the quality certificate for primary standard	the						
<ul> <li>expiration/retest date – a minimum of 12 months preferred (for ret</li> </ul>	est,						
information on standard retest possibility (yes/no))							
<ul> <li>2. Offer valid until 31 December 2023 with a price guarantee</li> <li>Part 9 name: Empagliflozin impurity standard (primary or secondary standard)</li> </ul>							
chemical name: (2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3(4-							
hydroxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate							
quantity: 20 mg (preferred 2 x 10 mg)							
quality requirements:							
1. Quality certificate containing at least the following data:							
<ul> <li>standard potency ≥ 90% or purity by HPLC ≥ 90% + water content</li> </ul>	t or TGA						
<ul> <li>standard storage conditions</li> <li>for a primary standard, identity (using at least 2 methods) confirm</li> </ul>	ng the						
of a primary standard, identity (using at least 2 methods) configuration structure of the compound (e.g. NMR, MS, IR), data confirming identity in the certificate or attached to the certificate							
for a secondary standard, please provide the results of identity test	ing						
against the primary standard, along with the quality certificate for primary standard	the						
<ul> <li>expiration/retest date – a minimum of 12 months preferred (for ret</li> </ul>	est,						
information on standard retest possibility (yes/no))							
2. Offer valid until 31 December 2023 with a price guarantee  name: Empagliflozin impurity standard (primary or secondary standard)							
chemical name: (2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3(4-							
hydroxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate							
quantity: 20 mg (preferred 2 x 10 mg)							
quality requirements:							
1. Quality certificate containing at least the following data:							
Part 10 • purity by HPLC $\geq$ 90%							
• standard storage conditions							
<ul> <li>for a primary standard, identity (using at least 2 methods) confirms structure of the compound (e.g. NMR, MS, IR), data confirming th identity in the certificate or attached to the certificate</li> </ul>	-						
<ul> <li>for a secondary standard, please provide the results of identity test</li> </ul>	ing						
against the primary standard, along with the quality certificate for primary standard	•						
<ul> <li>expiration/retest date – a minimum of 12 months preferred (for ret information on standard retest possibility (yes/no))</li> </ul>	est,						





	T							
	2. Offer valid until 31 December 2023 with a price guarantee							
	<b>name:</b> Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3-(4-							
	methoxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
Part 11	<ul> <li>standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA</li> <li>standard storage conditions</li> </ul>							
	• for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate							
	• for a secondary standard, please provide the results of identity testing							
	against the primary standard, along with the quality certificate for the primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							
	name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3-(4-							
	methoxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• purity by HPLC ≥ 90%							
Part 12	standard storage conditions							
	• for a primary standard, identity (using at least 2 methods) confirming the							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	identity in the certificate or attached to the certificate							
	for a secondary standard, please provide the results of identity testing							
	against the primary standard, along with the quality certificate for the primary standard							
	• expiration/retest date – a minimum of 12 months preferred (for retest,							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee							

	<b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl-5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol							
	quantity: 20 mg (preferred 2 x 10 mg)							
Part 13	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• standard potency $\geq 90\%$ or purity by HPLC $\geq 90\%$ + water content or TGA							
standard storage conditions								
	• for a primary standard, identity (using at least 2 methods) confirming the							
	structure of the compound (e.g. NMR, MS, IR), data confirming the							
	identity in the certificate or attached to the certificate							





	<ul> <li>for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard</li> <li>expiration/retest date – a minimum of 12 months preferred (for retest)</li> </ul>							
	<ul> <li>expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))</li> <li>Offer valid until 31 December 2023 with a price guarantee</li> </ul>							
	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl-5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	<ul> <li>quality requirements:</li> <li>1. Quality certificate containing at least the following data:</li> <li>purity by HPLC ≥ 90%</li> </ul>							
Part 14	<ul> <li>standard storage conditions</li> </ul>							
	• for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate							
	<ul> <li>for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard</li> </ul>							
	<ul> <li>expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))</li> </ul>							
	2. Offer valid until 31 December 2023 with a price guarantee							
	<b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3 yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 x 10 mg)							
	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• standard potency $\geq 90\%$ or purity by HPLC $\geq 90\%$ + water content or TGA							
Part 15	<ul> <li>standard storage conditions</li> </ul>							
	<ul> <li>for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate</li> </ul>							
	<ul> <li>for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard</li> </ul>							
	<ul> <li>expiration/retest date – a minimum of 12 months preferred (for retest,</li> </ul>							
	information on standard retest possibility (yes/no))							
	2. Offer valid until 31 December 2023 with a price guarantee  name: Empagliflozin impurity standard (primary or secondary standard)							
	chemical name: (2R,3R,4R,5S,6R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3							
	yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol							
	quantity: 20 mg (preferred 2 x 10 mg)							
Part 16	quality requirements:							
	1. Quality certificate containing at least the following data:							
	• standard potency $\geq 90\%$ or purity by HPLC $\geq 90\%$ + water content or TGA							
	• standard storage conditions							
	<ul> <li>for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate</li> </ul>							





