

PHARMACEUTICAL IMPURITIES

Decomposition of pharmaceutical ingredients may occur during the production of the final formulation, and the impurity profile will depend on the method used in the production.

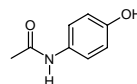
The pharmaceutical monographs regulate the analysis and the limits of impurities of a given substance. For this reason Chiron has produced standards for accurate measurement of such impurities in morphine, codeine and other pharmaceuticals.

Guidelines for impurities in pharmaceutical formulations are given in the monographs, from the manufacturer or in the International Conference on Harmonization (ICH) guidelines.

ACETAMINOPHENE

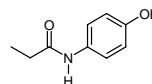
2524,8

Acetaminophene (98 %)
(4-Acetaminophenol)
[103-90-2]
1 mg/mL in 1 mL isopropanol
500mg



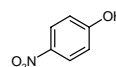
Imp. B
2549,9

N-(4-Hydroxyphenyl)-propionamide
[1693-37-4]
0.1 mg/mL in 1 mL isopropanol
100 mg



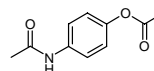
Imp. F
2087,6

4-Nitrophenol (99 %)
[100-02-7]
1 mg/mL in 1 mL isopropanol
100 mg



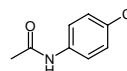
Imp. H
2550,10

N,O-Diacetyl-4-aminophenol (98 %)
[2623-33-8]
0.1 mg/mL in 1 mL isopropanol
100 mg



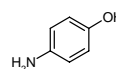
Imp. J
2512,8

4'-Chloroacetanilide (95 %)
[539-03-7]
1 mg/mL in 1 mL isopropanol
100 mg



Imp. K
2519,6

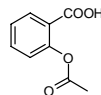
4-Aminophenol (97 %)
[123-30-8]
1 mg/mL in 1 mL isopropanol
500 mg



ACETYLSALISYLIC ACID

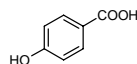
2513,9

Acetylsalicylic acid (99 %)
[50-78-2]
1 mg/mL in 1 mL isopropanol
500 mg



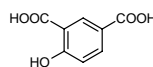
Imp. A (EP):
2514,7

4-Hydroxybenzoic acid (99 %)
[99-96-7]
1 mg/mL in 1 mL isopropanol
100 mg



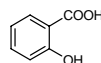
Imp. B (EP):
2539,8

4-Hydroxyisophthalic acid (99 %)
(4-Hydroxybenzene-1,3-dicarboxylic acid)
[636-46-4]
1 mg/mL in 1 mL isopropanol
100 mg



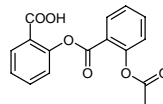
Imp. C (EP):
2515,7

Salicylic acid (99 %)
(2-Hydroxybenzoic acid)
[69-72-7]
1 mg/mL in 1 mL isopropanol
500 mg



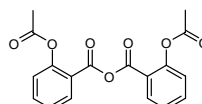
Imp. D (EP):
2516,16

Acetylsalicylsalicylic acid (97 %)
[530-75-6]
0.1 mg/mL in 1 mL isopropanol
10 mg, 25 mg, 100 mg



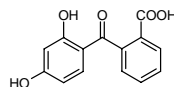
Imp. F (EP):
2551,18

O-Acetylsalicylic anhydride (98 %)
[1466-82-6]
0.1 mg/mL in 1 mL isopropanol
100 mg



2710,14

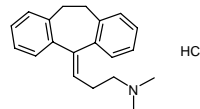
2-(2,4-Dihydroxybenzoyl)benzoic acid
[2513-33-9]
0.1 mg/mL in 1 mL isopropanol



AMITRITYLINE HYDROCHLORIDE

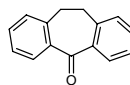
2543,20

Amitriptyline hydrochloride (98 %)
[549-18-8]
1 mg/mL in 1 mL isopropanol
100 mg



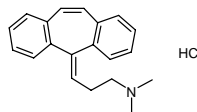
Imp. A (EP):
2544,15

Dibenzosuberone (97 %)
[1210-35-1]
0.1 mg/mL in 1 mL isopropanol
100 mg



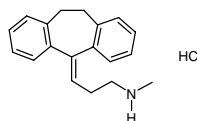
Imp. B (EP):
2697,20

Cyclobenzaprine hydrochloride
[6202-23-9]
0.1 mg/mL in 1 mL isopropanol
100 mg



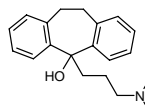
Imp. C (EP):
2698,19

Nortriptyline hydrochloride (98%)
[894-71-3]
0.1 mg/mL in 1 mL isopropanol
100 mg



