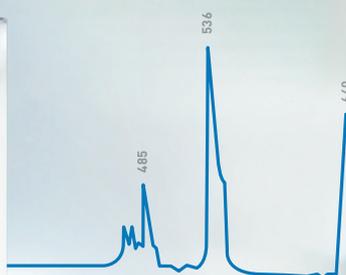


All you need to ensure conformity with the  
new European Pharmacopoeia (EP 10)

**Hellma**<sup>®</sup>  
**Analytics**  
High Precision in Spectro-Optics



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D-K-18752-01-00

**NIST**  
TRACEABLE

# Optical Reference Materials for UV/Vis Spectroscopy

CONTROL OF:  
WAVELENGTH ACCURACY  
ABSORBANCE ACCURACY

PHOTOMETRIC LINEARITY  
LIMIT OF STRAY LIGHT  
RESOLUTION

# WHY YOU NEED THE EUROPEAN PHARMACOPOEIA

The European Pharmacopoeia (Ph. Eur.) is a single reference work for the quality control of medicines. Used in over 100 countries, the latest version, EP 10, comes into force from January 2020.

## How will EP 10 impact the qualification of your spectrophotometer?

The relevant chapter, 2.2.25 Absorption spectrophotometry Ultraviolet and Visible, has undergone a comprehensive revision in the latest version. Amongst other things, for the purpose of absorbance accuracy, Nicotinic acid has been

introduced as an alternative to potassium dichromate which is listed in Annex XIV of the REACH regulations.



### FOR INFORMATION

EP 10 requires that all measurements are carried out with reference to the same solvent or the same mixture of solvent (blank).

The following parameters must be checked:

## 1 Control of wavelength accuracy:

### OLD EP 8

Holmium liquid filter is used to check wavelength accuracy from 240 nm to 650 nm

### NEW EP 10

„Control the wavelength accuracy, ..., in the intended spectral range using one or more reference materials. It is recommended to test at least 2 wavelengths that bracket the intended spectral range

- Holmium liquid filter continues to be used to check wavelength accuracy from 240 nm to 650 nm with extended selection of peaks
- for checking the wavelength accuracy above 650 nm the Didymium filter should be used
- for checking the wavelength accuracy below 240 nm the Cerium filter should be used.

## 2 Control of absorbance accuracy:

### OLD EP 8

#### UV-range:

Potassium dichromate solution with 60 mg/l is used

#### Vis-range:

Potassium dichromate solution with 600 mg/l is used

### NEW EP 10

“Control the absorbance accuracy at an appropriate number of wavelengths in the intended spectral range, ..., as a minimum, values at approximately the 2 limits of the expected absorbance range should be verified.”

#### UV-range:

Control of absorbance in the UV-range with solutions of Nicotinic acid (Niacin) up to 2 Abs (5 – 45 mg/l) / at wavelengths: 213, 261 nm

#### Vis-range:

Control of absorbance in the Vis-range with Neutral Density Glass Filters / up to 2 Abs

## 3 NEW EP 10 Control of photometric linearity

„Control the photometric linearity in the intended spectral range.”

UV-range: with Niacin Filters (5 – 40 mg/l)

Vis-range: with Neutral Density Glass Filters

## 4 Limit of stray light:

### OLD EP 8

Absorbance is not less than 2.0 with Potassium chloride in H<sub>2</sub>O at 198 nm.

### NEW EP 10

“Stray light is determined at an appropriate wavelength”

Potassium chloride in H<sub>2</sub>O continues to be used to check stray light not less than 2.0 A at 198 nm.

Absorbance is not less than 3.0 A using:

- Sodium iodide in H<sub>2</sub>O at 220 nm
- Potassium iodide in H<sub>2</sub>O at 250 nm
- Sodium nitrite in H<sub>2</sub>O at 340 and 370 nm

## 5 Control of resolution:

### OLD EP 8

With Toluene in Hexane and Hexane reference filter

No Changes!



