

1H-NMRと質量分析による同定
HPLCまたはGCによる純度測定

FT-IRやTGAでの分析
ご希望に応じたその他の評価結果

分析証明書の一例

TRUE COPY DAICEL CHIRAL TECHNOLOGIES (INDIA) PRIVATE LIMITED
DNV-GL US-FDA REG: 3009883135

ISO 9001:2015 CERTIFIED

CERTIFICATE OF ANALYSIS

Product Name: **Bendamustine Glycerol Ester**
Molecular formula: **C₂₁H₂₇ClN₃O₅**
Molecular weight: **432.31**
Molecular structure:

Batch Number: DCTI-SYN-197-017
Batch quantity: 2.7 g
Date of Manufacturing: 13-Jul-2022
Date of Analysis: 13-Jul-2022
Next Retest Date: 12-Jul-2024
CAS No.: Not Available
Catalogue No.: DCTI-C-001
COA No.: COA-AS-22-723

Storage Conditions: Store at 2-8°C
Chemical name: 2,3-dihydroxypropyl 4-(3-S-(2-chloroethylamino)-1-methyl-1H-benzimidazol-2-yl)butanoate

S.No.	Test	Result
1	Description	Off white color solid
2	Solubility	Freely soluble in Methanol
3	Identification by Mass spectrometry	Confirms to the structure
4	Identification by 1H NMR	Confirms to the structure
5	Identification by D ₂ O Exchange	Confirms to the structure
6	Identification by 13C NMR	Confirms to the structure
7	Identification by FT-IR	Confirms to the structure
8	Purity by HPLC (vs Area)	98.01
9	Loss on drying (LOD) by TGA (vs wt)	0.22
10	Potency (vs wt)	97.79

Other Notes: Not applicable.
Note: This is a certified standard suitable for identification, qualitative and quantitative analysis. Not for human or animal consumption.

Function	Compiled by	Checked by	Approved By
Name	Ch. Sri Lakshya	T. Shiva Shankar	P. Moorthy
Department	Analytical Services	Analytical Services	Quality Assurance
Sign & Date			

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HPLC

DAICEL CHIRAL TECHNOLOGIES (INDIA) PVT. LTD. CHROMATOGRAM

Sample Information: L.SI_2022_2-1000-2-L.SI_011_210722_008.ind
Applied by: L.N.MW.S
Prepared by: Srinivasan Glycerol Ester Impurity
Sample No: DCTI-SYN-197-017
Vial: 10
Injection Volume: 10
Method File: L.SI_HPLC_0011_218.km
Batch File: L.SI_011_210722_008.km
Data File: L.SI_011_210722_008.km
Date Acquired: 13-Jul-2022 12:00:00
Date Promoted: 22-Jul-2022 08:45:15
Comment: DCTI-SYN-00861

System Configuration: L.SI_2022_2-1000-2-L.SI_011_210722_008.km
Instrument: HPLC-0011

Chromatogram: L.SI_2022_2-1000-2-L.SI_011_210722_008.km

Peak	RT	Area	Area%	Mark	
1	12.24	581	1339	0.11	
2	17.37	0.81	889	20004	1.16
3	23.73	0.82	73	1219	0.06
4	28.82	1.00	45604	1766328	98.01
5	31.89	1.11	2516	8781	0.38
6	45.51	1.41	1064	3062	0.17
7	52.20	1.81	1527	13392	0.06
Total		47247	1798424	100.00	

Detector A 235nm
Flow: 1.00 mL/min
Temp: 30.00°C
Wavelength: 235.00 nm

0.2-4.2022 09:12:00 (0.30) - L.SI_011_210722_008.km
This Chromatogram is Electronically Signed