	<ul> <li>for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard</li> <li>expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))</li> <li>Offer valid until 31 December 2023 with a price guarantee</li> </ul>					
	Records					
For parts 1– 16  For each of the deliveries, the Contractor must provide a quality certificate confirming the fulfillment of the quality requirements set out in the order specification for the ordered standards (in accordance with point II.5 of this form). The certificate should be delivered in paper form with the delivery.						

## 6. Assessment

The selection of the Contractor will be made from among the Offers meeting the quality requirements indicated in point II.5 of this form.

The object of the assessment shall be the proposed price.





## Appendix no. 1 to the Market Insight Form

# Information template to be completed by the bidder:

Contractor's full name:	Contact details:
Contractor's address:	Payment terms:
NIP (Numer Identyfikacji Podatkowej [Tax ID Number]):	Offer drafting date:
Contact person:	

Qu	otation						Specification	Meeting the requirements of the specification YES/NO <sup>2)</sup>
Part#	Name of the subject of the order	Offered package size [mg]	Total net price for the whole (for each part)	Total gross price for the whole (for each part)	Delivery costs	Other costs <sup>1)</sup>		
1.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-hydroxybenzyl)phenyl)-6-						1.Quality certificate containing at least the following data: standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions	
	(hydroxymethyl tetra-hydro-2H-pyran-3,4,5-triol <b>quantity:</b> 20 mg (preferred 2 x 10 mg)						for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate	
							for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard	





	12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
2. <b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3 (4-hydroxybenzyl)phenyl)-6- (hydroxymethyl tetra-hydro-2H-pyran-3,4,5-triol <b>quantity:</b> 20 mg (preferr 2 x 10 mg)	1. Quality certificate containing at least the following data: purity by HPLC ≥ 90% standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
3. <b>name:</b> Empagliflozin impurity standard (primary or secondary	Quality certificate containing at least the following data:
standard) chemical name: (2S,3R,4R)-1-(4 chloro-3-(4-(((S)-tetrahydrofura	standard potency $\geq 90\%$ or purity by  HPLC $\geq 90\%$ + water content or TGA  standard storage conditions

expiration/retest date – a minimum of





3-yl)oxy) benzyl)phenyl)hexane- 1,2,3,4,5,6-hexaol  quantity: 20 mg (preferred 2 x 10 mg)	for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date — a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2.Offer valid until 31 December 2023 with a price guarantee
4. name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R)-1-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy) benzyl)phenyl)hexane-1,2,3,4,5,6-hexaol  quantity: 20 mg (preferred 2 x 10 mg)	1. Quality certificate containing at least the following data: purity by HPLC ≥ 90% standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee





5. <b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-methoxybenzyl)phenyl)-6-	1. Quality certificate containing at least the following data: standard potency $\geq 90\%$ or purity by HPLC $\geq 90\%$ + water content or TGA standard storage conditions
(hydroxymethyl)tetrahydro-2H- pyran-3,4,5-triol  quantity: 20 mg (preferred 2 x 10 mg)	for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality
	certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee

6.	name: Empagliflozin impurity standard (primary or secondary	1. Quality certificate containing at least the following data:
	standard)	purity by HPLC ≥ 90%
	chemical name: (2S,3R,4R,5S,6R)-2-(4-chloro-3-	standard storage conditions
	(4-methoxybenzyl)phenyl)-6- (hydroxymethyl)tetrahydro-2H- pyran-3,4,5-triol	for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR),
	quantity: 20 mg (preferred 2 x 10 mg)	data confirming the identity in the certificate or attached to the certificate
	2 x 10 mg)	for a secondary standard, please provide the results of identity testing against the





		primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
7.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-bromo-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)-	1. Quality certificate containing at least the following data: standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions  for a primary standard, identity (using at
	6(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol  quantity: 20 mg (preferred 2 x 10 mg)	least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality
		certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023
8.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2S,3R,4R,5S,6R)-2-(4-bromo-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl)-	with a price guarantee  1. Quality certificate containing at least the following data: purity by HPLC ≥ 90% standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure





6(hydroxymethyl)tetrahydro-2H- pyran-3,4,5-triol	of the compound (e.g. NMR, MS, IR), data confirming the identity in the
	certificate or attached to the certificate
quantity: 20 mg (preferred	for a secondary standard, please provide
2 x 10 mg)	the results of identity testing against the
	primary standard, along with the quality
	certificate for the primary standard
	expiration/retest date – a minimum of
	12 months preferred (for retest,
	information on standard retest possibility
	(yes/no))
	2. Offer valid until 31 December 2023
	with a price guarantee

9.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6S)-2- (acetoxymethyl)-6-(4-chloro-3(4- hydroxybenzyl)phenyl)tetrahydro- 2H-pyran-3,4,5-triyl triacetate quantity: 20 mg (preferred 2 x 10 mg)	1. Quality certificate containing at least the following data: standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard
		expiration/retest date – a minimum of 12 months preferred (for retest,





		information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
10.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6S)-2- (acetoxymethyl)-6-(4-chloro-3(4-hydroxybenzyl)phenyl)tetrahydro-2H-pyran-3,4,5-triyl triacetate quantity: 20 mg (preferred 2 x 10 mg)	1. Quality certificate containing at least the following data:     purity by HPLC ≥ 90%     standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))
		2. Offer valid until 31 December 2023 with a price guarantee
11.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6S)-2-(acetoxymethyl)-6-(4-chloro-3-(4-	1. Quality certificate containing at least the following data: standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions
	methoxybenzyl)phenyl)tetrahydro- 2H-pyran-3,4,5-triyl triacetate <b>quantity:</b> 20 mg (preferred 2 x 10 mg)	for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate





	for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of
	12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee

12.	name: Empagliflozin impurity standard (primary or secondary	1. Quality certificate containing at least the following data:
	standard) chemical name: (2R,3R,4R,5S,6S)-2- (acetoxymethyl)-6-(4-chloro-3-(4-methoxybenzyl)phenyl)tetrahydro-	purity by HPLC ≥ 90% standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure
	2H-pyran-3,4,5-triyl triacetate <b>quantity:</b> 20 mg (preferred 2 x 10 mg)	of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality
		certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))
13.		2. Offer valid until 31 December 2023 with a price guarantee  1. Quality certificate containing at least the following data:





name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl-5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol  quantity: 20 mg (preferred 2 x 10 mg)	standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date − a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
14. <b>name:</b> Empagliflozin impurity standard (primary or secondary standard) chemical name: (3R,4R,5R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3-yl)oxy)benzyl)phenyl-5-((R)-1,2-dihydroxyethyl)tetrahydrofuran-3,4-diol <b>quantity:</b> 20 mg (preferred 2 x 10 mg)	1. Quality certificate containing at least the following data: purity by HPLC ≥ 90% standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date – a minimum of 12 months preferred (for retest,





	information on standard retest possibility (yes/no))	
	2. Offer valid until 31 December 2023 with a price guarantee	

15.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6R)-2-(4-chloro-3-(4-(((S)-tetrahydrofuran-3 yl)oxy)benzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol  quantity: 20 mg (preferred 2 x 10 mg)	1. Quality certificate containing at least the following data: standard potency ≥ 90% or purity by HPLC ≥ 90% + water content or TGA standard storage conditions  for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the certificate or attached to the certificate for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard expiration/retest date − a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2. Offer valid until 31 December 2023 with a price guarantee
16.	name: Empagliflozin impurity standard (primary or secondary standard) chemical name: (2R,3R,4R,5S,6R)-2-(4-chloro-3-	1. Quality certificate containing at least the following data: purity by HPLC ≥ 90% standard storage conditions





(4-(((S)-tetrahydrofuran-3 yl)oxy)benzyl)phenyl)-6- (hydroxymethyl)tetrahydro-2H- pyran-3,4,5-triol	for a primary standard, identity (using at least 2 methods) confirming the structure of the compound (e.g. NMR, MS, IR), data confirming the identity in the
quantity: 20 mg (preferred 2 x 10 mg)	certificate or attached to the certificate  for a secondary standard, please provide the results of identity testing against the primary standard, along with the quality certificate for the primary standard
	expiration/retest date – a minimum of 12 months preferred (for retest, information on standard retest possibility (yes/no))  2.Offer valid until 31 December 2023 with a price guarantee

<sup>2)</sup> please enter YES or NO for each specification item	
Date and place	Signature