Birgit Kehl  
Compliance Manager | ISO/IEC 17025

“The new EP 10 opens up a wide spectrum for checking spectrophotometers. At the Hellma Analytics calibration laboratory, we have specially developed reference materials to fulfill the requirements of EP 10.”

# UP-DATE EXISTING FILTER SETS TO EP 10 COMPLIANCE

| ARTICLE-NO.                             | CONTENT   | WAVELENGTH nm                     |
|---|---|-----------------------------------|
| <b>1 Control of wavelength accuracy</b> |   |                                   |
| <b>Filters used today</b>               |   |                                   |
| 667400                                  | UV5: Holmium in perchloric acid<br>UV14: Perchloric acid (reference filter) | 241, 287, 361, 451, 485, 536, 640 |
| <b>Supplement if necessary</b>          |   |                                   |
| 667035                                  | UV35: Rare Earth (Cerium) in perchloric acid                                | 201, 211, 222, 239, 252           |
| 667025EPUSP                             | UV25EPUSP: Didymium in perchloric acid                                      | 512, 732, 740, 794, 801, 864      |

## 2 + 3 Control of absorbance accuracy and control of photometric linearity

### UV-range:

|   |   |                    |
|---|---|--------------------|
| <b>Filters used today</b>                 |   |                    |
| 667301                                    | UV60: Potassium dichromate 60 mg/l in perchloric acid<br>UV14: Perchloric acid (reference filter)   | 235, 257, 313, 350 |
| <b>Supplement if necessary</b>            |   |                    |
|   | At least 2x Potassium dichromate filters in perchloric acid with other concentrations from 20 mg/l - 140 mg/l. (Select appropriate filter according the 2 limits of expected absorbance). | 235, 257, 313, 350 |
| <b>Alternative: New Niacin filter set</b> |   |                    |
| 667S501                                   | Filter set S501 includes:<br>UV506: Niacin 6 mg/l (0.25 Abs),<br>UV512: Niacin 12 mg/l (0.5 Abs),<br>UV524: Niacin 24 mg/l (1.0 Abs),<br>UV599: Hydrochloric acid (reference filter)      | 213, 261           |

### Vis-range:

|                                |   |                           |
|--------------------------------|---|---------------------------|
| <b>Filters used today</b>      |   |                           |
| 667304                         | UV600: Potassium dichromate 600 mg/l in perchloric acid<br>UV14: Perchloric acid (reference filter) | 430                       |
| <b>Supplement if necessary</b> |   |                           |
| 666S002                        | Glass Filter Set S002 includes:<br>F2 (0.25 Abs), F3 (0.5 Abs) and F4 (1.0 Abs)                     | 440, 465, 546.1, 590, 635 |

## 4 Limit of stray light

|                                |   |             |
|--------------------------------|---|-------------|
| <b>Filters used today</b>      |   |             |
| 667100                         | UV1: Potassium chloride in pure water, at 198 nm<br>UV12: Pure water (Reference filter) | 200 Cut-off |
| <b>Supplement if necessary</b> |   |             |
| 667010                         | UV10, Sodium iodide in pure water, at 220 nm  | 259 Cut-off |
| 667023                         | UV23, Potassium iodide in pure water, at 250 nm   | 259 Cut-off |
| 667011                         | UV11, Sodium nitrite in pure water, at 340 and 370 nm                                   | 385 Cut-off |

## 5 Control of resolution

|                                |  |   |
|--------------------------------|--|---|
| <b>Filters used today</b>      |  |   |
| 667200                         | UV6: Toluene in Hexane<br>UV9: Hexane (reference filter) | Scan from 265 to 270, slit width: 0.5; 1.0; 1.5; 2.0; 3.0 |
| <b>No supplement necessary</b> |  |   |