Imp. D (EP):
2711,20

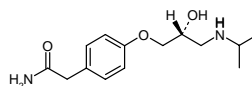
5-(3-Dimethylaminopropyl)-10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-ol
[1159-03-1]
0.1 mg/mL in 1 mL isopropanol



ATENOLOL

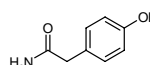
2545,14

Atenolol (98 %)
[29122-68-7]
1 mg/mL in 1 mL isopropanol
500 mg



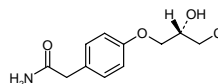
Imp. A (EP):
2521,8

2-(4-Hydroxyphenyl)acetamide (99 %)
[17194-82-0]
1 mg/mL in 1 mL isopropanol
100 mg



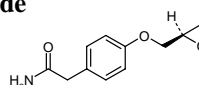
Imp. D (EP):
2712,11

2-[4-[(2RS)-3-chloro-2-hydroxypropoxy]phenyl]acetamide
[115538-83-5]
0.1 mg/mL in 1 mL isopropanol



Imp. C (EP):
2725,11

2-[4-[(2RS)-2-Oxiran-2-yl]methoxy]phenyl]acetamide
[29122-69-8]
100 mg



Imp. H (EP):

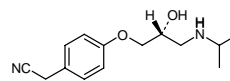
2699,14

2-[4-[(2RS)-2-hydroxy-3-[(1-methylethyl)amino]propoxy]phenyl]acetonitrile

[29277-73-4]

0.1 mg/mL in 1 mL isopropanol

100 mg



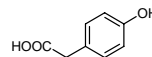
2522,8

4-Hydroxyphenylacetic acid (98 %)

[156-38-7]

1 mg/mL in 1 mL isopropanol

100 mg



CAFFEINE

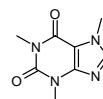
2517,8

Caffeine (98 %)

[58-08-2]

1 mg/mL in 1 mL isopropanol

500 mg



Imp. A (EP):

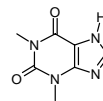
2518,7

Theophylline (99 %)

[58-55-9]

0.1 mg/mL in 1 mL isopropanol

500 mg



Imp. C (EP):

2700,8

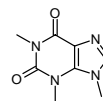
Isocaffeine

(1,3,9-Trimethylxanthine)

[519-32-4]

1 mg/mL in 1 mL isopropanol

10 mg, 25 mg



Other:

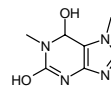
2540,7

Paraxanthine

[611-59-6]

1 mg/mL in 1 mL isopropanol

10 mg, 25 mg, 50 mg



CIMETIDINE DIHYDROCHLORIDE

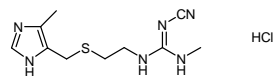
2701,11

Cimetidine hydrochloride

[70059-30-2]

1 mg/mL in 1 mL isopropanol

500 mg



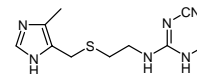
1634,10

Cimetidine (free base)

[51481-61-9]

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



Imp. C (EP):

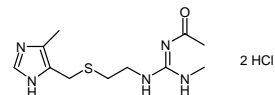
1633,11

Cimetidine amide dihydrochloride

0.1 mg/mL in 1 mL isopropanol

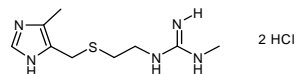
25 mg, 100 mg

Free base: [110592-19-3]



Imp. D (EP):
1632,9

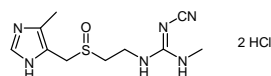
Cimetidine guanide derivative
(N-Methyl-N'-[2-[[[(5-methyl-H-imidazol-4-yl)-methyl]-thio]-ethyl]-guanidine dihydrochloride)
[59660-24-1]
0.1 mg/mL in 1 mL isopropanol
25 mg, 100 mg



