# Product data sheet

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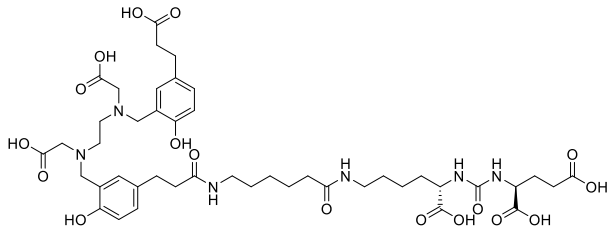
|---|---|
| MedKoo Cat#: 556010<br>Name: PSMA-11 free base<br>CAS#: 1366302-52-4 (free base)<br>Chemical Formula: $C_{44}H_{62}N_6O_{17}$<br>Exact Mass: 946.4171<br>Molecular Weight: 947.005 |  |
| Product supplied as: | Powder |
| Purity (by HPLC): | ≥ 98% |
| Shipping conditions | Ambient temperature |
| Storage conditions: | Powder: -20°C 3 years; 4°C 2 years. |
| | In solvent: -80°C 3 months; -20°C 2 weeks. |

**1. Product description:**
PSMA-11, also known as DKFZ-PSMA-11, HBED-CC-PSMA or Psma-hbed-CC, is a ligand to make gallium Ga 68-labeled PSMA-11, which has potential use as a tracer for PSMA-expressing tumors during positron emission tomography (PET). Upon intravenous administration of gallium Ga 68-labeled PSMA-11, the Glu-urea-Lys(Ahx) moiety targets and binds to PSMA-expressing tumor cells. Upon internalization, PSMA-expressing tumor cells can be detected during PET imaging. PSMA, a tumor-associated antigen and type II transmembrane protein, is expressed on the membrane of prostatic epithelial cells and overexpressed on prostate tumor cells

**2. CoA, QC data, SDS, and handling instruction**
SDS and handling instruction, CoA with copies of QC data (NMR, HPLC and MS analytical spectra) can be downloaded from the product web page under "QC And Documents" section. Note: copies of analytical spectra may not be available if the product is being supplied by MedKoo partners. Whether the product was made by MedKoo or provided by its partners, the quality is 100% guaranteed.

**3. Solubility data**

| Solvent | Max Conc. mg/mL | Max Conc. mM |
|---|---|---|
| DMSO | 100 | 105.6 |

**4. Stock solution preparation table:**

| **Concentration / Solvent Volume / Mass** | **1 mg** | **5 mg** | **10 mg** |
|---|---|---|---|
| 1 mM | 1.06 mL | 5.28 mL | 10.56 mL |
| 5 mM | 0.21 mL | 1.06 mL | 2.11 mL |
| 10 mM | 0.11 mL | 0.53 mL | 1.06 mL |
| 50 mM | 0.02 mL | 0.11 mL | 0.21 mL |

**5. Molarity Calculator, Reconstitution Calculator, Dilution Calculator**
Please refer the product web page under section of "Calculator"

**6. Recommended literature which reported protocols for in vitro and in vivo study**
In vitro study

Reverchon J, Khayi F, Roger M, Moreau A, Kryza D. Optimization of the radiosynthesis of [68Ga]Ga-PSMA-11 using a Trasis MiniAiO synthesizer: do we need to heat and purify? Nucl Med Commun. 2020 Sep;41(9):977-985. doi: 10.1097/MNM.0000000000001233. PMID: 32796487.

In vivo study

Fendler WP, Calais J, Eiber M, Flavell RR, Mishoe A, Feng FY, Nguyen HG, Reiter RE, Rettig MB, Okamoto S, Emmett L, Zacho HD, Ilhan H, Wetter A, Rischpler C, Schoder H, Burger IA, Gartmann J, Smith R, Small EJ, Slavik R, Carroll PR, Herrmann K, Czernin J, Hope TA. Assessment of 68Ga-PSMA-11 PET Accuracy in Localizing Recurrent Prostate Cancer: A Prospective Single-Arm Clinical Trial. JAMA Oncol. 2019 Jun 1;5(6):856-863. doi: 10.1001/jamaoncol.2019.0096. PMID: 30920593; PMCID: PMC6567829.

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**7. Bioactivity**

Biological target:

Ga 68 PSMA-11 binds to prostate-specific membrane antigen (PSMA). It binds to cells that express PSMA, including malignant prostate cancer cells, which usually overexpress PSMA. Gallium-68 (Ga 68) is a β+ emitting radionuclide that allows positron emission tomography (PET).

In vitro activity

The procedure was completely automated and provided a high radiochemical yield. It can be performed several times a day, facilitating the clinical demand of this radiopharmaceutical.

Reference: Reverchon J, Khayi F, Roger M, Moreau A, Kryza D. Optimization of the radiosynthesis of [68Ga]Ga-PSMA-11 using a Trasis MiniAiO synthesizer: do we need to heat and purify? Nucl Med Commun. 2020 Sep;41(9):977-985. doi: 10.1097/MNM.0000000000001233. PMID: 32796487.

In vivo activity

A total of 635 men were enrolled with a median age of 69 years (range, 44-95 years). On a per-patient basis, PPV was 0.84 (95% CI, 0.75-0.90) by histopathologic validation (primary endpoint, n = 87) and 0.92 (95% CI, 0.88-0.95) by the composite reference standard (n = 217). 68Ga-PSMA-11 PET localized recurrent prostate cancer in 475 of 635 (75%) patients; detection rates significantly increased with prostate-specific antigen (PSA): 38% for <0.5 ng/mL (n = 136), 57% for 0.5 to <1.0 ng/mL (n = 79), 84% for 1.0 to <2.0 ng/mL (n = 89), 86% for 2.0 to <5.0 ng/mL (n = 158), and 97% for ⩾5.0 ng/mL (n = 173, P < .001). Interreader reproducibility was substantial (Fleiss κ, 0.65-0.78). There were no serious adverse events associated with 68Ga-PSMA-11 administration. PET-directed focal therapy alone led to a PSA drop of 50% or more in 31 of 39 (80%) patients.Using blinded reads and independent lesion validation, high PPV for 68Ga-PSMA-11 PET, detection rate and interreader agreement for localization of recurrent prostate cancer.

Reference: Fendler WP, Calais J, Eiber M, Flavell RR, Mishoe A, Feng FY, Nguyen HG, Reiter RE, Rettig MB, Okamoto S, Emmett L, Zacho HD, Ilhan H, Wetter A, Rischpler C, Schoder H, Burger IA, Gartmann J, Smith R, Small EJ, Slavik R, Carroll PR, Herrmann K, Czernin J, Hope TA. Assessment of 68Ga-PSMA-11 PET Accuracy in Localizing Recurrent Prostate Cancer: A Prospective Single-Arm Clinical Trial. JAMA Oncol. 2019 Jun 1;5(6):856-863. doi: 10.1001/jamaoncol.2019.0096. PMID: 30920593; PMCID: PMC6567829.