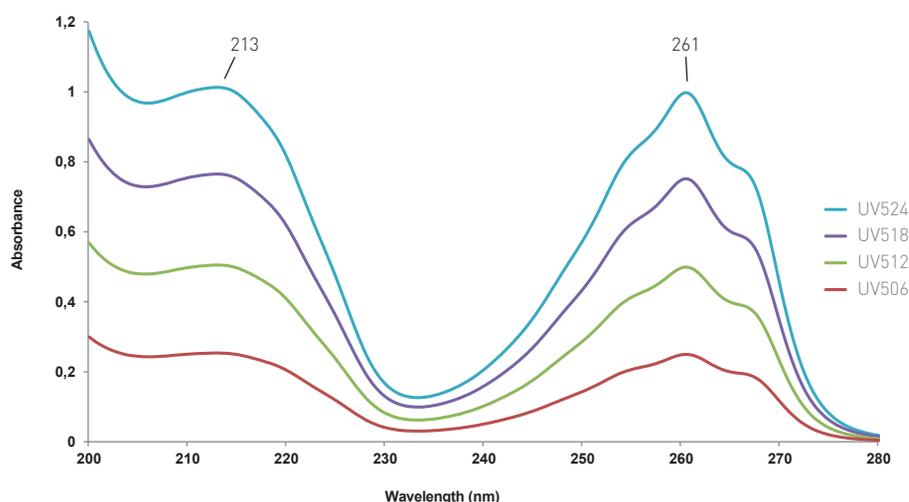
We are happy to help.  
+49 7631 182 1010

**NEW**

# NEW BASIC FILTER SETS FOR EP 10 COMPLIANCE

| PARAMETER  | ARTICLE-NO.      | CONTENT  | WAVELENGTH nm   |
|--|------------------|--|---|
| <b>EP-Basic Set UV/Vis</b>   |                  |  |   |
| <b>(for wavelength range 240 – 640 nm and absorbance range 0.25 – 1.0)</b> |                  |  |   |
| Photometric accuracy UV-range  | 667S501          | Filter set includes:<br>UV506, Niacin filter 6 mg/l (0.25 Abs)<br>UV512, Niacin filter 12 mg/l (0.5 Abs)<br>UV524, Niacin filter 24 mg/l (1.0 Abs)<br>UV599, reference filter with hydrochloric acid | 213, 261  |
| Photometric accuracy Vis-range   | 666S002          | Glass Filter Set S002 with:<br>F2 (0.25 Abs), F3 (0.5 Abs) and F4 (1.0 Abs)  | 440, 465, 546.1, 590, 635                                   |
| Wavelength accuracy  | 667400           | Filter set, UV5 Holmium in perchloric acid and UV14 perchloric acid (reference filter)   | 241, 287, 361, 451, 485, 536, 640                           |
| Stray Light  | 667102           | Filter set, UV11 Sodium nitrite in pure water and UV12 pure water (reference filter) 3 Abs at 340 and 370 nm   | 385 Cut-off   |
| Resolution   | 667200           | Filter set, UV6 Toluene in Hexane and UV9 Hexane (reference filter)  | Scan from 265 to 270<br>slit width: 0.5; 1.0; 1.5; 2.0; 3.0 |
| <b>Total</b>   | <b>667EP1001</b> | <b>EP Basic set UV/Vis</b>   |   |

|  |                  |  |   |
|--|------------------|--|---|
| <b>EP-Basic Set UV</b>   |                  |  |   |
| <b>(for wavelength range 240 – 400 nm and absorbance range 0.25 – 1.0)</b> |                  |  |   |
| Photometric accuracy UV-range  | 667S501          | Filter set includes:<br>UV506, Niacin filter 6 mg/l (0.25 Abs)<br>UV512, Niacin filter 12 mg/l (0.5 Abs)<br>UV524, Niacin filter 24 mg/l (1.0 Abs)<br>UV599, reference filter with hydrochloric acid | 213, 261  |
| Wavelength accuracy  | 667400           | Filter set, UV5 Holmium in perchloric acid and UV14 perchloric acid (reference filter)   | 241, 287, 361, 451, 485, 536, 640                           |
| Stray Light  | 667107           | Filter set, UV23 Potassium iodide in pure water and UV12 pure water (reference filter) 3 Abs at 250 nm   | 259 Cut-off   |
| Resolution   | 667200           | Filter set, UV6 Toluene in Hexane and UV9 Hexane (reference filter)  | Scan from 265 to 270<br>slit width: 0.5; 1.0; 1.5; 2.0; 3.0 |
| <b>Total</b>   | <b>667EP1002</b> | <b>EP Basic set UV</b>   |   |



