

Certificate

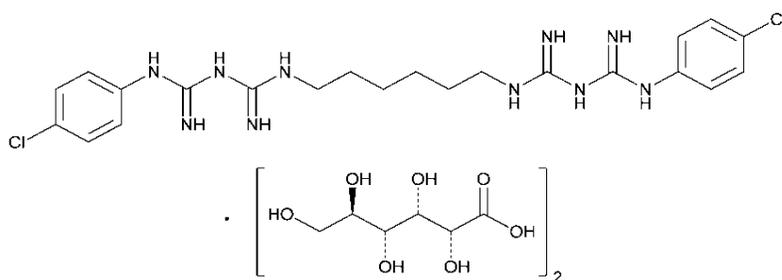
CHLORHEXIDINE SYSTEM SUITABILITY MIXTURE

USP Catalog No.: 1111012

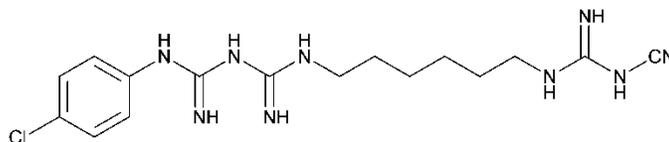
USP Lot No.: F016F0

Only compendial components as listed in the monograph are shown below

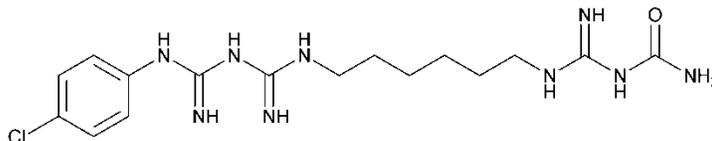
(1)



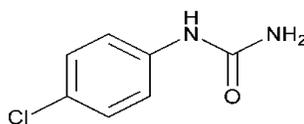
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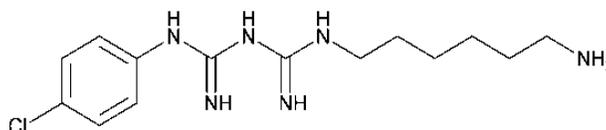
(3)



(4)



(5)



Only compendial components as listed in the monograph shown below

Item	Name/Chemical name	CAS	Molecular Weight	Molecular Formula	Content
1	Chlorhexidine Gluconate / 1,1'-Hexamethylenebis[5-(p-chlorophenyl)biguanide] di-D-gluconate	18472-51-0	897.76	$C_{22}H_{30}Cl_2N_{10} \cdot 2 C_6H_{12}O_7$	97.02
2	Chlorhexidine nitrile / 1-(4-Chlorophenyl)-5-[6- [[cyanocarbamimidoyl]amino]hexyl]biguanide	152504-08-0	377.88	$C_{16}H_{24}ClN_9$	0.11
3	Chlorhexidine urea / N-[[6-[[[(4-Chlorophenyl)carbamimidoyl]carbamimidoyl]amino) hexyl]carbamimidoyl]urea	1308292-89-8	395.89	$C_{16}H_{26}ClN_9O$	0.13
4	p-Chlorophenyl Urea / 1-(4-Chlorophenyl)urea	140-38-5	170.60	$C_7H_7ClN_2O$	0.24
5	Chlorhexidine amine / 1-(6-Aminohexyl)-5-(4-chlorophenyl)biguanide	152504-09-1	310.83	$C_{14}H_{23}ClN_6$	0.12
6	Chlorhexidine dimer / 1,5-Bis[5-(4-chlorophenyl)biguanidyl]hexyl]biguanide	--	688.70	$C_{30}H_{47}Cl_2N_{15}$	0.12
7	Chlorhexidine glucityl triazine / 1-(4-Chlorophenyl)-5-[6-[[4- chlorophenyl]amino]-6-[[1S,2R,3R,4R]-1,2,3,4,5-pentahydroxypentyl]-1,3,5-triazin-2-yl]amino]hexyl]biguanide	--	665.57	$C_{28}H_{38}Cl_2N_{10}O_5$	0.19
8	Oxochlorhexidine / N-(4-Chlorophenyl)-N'-[[6-[[[(4-chlorophenyl)carbamimidoyl]carbamimidoyl]amino) hexyl] carbamimidoyl]urea	1381962-77-1	506.43	$C_{22}H_{29}Cl_2N_9O$	0.22
9	Chlorhexidine Oxazinone analog / (5R,6S)-2-[(4-Chlorophenyl)amino]-5-hydroxy-6- [[1R,2R]-1,2,3-trihydroxypropyl]-5,6-dihydro-4H-1,3-oxazin-4-one	--	330.72	$C_{13}H_{15}ClN_2O_6$	0.09
10	Chlorhexidine guanidine / 1-[6-(Carbamimidoylamino)hexyl]-5-(4-chlorophenyl)biguanide	152504-10-4	352.87	$C_{15}H_{25}ClN_8$	1.01
11	o-Chlorhexidine / 1-(2-Chlorophenyl)-5-[6-[[[(4-chlorophenyl)carbamimidoyl]carbamimidoyl]amino]hexyl]biguanide	--	505.45	$C_{22}H_{30}Cl_2N_{10}$	0.21*
12	Specified unidentified impurity 2	--	unknown	unknown	

* If present, o-chlorhexidine and specified unidentified impurity 2 may not be completely resolved by the method. These peaks are integrated together to determine conformance.

