DIAFIT®

Adhesives for transdermal drugs

Daido Chemical Corporation
Life science division

DIAFIT® is an acrylic ester copolymer-based medical adhesive for transdermal drug developed by Daido Chemical Corporation.
We have Japanese Pharmaceutical Excipients grade and also new polymer development grades.
Our Japanese Pharmaceutical Excipients grade complies to the standard and also has high cohesive force.
New polymer development grade can be customized its resin structure accordingly to the used API's feature.

Japanese Pharmaceutical Excipients (JPE) grade

Grade name	Indication	Standard
4801	2-Ethylhexyl acrylate, 2-ethylhexyl methacrylate, dodecyl methacrylate copolymer solution	JPE
4802 4802B	2-Ethylhexyl acrylate Vinyl pyrrolidone copolymer solution	JPE

※ Ethyl acetate are used as solvent

Japanese Pharmaceutical Excipients (JPE) grade

		4801	4802, 4802B
Appearance		Colorless transparent viscose liquid with characteristic odor	White to yellowish liquid with characteristic odor
Identification		Complies to standard	Complies to standard
Viscosity		Intrinsic viscosity not less than 1.1	5000mPa・s/ 25degC
Purity test	Heavy metals	Not more than 20ppm	Not more than 20ppm
	Arsenic	-	Not more than 1ppm
	Elution test (i, ii)	-	Complies to standard
	2-Ethylhexyl acrylate 2-Ethylhexyl methacrylate Dodecyl methacrylate	Not more than 0.2%	-
	2-Ethylhexyl acrylate Vinyl pyrrolidone	-	Complies to standard
Loss on drying		30.0-70.0%	61.5-68.5%
Ignition residue		Not more than 0.1%	Not more than 0.5%

Japanese Pharmaceutical Excipients (JPE) grade [general properties]

Grade name	4801	4802	4802B
Appearance	Transparent liquid	Clouded liquid	Transparent liquid
Non volatiles (%)	50	37	33
Viscosity (mPa・s/25degC)	19000	7000	25000
Remarks	Intrinsic viscosity 1.3		High cohesion grade

※ Data on this leaflet are not standard.

Adhesive properties test conditions

Measurement environment： 23degC / 65%RH

Adhesive sheet composition：

[base] corona-treated PET / [adhesive] 25μm (dry) / [separator] PET 38μm

Adhesive strength：180° peeling method (300mm/min) [adherends] Glass, SUS430BA

Holdings strength：40° C or 80° C, 1kg load, 1 hour, sample area 25mm x 25mm,
evaluation by displacement distance or drop time
[adherends] Glass, SUS304

Ball-tac：J.Dow method (inclined ball tuck test method), aiding 100mm

Adhesive property 1 [Basic 3 properties of adhesion]

Grade name		4801	4802	4802B
Adhesion N/25mm	VS glass	4	18	15
	VS SUS	3	15	13
Holding strength		Stayed	Dropped in 16min	Moved 13mm
Ball tack		Not more than 2	15	26

Features

DIAFIT 4801：low tack / high cohesion

DIAFIT 4802B：high tack / high adhesion

Adhesion property 2-1 [absorption enhancer blending test：DIAFIT4801]

4801		Base	Isopropyl myristate			Fatty acid triglycerides		
Blend amount (%/Solid matter)		0	10	20	30	10	20	30
Adhesion N/25mm	VS glass	4.0	2.5	0.7	0.3	4.8	0.9	0.4
	VS SUS	3.0	4.0	0.9	0.4	5.0	1.9	0.8
Holding strength		Stayed	Dropped in 17min.	Dropped in 1min.	Dropped immediately	Dropped in 16min.	Dropped in 1min.	Dropped in 10sec.

2-Octyldodecanol			1,3-BG			Polyethylene glycol lauryl ether		
10	20	30	10	20	30	1	3	5
2.6	0.6	0.4	1.4	Adhesion layer whitened		Tack reduced		
3.2	1.4	0.7	1.8	Adherend surface contaminated		Not measurable		
Dropped 11min.	Dropped in 1min.	Dropped in 10sec.	Stayed	Stayed	Moved 1mm			

Compatible with lipophilic additives and does not cause cohesive failure even when blended at 30%.