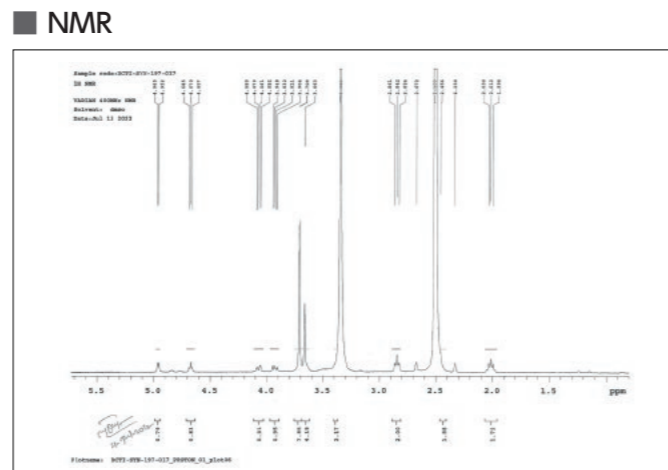
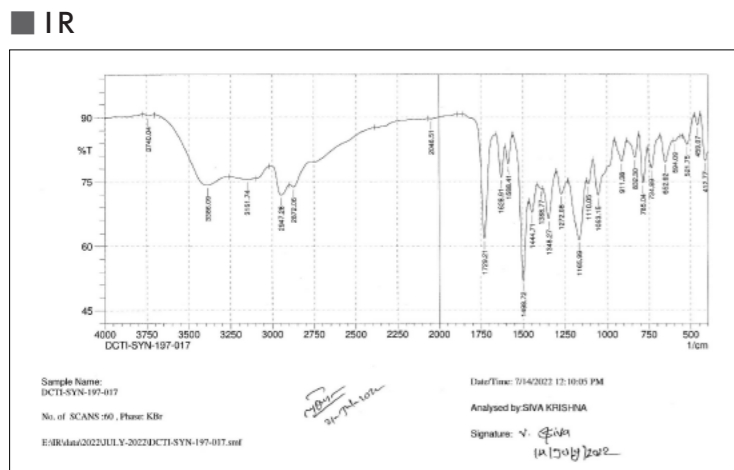
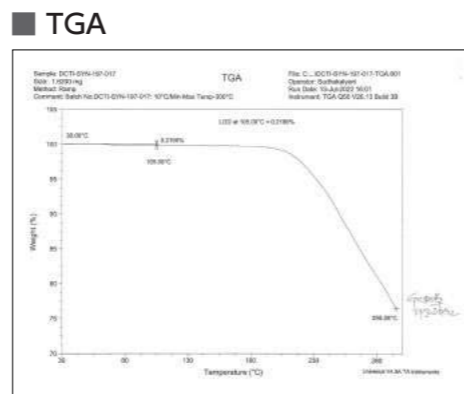
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CALCULATOR SHEET FOR POTENCY CALCULATION FOR RAW OR A SAMPLE

Product Name	Batch No	USP Purity%	LOD (%)	Potency (%)
Bendamustine Glycerol Ester Impurity	DCTI-SYN-197-017	98.01	0.22	97.79

Polysyllable: (IMP) IMPURITY

Applied By: Srinivasan
Checked By: Srinivasan



お問合せフォームはこちら →



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カスタムメイド
充実した分析証明書
米国FDA認証設備での品質保証

LABELLED STANDARDS



■豊富なラインナップ

- ・医薬品原薬/代謝物の標識化合物
- ・重水素標識化合物
- ・グルクロン酸抱合体標識化合物
- ・安定同位体の標識化合物

■カスタムメイド

長年培った合成技術で、お客様のニーズに応じて
カスタムメイドが可能

■化合物例

製品名	Phytonadione D7	Ubrogepant D5	Ruxolitinib D9
構造式			
CAS No. 製品番号	NA DCTI-A-011	NA DCTI-A-290	941678-49-5(Unlabelled) DCTI-A-142
Bupropion Hydrochloride-D9	Cyclosporine D4	Sildenafil-D8	Vortioxetine-D8
1189725-26-5 DCTI-A-075	59865-13-3 (Un Labelled) DCTI-A-144	951385-68-5 DCTI-A-135	2140316-62-5 DCTI-A-053
Velpatasvir-13CD3	Nitroso aryl piperazine	Nitroso aryl piperazine-D8	
1377049-84-7 (Un Labelled) DCTI-A-059	NA DCTI-C-2237	NA DCTI-A-286	

ラインナップは
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ラインナップにない場合には、こちら (chiral@jp.daicel.com) へお問合せください

IMPURITY STANDARDS



■豊富なラインナップ

2,000以上の不純物標品を保有

■高品質・高純度な製品

- ・分取用HPLC, SFC装置により精製が可能
- ・ELSD, MS検出で0.1%レベルの微量類縁体の分離を実現

■カスタムメイド

長年の経験で培った合成技術
構造が複雑な類縁物質も合成可能

■化合物例

製品名	Daptomycin impurity-1	Vasopressin D5	Leuprolide Impurity 6
構造式			
CAS No. 製品番号	NA DCTI-D-013	NA DCTI-D-067	NA DCTI-D-019
D-Thr(6)-Octreotide	Calcitonin Salmon D10 Impurity	Edoxaban Tosylate-RRS-isomer Impurity	Fosfomycin Impurity D
NA DCTI-D-042	NA DCTI-D-044	480449-28-3 (HCl Salt) DCTI-C-604	1262243-12-8 DCTI-C-869
Levothyroxine Impurity-H	Isavuconazole Impurity-2	Phytonadione Diol Impurity	
2055-97-2 DCTI-C-190	2001051-99-4 DCTI-C-1922	107759-10-4 DCTI-C-045	

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