Typical scanlines of Niacin liquid filters, measured at a slit width of 1 nm

# EXPANSION OPTIONS FOR CONFORMANCE TO THE NEW EP 10

| PARAMETER   | ARTICLE-NO.                             | CONTENT  | WAVELENGTH nm             |
|---|---|--|---------------------------|
| Photometric accuracy<br>UV range<br><br><b>Niacin</b>               | 667506                                  | UV506, Niacin filter 6 mg/l (0.25 Abs)   | 213, 261                  |
|   | 667512                                  | UV512, Niacin filter 12 mg/l (0.5 Abs)   | 213, 261                  |
|   | 667518                                  | UV518, Niacin filter 18 mg/l (0.75 Abs)  | 213, 261                  |
|   | 667524                                  | UV524, Niacin filter 24 mg/l (1.0 Abs)   | 213, 261                  |
|   | 667536                                  | UV536, Niacin filter 36 mg/l (1.5 Abs)   | 213, 261                  |
|   | 667548                                  | UV548, Niacin filter 48 mg/l (2.0 Abs)   | 213, 261                  |
|   | 667599                                  | UV599, Hydrochloric acid (reference filter)  | 213, 261                  |
|   | 667350                                  | Linearity Set UV350, includes Niacin with 6, 12, 18 and 24 mg/l and reference filter | 213, 261                  |
|   | 6675501                                 | Linearity Set UVS501, includes Niacin with 6, 12, and 24 mg/l and reference filter   | 213, 261                  |
| Photometric accuracy<br>UV range<br><br><b>Potassium Dichromate</b> | 667020                                  | UV20, Potassium dichromate, 20mg/l, (0.1 - 0.3 Abs)                                  | 235, 257, 313, 350        |
|   | 667040                                  | UV40, Potassium dichromate, 40mg/l, (0.2 - 0.6 Abs)                                  | 235, 257, 313, 350        |
|   | 667060                                  | UV60, Potassium dichromate, 60mg/l, (0.3 - 0.9 Abs)                                  | 235, 257, 313, 350        |
|   | 667080                                  | UV80, Potassium dichromate, 80mg/l, (0.4 - 1.2 Abs)                                  | 235, 257, 313, 350        |
|   | 6670100                                 | UV0100, Potassium dichromate, 100mg/l, (0.5 - 1.45 Abs)                              | 235, 257, 313, 350        |
|   | 6670120                                 | UV0120, Potassium dichromate, 120mg/l, (0.6 - 1.7 Abs)                               | 235, 257, 313, 350        |
|   | 6670140                                 | UV0140, Potassium dichromate, 140mg/l, (0.7 - 2.0 Abs)                               | 235, 257, 313, 350        |
|   | 6670160                                 | UV0160, Potassium dichromate, 160mg/l, (0.8 - 2.3 Abs)                               | 235, 257, 313, 350        |
|   | 6670180                                 | UV0180, Potassium dichromate, 180mg/l, (0.9 - 2.6 Abs)                               | 235, 257, 313, 350        |
|   | 6670200                                 | UV0200, Potassium dichromate, 200mg/l, (1.0 - 3.0 Abs)                               | 235, 257, 313, 350        |
| 667014  | UV14, Perchloric acid, reference filter | 235, 257, 313, 350   |                           |
| Vis-range<br><br><b>Glass Filter</b>                                | 666F0-71                                | F0, Empty filter frame (reference filter)  |                           |
|   | 666F390-25                              | F390, Glass Filter with 0.04 Abs   | 440, 465, 546.1, 590, 635 |
|   | 666F2-39                                | F2, Neutral Density Glass Filter with 0.25 Abs                                       | 440, 465, 546.1, 590, 635 |
|   | 666F201-39                              | F201, Neutral Density Glass Filter with 0.3 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666F3-38                                | F3, Neutral Density Glass Filter with 0.5 Abs  | 440, 465, 546.1, 590, 635 |
|   | 666F204-37                              | F204, Neutral Density Glass Filter with 0.7 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666F4-37                                | F4, Neutral Density Glass Filter with 1.0 Abs  | 440, 465, 546.1, 590, 635 |
|   | 666F202-36                              | F202, Neutral Density Glass Filter with 1.5 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666F203-36                              | F203, Neutral Density Glass Filter with 2.0 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666F301-361                             | F301, Neutral Density Glass Filter with 2.5 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666F303-361                             | F303, Neutral Density Glass Filter with 3.0 Abs                                      | 440, 465, 546.1, 590, 635 |
|   | 666S002                                 | Glass Filter Set S002 includes F2 (0.25 Abs), F3 (0.5 Abs) and F4 (1.0 Abs)          | 440, 465, 546.1, 590, 635 |
|   | 666S006                                 | Glass Filter Set S006 includes F0, F2 (0.25 Abs), F3 (0.5 Abs) and F4 (1.0 Abs)      | 440, 465, 546.1, 590, 635 |