LABEL TEXT

For use with specified USP compendial tests.
Not for use as a drug. See SDS prior to use
at www.usp.org/sds.



Lot: F016F0

USP REFERENCE STANDARD

CHLORHEXIDINE SYSTEM SUITABILITY MIXTURE 50 mg

See Certificate and Typical Chromatogram

Danger! May cause an allergic skin reaction. Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Do not dry. Protect from light. The material is hygroscopic.
Store in a refrigerator.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666
CAT No. 1111012 Material mfd. in Spain

Contaminated work clothing must not be allowed out of the workplace.
Wear protective gloves. Wear eye/face protection. In case of inadequate
ventilation wear respiratory protection. If on skin: Wash with plenty of
water. If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse. If inhaled: If breathing is
difficult, remove person to fresh air and keep comfortable for breathing.
If experiencing respiratory symptoms: Call a poison center/doctor. If in
eyes: Rinse cautiously with water for several minutes. Remove contact
lenses, if present and easy to do. Continue rinsing. Immediately call a
poison center/doctor. Dispose of contents/container in accordance with
local/regional/national/international regulations.

Jeri L. Joth

Quality Assurance

Calculation Value

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

Expiration

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at www.usp.org.

Instructions for Use

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

Non-Monograph Use

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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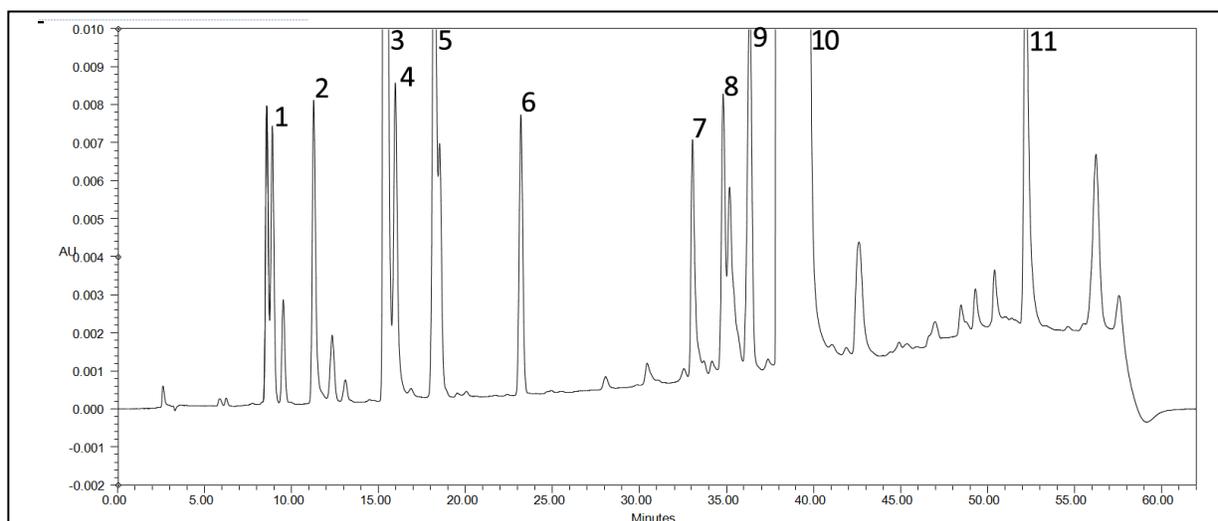
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Typical Chromatogram

USP CHLORHEXIDINE SYSTEM SUITABILITY MIXTURE RS

Catalog Number: 1111012
Lot: F016F0
Monograph: Chlorhexidine Gluconate Solution
Publication: PF40(2)
Test: Organic Impurities
Sample: System Suitability Solution



- | | |
|-----------------------------------|--|
| 1. Chlorhexidine oxazinone analog | 7. Chlorhexidine dimer |
| 2. Chlorhexidine amine | 8. o-Chlorhexidine and Specified unidentified impurity 2 |
| 3. Chlorhexidine guanidine | 9. Chlorhexidine glucityl triazine |
| 4. Chlorhexidine urea | 10. Chlorhexidine |
| 5. p-Chlorophenyl urea | 11. Oxochlorhexidine |
| 6. Chlorhexidine nitrile | |

Note: Other impurities/components may also be present. One of the additional minor components of the Mixture is shown to elute close to p-chlorophenyl urea peak. This component may coelute with this peak, or elute immediately before or after it, depending on the column used.

This chromatogram is supplied for information only, unless otherwise specified in an applicable monograph or general chapter.