Adhesion property 2-2 [absorption enhancer blending test：DIAFIT4802]

4802		Base	Isopropyl myristate			Fatty acid triglycerides		
Blend amount (%/Solid matter)		0	10	20	30	10	20	30
Adhesion N/25mm	VS glass	10.0	5.0	15.2CF	7.3CF	6.4	3.7	0.4CF
	VS SUS	11.3	6.0	16.8CF	07.4CF	7.1	4.1	0.8CF
Holding strength		Dropped in 27min.	Dropped in 2min.	Dropped in 30sec.	Dropped immediately	Dropped in 3min.	Dropped in 45sec.	Dropped immediately

2-Octyldodecanol			1,3-BG			Polyethylene glycol lauryl ether		
10	20	30	10	20	30	1	3	5
5.7	4.2	7.5CF	12.9	8.7	9.0	15.0	4.9	2.7
6.0	5.2	7.8CF	12.4	14.7	8.2	11.4	6.3	5.1
Dropped 3min.	Dropped in 20sec.	Dropped immediately	Dropped in 31min.	Dropped in 27min.	Dropped in 20min.	Dropped in 26min.	Dropped in 10min.	Dropped in 9min.

Compatible with all enhancers but tends to cause cohesive failure when added large amounts.

Adhesion property 2-3 [absorption enhancer blending test：DIAFIT4802B]

4802		Base	Isopropyl myristate			Fatty acid triglycerides		
Blend amount (%/Solid matter)		0	10	20	30	10	20	30
Adhesion N/25mm	VS glass	13.4	10.1	3.2	2.4CF	5.4	1.4	2.0
	VS SUS	10.7	3.8	2.1	9.3CF	6.1	2.5	2.2
Holding strength		Moved 1mm	Dropped in 7min.	Dropped in 2min.	Dropped in 20sec.	Dropped in 8min.	Dropped in 1min.	Dropped in 10sec

2-Octyldodecanol			1,3-BG			Polyethylene glycol lauryl ether		
10	20	30	10	20	30	1	3	5
4.5	1.8	1.4	12.7	13.0	8.0	11.2	3.4	0.4
5.1	2.4	2.3	13.3	13.6	7.4	9.9	4.3	4.3
Dropped in 5min.	Dropped in 45sec.	Dropped in 10sec.	Moved 3mm	Dropped in 47min.	Dropped in 44min.	Moved 1mm	Dropped in 33min.	Dropped in 24min.

Compatible with all enhancers does not cause cohesive failure even when blended at 30%.

Adhesion property 3-1 [adhesive blending test 1]

		4801	4801:4802 [solid matter ratio]			4802
		Alone	2:1	1:1	1:2	alone
Adhesion N/25mm	VS glass	4	5.0CF	9.9CF	12.5	18
	VS SUS	3	7.7CF	11.2CF	11.3	15
Holding strength		Stayed	Moved 1mm	Moved 5mm	Moved 6mm	Dropped in 16min.
Appearance		Transparent	Turbid→isolate	Turbid→isolate	Turbid→isolate	Turbid

○ When the ratio of 4801 (2EHA/2EHMA/LMA) is more than half, cohesive failure will occur due to incompatibility between the adhesives.

○ When the ratio of 4802 (2EHA/NVP) is high, the cohesive strength increases while the adhesive strength decreases.

○ As 4801 and 4802 are incompatible, blends will separate over time (can be re-mixed).

Adhesion property 3-2 [adhesive blending test 2]

		4801	4801:4802B [solid matter ratio]			4802B
		Alone	2:1	1:1	1:2	Alone
Adhesion N/25mm	VS glass	4	11.2	13.4CF	13.1	15
	VS SUS	3	10.7	12.3CF	11.8	13
Holding strength		Stayed	Stayed	Moved 0.8mm	Moved 1.2mm	Moved 13mm
Appearance		Transparent	Turbid→isolate	Turbid→isolate	Turbid→isolate	Transparent

○ When the ratio is equal, due to the incompatibility will cause cohesive failure.

○ When blending small amount of 4802B into 4801, the adhesive strength is improved while maintaining the cohesive strength.

○ When blending small amount of 4801 into 4802B, reduces the decrease in adhesive strength and improves cohesive strength.