Imp. E (EP)
1631,10

Cimetidine sulphoxide dihydrochloride
25 mg, 100 mg

Free base:
[54237-72-8]



2523,2

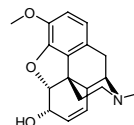
Cyanoguanidine (99 %)
[461-58-5]
1 mg/mL in 1 mL isopropanol
100 mg



CODEINE

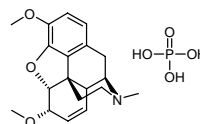
1562,18

Codeine (free base)
(Controlled substance)
[76-57-3]
1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



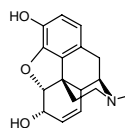
Imp. A (EP):
1898,19

6-O-Methylcodeine phosphate
(Methylcodein phosphate)
(Controlled substance)
[2859-16-7] as free base
0.1 mg/mL in 1 mL isopropanol
10 mg, 25 mg, 100 mg, 250 mg



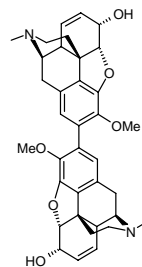
Imp. B (EP):
1574,17

Morphine (free base)
(Controlled substance)
[57-27-2]
1 mg/mL in 1 mL isopropanol
10 mg, 25 mg, 100 mg, 250 mg



Imp. C (EP):
1572,38

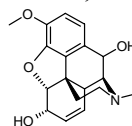
Dimethylpseudomorphine
(Codeine dimer)
[121395-47-9]
0.1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



Imp. E (EP):
1566,18

10-Hydroxycodeine

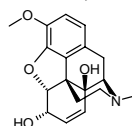
7,8-Didehydro-4,5 α -epoxy-3-methoxy-17-methylmorphinan-6 α ,10-diol
[1777-89-5]
0.1 mg/mL in 1 mL isopropanol
10 mg, , 25 mg, 100 mg, 250 mg



Imp. F (EP):
1573,18

14-Hydroxycodeine

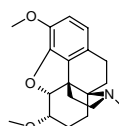
7,8-Didehydro-4,5 α -epoxy-3-methoxy-17-methylmorphinan-6 α ,14-diol
[4829-46-3]
0.1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



Imp. G (EP):
2702,19

Thebaine

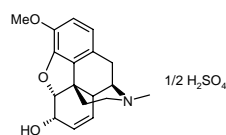
[115-37-7]
0.1 mg/mL in 1 mL isopropanol
25 mg, 50 mg



Other:
1565,36

Dicodein sulphate

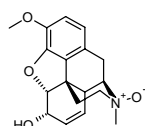
(Controlled substance)
[1420-53-7]
1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



1567,18

Codeine N-oxide (free base)

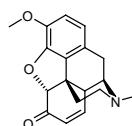
(Controlled substance)
[3688-65-1]
0.1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



1571,18

Codeinone

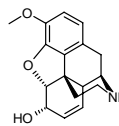
[467-13-0]
0.1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



1569,17

Norcodeine

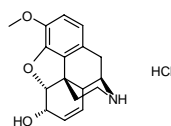
(controlled substance)
[467-15-2]
1 mg/mL in 1 mL isopropanol
10 mg, 100 mg, 250 mg



1899,17

Norcodeine hydrochloride

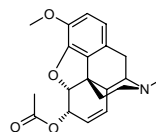
(Controlled substance)
[14648-14-7]
1 mg/mL in 1 mL isopropanol
10 mg, 25 mg, 100 mg, 250 mg



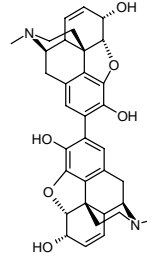
2546,20

6-O-Acetylcodein

(Controlled substance)
[6703-27-1]
0.1 mg/mL in 1 mL isopropanol
10 mg, 25 mg

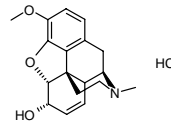


1570,18 **Pseudomorphine** (free base)
[125-24-6]
0.1 mg/mL in 1 mL isopropanol
10 mg, 25 mg, 100 mg, 250 mg