| PARAMETER           | ARTICLE-NO.                           | CONTENT   | WAVELENGTH nm   |
|---------------------|---------------------------------------|---|---|
| Wavelength accuracy | 667035                                | UV35, Rare Earth (Cerium) liquid filter   | 201, 211, 222, 239, 252   |
|                     | 667005                                | UV5, Holmium liquid filter (according EP 10)  | 241, 287, 361, 451, 485, 536, 640                               |
|                     | 667400                                | UV5, Holmium liquid filter set (incl. UV14 according EP 10)   | 241, 287, 361, 451, 485, 536, 640                               |
|                     | 666F1-339                             | Holmium Glass Filter  | 279, 361, 454, 536, 638   |
|                     | 667025EPUSP                           | UV25, Didymium liquid filter for testing wavelength accuracy above 640 nm [according EP 10 and USP 857]   | 512, 732, 740, 794, 801, 864                                    |
|                     | 667045EPUSP                           | UV45, HoDi Filter (Holmium and Didymium in Perchloric acid) for testing wavelength accuracy from 240 up to 870 nm [according EP 10 and USP 857] | 241, 287, 361, 451, 482, 512, 537, 641, 732, 740, 794, 801, 864 |
|                     | 667014                                | UV14, Reference Filter (Perchloric acid)  | 235, 257, 313, 350  |
| Stray Light         | 667001                                | UV1, Potassium chloride in pure water, 2 Abs at 198 nm  | 200 Cut-off   |
|                     | 667010                                | UV10, Sodium iodide in pure water, 3 Abs at 220 nm  | 259 Cut-off   |
|                     | 667023                                | UV23, Potassium iodide in pure water, 3 Abs at 250 nm   | 259 Cut-off   |
|                     | 667011                                | UV11, Sodium nitrite in pure water, 3 Abs at 340 and 370 nm   | 385 Cut-off   |
|                     | 667012                                | UV12, Pure Water (reference filter)   | 198, 200, 300, 400  |
|                     | 667100                                | Filter set includes: UV1 and UV12   | 200 Cut-off   |
|                     | 667101                                | Filter set includes: UV10 and UV12  | 259 Cut-off   |
|                     | 667107                                | Filter set includes: UV23 and UV12  | 259 Cut-off   |
|                     | 667102                                | Filter set includes: UV11 and UV12  | 385 Cut-off   |
|                     | 667103                                | Filter set includes: UV1, UV10, UV11, UV12  | Cut-off: 200, 259, 385  |
| 667104              | Filter set includes: UV10, UV11, UV12 | Cut-off: 259, 385   |   |
| Resolution          | 667006                                | UV6, Toluene in Hexane  | slit width: 0.5; 1.0; 1.5; 2.0; 3.0                             |
|                     | 667009                                | UV9, Hexane (reference filter)  |   |
|                     | 667200                                | Filter set: Toluene in hexane with Hexane reference filter  | Scan from 265 to 270, slit width: 0.5; 1.0; 1.5; 2.0; 3.0       |

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