

Certificate of Analysis

Conclusion

Dispensed material – 10 mg/vial. All test results are within specification. The material is suitable for use as working reference standard for GE-067/Vizamyl

Material Information

Product	AH111832
Reference standard no.	WS 0670.013
SAP Batch no	13983833
Vendor Batch no	FFC0029/033-03
Manufactured by	GE Healthcare AS
Date of production	15-DEC-2017
Expiry / Retest date	11-JAN-2020
Storage conditions	2°C - 8°C, in closed vial protected from light
Reference	S-2018-0002228 Journal NKK.16.001/043

Test results

Tests	Acceptance Criteria	Results
Description		
Appearance	Orange-red to dark red solid	Orange-red to dark red solid
Identification		
Identification by IR ¹	IR spectrum conforms to reference spectrum	IR spectrum conforms to reference spectrum
Purity		
Purity by HPLC	NLT ² 90.0 % area ³	97.4 % area

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¹ Performed at release and reported in REF 0670.15.0002

² NLT = Not Less Than

³ Acceptance for retest is 90.0% area (acceptance for release is 95.0% area)

Effective Date: 25-May-2018

SIGNATURE PAGE

Certificate of Analysis for Working Reference Standard AH111832 - WS0670.013 -
10mg

Responsible Author: Fritzell Tone

Date (UTC):

Signed by:

Justification:

25-May-2018 09:17:50 Mahlum Christine

Approved on behalf of Department

This is a representation of an electronic record that was signed electronically in accordance with GxP guidelines and controls. The information above is a valid manifestation of the electronic signature(s) and is legally binding.

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