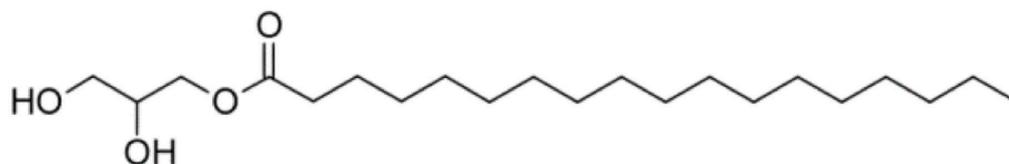




## Water determination in Glycerol Monostearate

HYDRANAL™ Laboratory Report L 705

(2,3-Dihydroxypropyl Octadecanoate)



This long-chained stearate does not dissolve in the alcoholic Karl Fischer working media. Thus it is necessary to use a solubilizing agent.

In the European Pharmacopoeia (Ph. Eur.) pyridine is used as a solubilizing agent, at elevated temperature. However, the endpoint detection in pure pyridine is not ideal, as the system tends to over-titrate. For good results, we recommend using a mixture of methanol and chloroform.

### Procedure for volumetric one-component titration:

Add 40 mL Hydranal™-LipoSolver CM, or a mixture of 20 mL Hydranal-Methanol dry or Hydranal-Methanol Rapid and 20 mL Hydranal-Chloroform to the titration vessel. Titrate to dryness with Hydranal-Composite 5.

Precisely weigh-in a 1 g sample using differential weighing and titrate the water content with Hydranal-Composite 5.

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### Procedure for volumetric two-component titration:

Add 40 mL Hydranal-Solvent CM or a mixture of 20 mL Hydranal-Solvent and 20 mL Hydranal-Chloroform to the titration vessel. Titrate to dryness with Hydranal-Titrant 5. Precisely weigh-in a 1 g sample using differential weighing and titrate the water content with Hydranal-Titrant 5.

Hydranal-Water Standard 10.0, Hydranal-Water Standard 1.0, and Hydranal-Standard Sodium Tartrate Dihydrate are suitable for determination of the titer or control of the volumetric determination.

## VOLUMETRIC REAGENTS

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[34805](#) HYDRANAL-Composite 5

[37855](#) HYDRANAL-LipoSolver CM

[34741](#) HYDRANAL-Methanol dry

[37817](#) HYDRANAL-Methanol Rapid

[37863](#) HYDRANAL-Chloroform

[34801](#) HYDRANAL-Titrant 5

[34812](#) HYDRANAL-Solvent CM

[34800](#) HYDRANAL-Solvent

## WATER STANDARDS

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[34849](#) HYDRANAL-Water Standard 10.0

[34425](#) HYDRANAL-CRM Water Standard 10.0

[34828](#) HYDRANAL-Water Standard 1.0

[34426](#) HYDRANAL-CRM Water Standard 1.0

[34696](#) HYDRANAL-Standard Sodium Tartrate Dihydrate

[34424](#) HYDRANAL-CRM Sodium Tartrate Dihydrate

## AUXILIARIES

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[34788](#) HYDRANAL-Humidity Absorber

[34241](#) HYDRANAL-Molecular Sieve 0.3 nm

### Enclosure:

Suitability Test according to Ph. Eur. (also available separately, on request).

Suitability test according to Ph. Eur., method 2.5.12 Water semi-micro determination

Water determination by Karl Fischer titration using HYDRANAL-Composite

**Product** **Glycerol monostearate 40-55**

**Titrant** HYDRANAL-Composite 5 **Titer** 5.295 mg/mL

**Working medium** 40 ml Pyridine

**Sample handling** By means of a powder funnel. Weigh by difference.

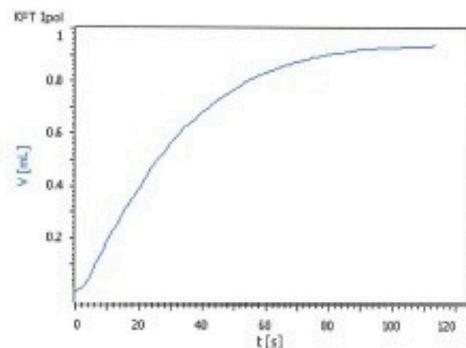
**Procedure** The working medium is placed in the titration vessel, heated to 40°C and titrated to dryness with the titrant. Then the sample is added and titrated in the same way to a stable end point.

**Recovery of water added** After achieving the end point, sequential known amounts of water are added and titrated in the same way.

	Sample	Water added				
		1	2	3	4	5
Sample size (g)	0.9900					
Water added (mg)		3.68	3.82	3.71	3.91	3.78
Water found (mg)	4.9610	3.70	3.85	3.71	3.93	3.79
Water content %	0.5011					
Recovery %		100.56	100.86	99.89	100.59	100.29

The reagent/solvent system is considered to be acceptable if:

The mean recovery is between 97.5% and 102.5%	Mean recovery (%)	100.44
The slope b is between 0.975 and 1.025 (deviation +/-2.5%)	Slope	1.004
The error e1 and e2 are not greater than 2.5%	Error 1 (%)	0.26
	Error 2 (%)	0.12



Test results fulfil the requirements according to Ph. Eur.

This approach, using pyridine, is recommended by Ph. Eur. 7.6. But please note, that end point detection in pure pyridine is not perfect.

Attached you will find the procedure that is favored by the HYDRANAL-laboratory, using a mixture of methanol and chloroform as working medium.

*Seelze, 10.09.13*

Suitability test according to Ph. Eur., method 2.5.12 Water semi-micro determination

Water determination by Karl Fischer titration using HYDRANAL-Composite



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**Product** **Glycerol monostearate 40-55**

**Titrant** HYDRANAL-Composite 5 **Titer** 5.295 mg/mL

**Working medium** 20 ml HYDRANAL-Methanol dry + 20 ml HYDRANAL-Chloroform

**Sample handling** By means of a powder funnel. Weigh by difference.

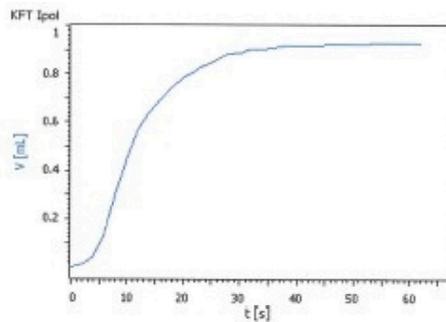
**Procedure** The working medium is placed in the titration vessel and titrated to dryness with the titrant. Then the sample is added and titrated in the same way to a stable end point.

**Recovery of water added** After achieving the end point, sequential known amounts of water are added and titrated in the same way.

	Sample	Water added				
		1	2	3	4	5
Sample size (g)	0.9911					
Water added (mg)		3.75	3.48	3.78	3.69	4.00
Water found (mg)	4.8022	3.78	3.49	3.85	3.72	4.01
Water content %	0.4845					
Recovery %		100.65	100.40	101.93	100.95	100.08

**The reagent/solvent system is considered to be acceptable if:**

The mean recovery is between 97.5% and 102.5%	Mean recovery (%)	100.80
The slope b is between 0.975 and 1.025 (deviation +/-2.5%)	Slope	1.010
The error e1 and e2 are not greater than 2.5%	Error 1 (%)	0.25
	Error 2 (%)	1.19



Test results fulfil the requirements according to Ph. Eur.

*Seelze, 05.09.13 WSK*

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