CODEINE HYDROCHLORIDE DIHYDRATE

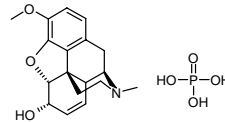
1564,18 **Codeine Hydrochloride**
(Controlled substance)
[1422-07-7]
1 mg/mL in 1 mL isopropanol
10, 100 mg, 250 mg



Impurities: See Codeine

CODEINE PHOSPHATE HEMIHYDRATE

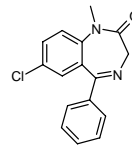
1563,18 **Codeine Phosphate Hemihydrate**
(Controlled substance)
10, 100, 250 mg



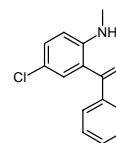
Impurities: See Codeine

DIAZEPAM

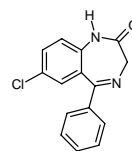
2541,16 **Diazepam**
(Controlled substance)
[439-14-5]
1 mg/mL in 1 mL isopropanol
25 mg, 100 mg



2542,14 **5-Chloro-2-(methylamino)benzophenone**
[1022-13-5]
1 mg/mL in 1 mL isopropanol
100 mg



2703,15 **Nordiazepam**
(Desmethyldiazepam)
(Controlled substance)
[1088-11-5]
0.1 mg/mL in 1 mL isopropanol



DIHYDROCODEINE HYDROGEN TARTRATE

Imp. A (EP):

1562,18

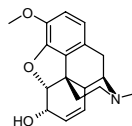
Codeine (free base)

(Controlled substance)

[76-57-3]

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



Imp. B (EP):

1574,17

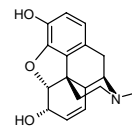
Morphine (free base)

(Controlled substance)

[57-27-2]

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



HYDROCODONE/APAP BITARTRATE

2524,8

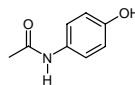
Acetaminophene, (98 %)

(4-Acetaminophenol)

[103-90-2]

1 mg/mL in 1 mL isopropanol

500 mg



Imp. (USP):

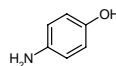
2519,6

4-Aminophenol

[123-30-8]

1 mg/mL in 1 mL isopropanol

500 mg



Imp (USP):

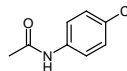
2512,8

4'-Chloroacetanilide

[539-63-7]

1 mg/mL in 1 mL isopropanol

100 mg



IBUPROFEN

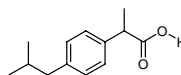
2525,13

Ibuprofen (99 %)

[15687-27-1]

1 mg/mL in 1 mL isopropanol

100 mg, 500 mg



Imp. B (EP):

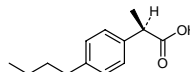
2532,13

(2RS)-2-(4-Butylphenyl)propanoic acid (98 %)

[3585-49-7]

0.1 mg/mL in 1 mL isopropanol

100 mg



(Imp. B2 (EP):)

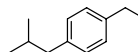
2704,12

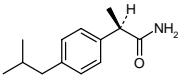
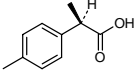
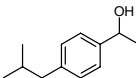
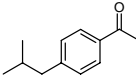
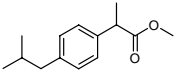
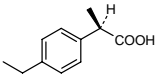
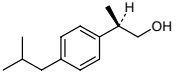
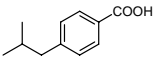
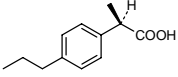
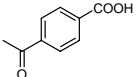
1-Ethyl-4-(2-methylpropyl)benzene

[100319-40-2]

