

High risk APIs List that can form nitrosamine impurities

API list				
Serial	Name	Name of impurity	AI Based on	AI(ng/d)
1	Sartans	Small molecule nitrosamines	-----	-----
2	Metformin	Small molecule nitrosamines	-----	-----
3	Amitriptyline HCL	N-nitroso- desmethyl- amitriptyline	CPCA class 1	26.5
4	Atomoxetine	N-nitroso- atomoxetine	SAR, 4- (methylnitrosoamino)- 1-(3-pyridinyl)-1- butanone (NNK)	100
5	Betahistine	N-nitroso- betahistine	CPCA class 1	26.5
6	Carvedilol	N-nitroso- carvedilol	CPCA class 3	400
7	Chlorpromazine HCL	N-nitroso- Chlorpromazine	CPCA class 1	26.5
8	Cinacalcet	N-nitroso-cinacalcet	CPCA class 3	400
9	Dabigatran Etexilate	N-nitroso- dabigatran etexilate	Limit based on negative bacterial reverse mutation test	1500
10	Desloratadine	N-nitroso- desloratadine	CPCA class 3	400
11	Diltiazem HCL	N-nitroso-	SAR, 4-	100

		desmethyl-diltiazem	(methylnitrosoamino)-1-(3-pyridinyl)-1-butanone (NNK)	
12	Dorzolamide	N-nitroso-dorzolamide	Limit based on negative bacterial reverse mutation test	1500
13	Duloxetine	N-nitroso-duloxetine	SAR, 4-(methylnitrosoamino)-1-(3-pyridinyl)-1-butanone (NNK)	100
14	maprotiline Hcl	N-nitroso-maprotiline	CPCA class 1	26.5
15	Sitagliptin	NTTP	CPCA class 2	100
16	Bisoprolol	N-nitroso-bisoprolol	CPCA class 4	1500
17	Dopxepin Hcl	N-nitroso-desmethyl-doxepin	CPCA class 1	26.5
18	Fluoxetine	N-nitroso-fluoxetine	SAR, 4-(methylnitrosoamino)-1-(3-pyridinyl)-1-butanone (NNK)	100
19	Nizatidine	N-nitroso-desmethyl-Nizatidine	CPCA class 1	26.5
		N-nitroso-Nizatidine-1	CPCA class 2	100
		N-nitroso-Nizatidine-2	CPCA class 3	400

20	Orphenadrine citrate	N-nitroso-orphenadrine	CPCA class 1	26.5
21	quinapril HCL	N-nitroso-quinapril	CPCA class 5	1500
22	Ranitidine HCl	N-nitroso-desmethyl-Ranitidine	CPCA class 1	26.5
		N-nitroso-Ranitidine -1	CPCA class 3	400
		N-nitroso-Ranitidine -2	CPCA class 2	100
23	Rifampin	1-methyl-4-nitrosopiperazine	CPCA class 3	400
24	Rifapentin	CPNP	CPCA class 3	400
25	Rizatriptan benzoate	N-nitroso-desmethyl-rizatriptan	CPCA class 1	26.5
26	Methylphenidate	N-nitroso-methylphenidate	SAR, N-nitrosopiperidine	1300
		N-nitroso-ritalinic acid	CPCA class 4	1500
27	Vildagliptin	N-nitroso-vildagliptin	CPCA class 5	1500
		N-nitroso vildagliptin amide impurity	CPCA class 5	1500
28	metoprolol	N-nitroso-metoprolol	CPCA class 4	1500

أعضاء اللجنة

رئيس اللجنة

Arab Republic of Egypt
Egyptian Drug Authority



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د. وديان يونس