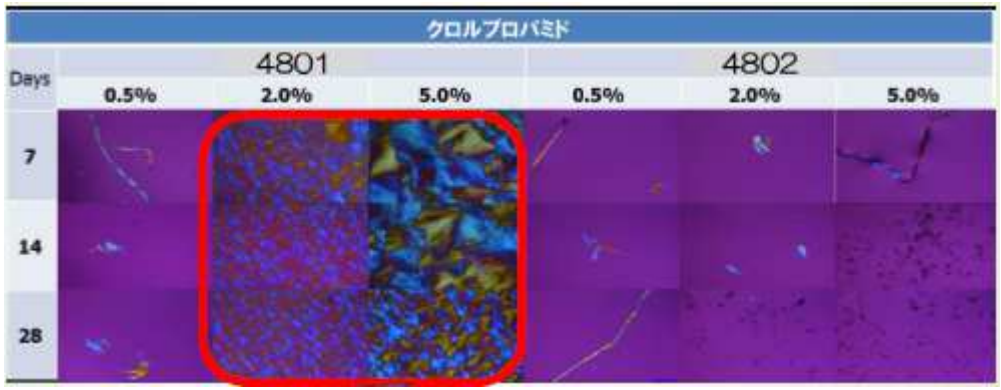
○ As 4801 and 4802B are incompatible, blends will separate over time (can be re-mixed).

Compatibility with drugs 1-1

[Method of evaluation]

Mixed various APIs at 0.5, 2.0, and 5.0% of the adhesive solid content and mix uniformly. Apply the mixed The mixed sample is applied to a glass slide and dried at room temperature to create a sample for observation. Applied mixed samples to a glass slide and dried at room temperature to prepare for observation. Observed the main drug's crystalline state in the acrylic polymer by polarizing microscope. Samples were stored at room temperature.

(Chlorpropamide)



When the solubility of the drug substance was excessive, precipitation and crystallization were observed.

Compatibility with drugs 1-2

Not crystalized	Crystalized
○	X

Chlorpropamide						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	X	X	○	○	○
14	○	X	X	○	○	○
28	○	X	X	○	○	○

Haloperidol						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	X	X	○	○	X
14	○	X	X	○	○	X
28	○	X	X	○	○	X

Tolbutamide						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	○	X	○	○	○
14	○	○	X	○	○	○
28	○	○	X	○	○	○

Acetaminophen						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	X	X	X	○	○	○
14	X	X	X	○	○	○
28	X	X	X	○	○	○

Nifedipine						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	○	○	○	○	○
14	○	○	○	○	○	○
28	○	○	○	○	○	○

Ketoprofen						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	○	○	○	○	○
14	○	○	○	○	○	○
28	○	○	○	○	○	○

Compatibility with drugs 1-3

Griseofulvin						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	X	X	○	X	X
14	○	X	X	○	X	X
28	○	X	X	○	X	X

Indomethacin						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	○	○	○	○	○
14	○	○	○	○	○	○
28	○	○	○	○	○	○

Phenytoin						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	○	X	X	○	X	X
14	○	X	X	○	X	X
28	○	X	X	○	X	X

Carbamazepine						
Days	4801			4802		
	0.5%	2.0%	5.0%	0.5%	2.0%	5.0%
7	X	X	○	○	○	X
14	X	X	○	○	○	X
28	X	X	○	○	○	X

As 4802 has a pyrrolidone group in polymer and therefore has excellent affinity for drugs that are generally considered to be poorly water-soluble.

Developments of new polymer

We also develop new polymer adhesives that are not listed in the pharmaceutical excipients standard by utilizing our specialty radical polymerization technology. We develop adhesives that are compatible with drugs and that meet the intended use.

Example of development of new adhesives

		P-7305	P-7310	P-7306
Structure		Acrylic ester/vinyl acetate copolymer	Acrylic ester/vinyl acetate copolymer	Acrylic acid/acrylic ester copolymer
Appearance		Turbid liquid	Slightly turbid liquid	Turbid liquid
Non volatiles (%)		39.0	50.0	35.0
Viscosity (mPa・s)		10,000	18,000	7,000
Molecular weight		Approx. 800,000	Approx. 700,000	Approx. 750,000
Resin acid value (mgKOH/g)		Not more than 0.5	Not more than 0.5	19
Adhesion N/25mm	VS glass	14.8	13.7	13.4
	VS SUS	8.4	13.6	8.7
Holding strength		Moved 2mm	Dropped in 15min.	Moved 3.5mm

Example of development of new adhesives

		P-7305			
IPM blending amount (%/solid matter)		0	10	20	30
Adhesion N/25mm	VS glass	8.9	6.5	4.7	1.0
	VS SUS	7.4	5.7	3.1	1.1
Holding strength		Moved 3mm	Dropped in 7min.	Dropped in 1min.	Dropped in 20sec.

This is an example of the development of an adhesive copolymerized with vinyl acetate, which has high cohesion.
Even when blended with an absorption promoting agent (IPM), it does not cause cohesive failure.
Other adjustments can be made to meet your needs.