0.1 mg/mL in 1 mL isopropanol

100 mg



<u>Imp. C (EP):</u> 2718,13	(2RS)-2-[4-(2-Methylpropyl)phenyl]propanamide [59512-17-3] 0.1 mg/mL in 1 mL isopropanol	
<u>Imp. D (EP):</u> 2535,10	(2RS)-2-(4-Methylphenyl)propanoic acid (98 %) [938-94-3] 1 mg/mL in 1 mL isopropanol 100 mg	
<u>(Imp. D2 (EP):)</u> 2537,12	(1-Hydroxyethyl)-4-(2-methylpropyl)benzene (98 %) [40150-92-3] 0.1 mg/mL in 1 mL isopropanol 100 mg	
<u>Imp. E (EP):</u> 2547,12	1-[4-(2-Methylpropyl)phenyl]ethanone (98 %) [38861-78-8] 0.1 mg/mL in 1 mL isopropanol 25 mg, 100 mg	
<u>(Imp. F2 (EP):)</u> 2708,14	Methyl 2-[4-(2-methylpropyl)phenyl]propanoate [61566-34-5] 0.1 mg/mL in 1 mL isopropanol 100 mg	
<u>Imp. N (EP):</u> 2533,11	(2RS)-2-(4-Ethylphenyl)propanoic acid (99 %) [3585-52-2] 0.1 mg/mL in 1 mL isopropanol 25 mg, 100 mg	
<u>Imp. P (EP):</u> 2536,13	(2RS)-2-[4-(2-Methylpropyl)phenyl]propan-1-ol (99 %) [36039-36-8] 0.1 mg/mL in 1 mL isopropanol 25 mg, 100 mg	
<u>(Imp. S (EP):)</u> 2527,11	4-Isobutylbenzoic acid (99 %) [38861-88-0] 0.1 mg/mL in 1 mL isopropanol 100 mg	
2534,12	(2RS)-2-(4-n-Propylphenyl)propanoic acid (98 %) [3585-47-5] 0.1 mg/mL in 1 mL isopropanol 100 mg	
<u>(Imp. U (EP):)</u> 2526,9	4-Acetylbenzoic acid (98 %) [586-89-0] 0.1 mg/mL in 1 mL isopropanol 25 mg, 100 mg	

Imp. W (EP):

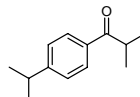
2713,13

2-Methyl-1-[4-(1-methylethyl)phenyl]-1-propanone

[72846-62-9]

0.1 mg/mL in 1 mL isopropanol

25 mg, 100 mg



LORAZEPAM

2548,15

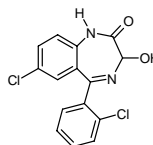
Lorazepam

(Controlled substance)

[846-49-1]

0.1 mg/mL in 1 mL isopropanol

100 mg



Imp. A (EP):

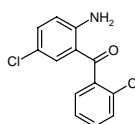
2360,13

2-Amino-2',5-dichlorobenzophenone (99 %)

[2958-36-3]

0.1 mg/mL in 1 mL isopropanol

100 mg



METFORMIN HYDROCHLORIDE

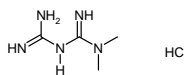
1579,4

Metformin hydrochloride

[1115-70-4]

1 mg/mL in 1 mL isopropanol

100 mg, 250 mg



Imp. A (EP):

1581,2

Dicyanodiamide

(Cyanoguanidine)

[461-58-5]

0.1 mg/mL in 1 mL isopropanol

10, 100 or 250 mg



Imp. C (EP):

2709,5

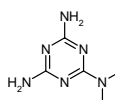
2,4-Diamino-6-dimethylamino-1,3,5-triazine (95 %)

(N,N-Dimethyl-1,3,5-triazine-2,4,6-triamine)

[1985-46-2]

0.1 mg/mL in 1 mL isopropanol

100 mg



Imp. D (EP):

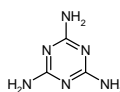
2528,3

1,3,5-Triazine-2,4,6-triamine (99 %)

[108-78-1]

0.1 mg/mL in 1 mL isopropanol

100 mg



Imp. F (EP):

2705,2

Dimethylamine

[124-40-3]

1 mg/mL in 1 mL isopropanol

100 mg



2728,3

1,1-Dimethylguanidine

[6145-42-2]

0.1 mg/mL in 1 mL isopropanol

25 mg, 100 mg



MORPHINE HYDROCHLORIDE

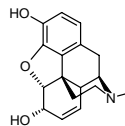
1574,17

Morphine (free base)

[57-27-2]

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg or 250 mg



Imp. A (EP):

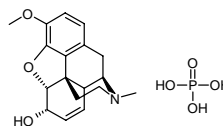
1563,18

Codeine phosphate hemihydrate

(Controlled substance)

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



Imp. B (EP):

1570,18

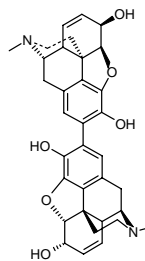
Pseudomorphine (free base)

(2,2'-Bimorphine)

[125-24-6]

0.1 mg/mL in 1 mL isopropanol

10 mg, 25mg, 100 mg, 250 mg



Other:

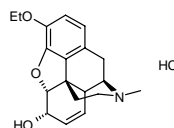
1576,19

Ethylmorphine hydrochloride

[76-58-4]

0.1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



See also Codein

MORPHINE SULPHATE

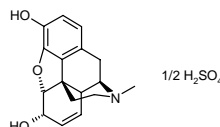
1897,34

Dimorphine sulfate

(Controlled substance)

0.1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



Imp. B (EP)

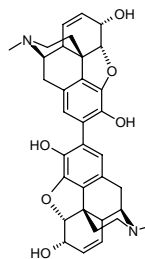
1570,18

Pseudomorphine (free base)

[125-24-6]

0.1 mg/mL in 1 mL isopropanol

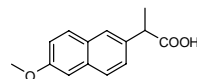
10 mg, 100 mg, 250 mg



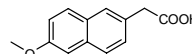
See also Morphine hydrochloride and Codeine

NAPROXEN

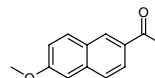
2538,14 **Naproxen** (99 %)
[22204-53-1]
0.1 mg/mL in 1 mL isopropanol
100 mg



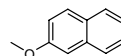
Imp. I (EP):
2531,13 **(6-Methoxy-2-naphthyl)acetic acid** (98 %)
[23981-47-7]
0.1 mg/mL in 1 mL isopropanol



Imp. L (EP):
2529,13 **2-Acetyl-6-methoxynaphthalene** (98 %)
[3900-45-6]
0.1 mg/mL in 1 mL isopropanol
100 mg

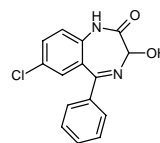


Imp. M (EP):
2530,11 **2-Methoxynaphthalene** (98 %)
[93-04-9]
0.1 mg/mL in 1 mL isopropanol
100 mg

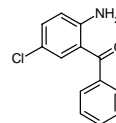


OXAZEPAM

2706,15 **Oxazepam**
(Controlled substance)
[604-75-1]
1 mg/mL in 1 mL isopropanol
10 mg, 25 mg

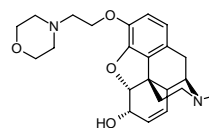


2520,13 **2-Amino-5-chlorobenzophenone** (98 %)
[719-59-5]
1 mg/mL in 1 mL isopropanol
100 mg

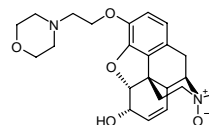


PHOLCODINE

1577,23 **Pholcodine**
[509-67-1]
10 mg, 100 mg, 250 mg



1578,23 **Pholcodine-N-oxide**
[433308-89-5]
10 mg, 100 mg, 250 mg



PROGUANIL

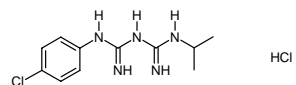
1582,11

Proguanil hydrochloride

[637-32-1]

1 mg/mL in 1 mL isopropanol

10 mg, 100 mg, 250 mg



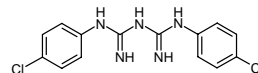
2106,14

1,5-Bis-(4-chlorophenyl)-biguanide

[13590-88-0]

0.1 mg/mL in 1 mL isopropanol

25 mg, 100 mg



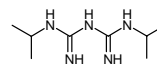
2105,8

1,5-Bis-(1-methylethyl)-biguanide

[45095-69-0]

0.1 mg/mL in 1 mL isopropanol

25 mg, 100 mg



TRAMADOL HYDROCHLORIDE

2707,16

Tramadol hydrochloride

[36282-47-0]

0.1 mg/mL in 1 mL isopropanol

