

Reference Doc. :

ANNEXURE-IV PRODUCT MATRIX

Name of Product	Active Ingredient	Pharmacological Category	Strength (mg)	Solubility Rating		Cleanability Rating (B)	Lowest Therapeutic Dose		Risk Value	Maximum Units/Day	PDE Value	Maximum daily dose in mg
				Solubility	Rating (A)		LTD	Rating (C)	(A*B*C)			
	Dicyclomine Hydrochloride	Anti cholinergic	20	Freely Soluble	1	1	10	4	4	3	0.1	60
	Paracetamol	Antipyretic	500	Sparingly soluble	3	1	500	1	3		0.0667	4000
	Phenylephrine Hydrochloride	Anticold	10	Freely Soluble	1	1	10	4	4	6	0.18333	60
	Paracetamol	Antipyretic	500	Sparingly soluble	3	1	500	1	3		0.0667	4000
	Chlorpheniramine Maleate	Anticold	2	Freely Soluble	1	1	2	5	5		0.012	24
	Gliclazide	Anti diabetic	40	Practically insoluble	6	2	40	4	48	2	0.4	320
	Metformin Hydrochloride	Anti diabetic	400	Freely Soluble	1	2	500	1	2		0.02	3000
	Gliclazide	Anti diabetic	80	Practically insoluble	6	2	40	4	48	2	0.4	320
	Metformin Hydrochloride	Anti diabetic	500	Freely Soluble	1	2	500	1	2		0.02	3000
	Mecobalamin	Vitamins Supplement	0.5	Sparingly soluble	3	2	0.5	6	36	3	0.0595	2400
	Pyridoxine Hydrochloride	Vitamins supplement	10	Freely Soluble	1	1	10	4	4		50	100
	Folic Acid	Vitamins supplement	5	Practically insoluble	6	1	0.25	6	36		0.02	15
	Azithromycin	Antibiotic	250	Practically insoluble	6	2	100	3	36	2	0.667	2000
	Azithromycin	Antibiotic	500	Practically insoluble	6	2	100	3	36	1	0.667	2000
	Calcium Citrate	Calcium Supplement	1000	Slightly Soluble	4	2	400	2	16	2	1.25	
	Vitamin D3	Vitamins supplement	200 IU	Practically Insoluble	6	2	0.005	5	60		0.0025	
	Mecobalamin	Vitamins supplement	0.5	Sparingly soluble	3	2	0.5	6	36		0.0025	2400
	Pyridoxine Hydrochloride	Vitamins supplement	10	Freely Soluble	1	2	10	4	8		50	100
	Folic Acid	Vitamins supplement	5	Practically insoluble	6	1	0.25	6	36		0.02	15
	Glimepiride	Antidiabetic	2	Practically Insoluble	6	2	1	6	72	4	0.00196	8
	Glimepiride	Antidiabetic	1	Practically Insoluble	6	2	1	6	72	8	0.00196	8
	Amlodipine Basilate	Hypertensive	5	Slightly Soluble	4	1	5	5	20	2		10
	Atenolol	Hypertensive	50	Sparingly Soluble	3	1	50	3	9		0.015	200
	Azithromycin	Antibiotic	100	Practically Insoluble	6	2	100	3	36	2	0.667	2000
	Paracetamol	Antipyretic	650	Sparingly soluble	3	1	500	1	3	8	0.0667	4000
	Metformin Hydrochloride	Antidiabetic	1000	Freely Soluble	1	1	500	1	1	1	0.02	3000
	Paracetamol	Antipyretic	500	Sparingly soluble	3	1	500	1	3	8	0.0667	4000
	Dicyclomine Hydrochloride	Anto cholinergic	20	Freely Soluble	1	1	10	4	4	3	0.1	60
	Mefenamic Acid	NSAID	250	Practically Insoluble	6	2	250	2	24			500
	Mefenamic Acid	NSAID	250	Practically Insoluble	6	2	250	2	24	3		500
	Dicyclomine Hydrochloride	Anti cholinergic	10	Freely Soluble	1	1	10	4	4		0.1	60
	Amlodipine Basilate	Hypertensive	5	Slightly Soluble	4	1	5	5	20	2		10
	Dicyclomine Hydrochloride	Anti cholinergic	20	Freely Soluble	1	1	10	4	4	3	0.1	60
	Paracetamol	Antipyretic	500	Sparingly soluble	3	1	500	1	3		0.0667	4000
	Mefenamic Acid	NSAID	250	Practically Insoluble	6	2	250	2	24			500
	Paracetamol	Antipyretic	500	Sparingly soluble	3	1	500	1	3	8	0.0667	4000

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Name of Product	Active Ingredient	Pharmacological Category	Strength (mg)	Solubility Rating		Cleanability Rating (B)	Lowest Therapeutic Dose		Risk Value	Maximum Units/Day	PDE Value	Maximum daily dose in mg
				Solubility	Rating (A)		LTD	Rating (C)	(A*B*C)			
	Doxylamine Succinate	Anti Histamine	10	Freely in Water	1	1	25	4	4	2	0.01333	150
	Pyridoxine Hydrochloride	Vitamins supplement	10	Freely Soluble	1	1	10	4	4		50	100
	Allopurinol	Anti gout	300	Very Slightly Soluble	5	2	100	3	30	3	0.08	900
	Allopurinol	Anti gout	100	Very Slightly Soluble	5	2	100	3	30	3	0.08	900
	Ketorolac Tromethamine	NSAID	10	Freely Soluble in water	1	1	10	4	4	4	1.44	90
	Ibuprofen IP	Anti-inflammatory	400	Practically Insoluble	6	2	200	2	24	4	0.0667	3200
	Paracetamol	Antipyretic	325	Sparingly soluble	3	1	500	1	3			4000
	Ibuprofen IP	Anti-inflammatory	400	Practically Insoluble	6	2	200	2	24	4	0.0667	3200
	Paracetamol	Antipyretic	325	Sparingly soluble	3	1	500	1	3			4000
	Etamsylate BP	Antifibrinolytic	250	Very Soluble	1	1	250	2	2	8	12.5	4000
	Etamsylate BP	Antifibrinolytic	500	Very Soluble	1	1	250	2	2	4	12.5	4000
	Aluminium Hydroxide USP	Antacid	306	Practically Insoluble	6	2	200	2	24	5	30.72	10000
	Magnesium Hydroxide USP	Antacid	400	Practically Insoluble	6	2	200	2	24		40	5000
	Albendazole IP	Broad spectrum Anthelmintic	400	Practically Insoluble	6	2	400	2	24	2		800
	Cetirizine Hydrochloride IP	Anti Histamine	10	Freely Soluble	1	2	2.5	5	10	1		10
	Paracetamol BP	Antipyretic	500	Sparingly soluble	3	1	500	1	3	8	0.0667	4000
	Paracetamol BP	Antipyretic	500	Sparingly soluble	3	1	500	1	3	8	0.0667	4000

Prepared By (Sign & Date)

Approved By (Sign & Date)

Batch Size in Kg	Daily Intake	Highest unit dose weight (mg)	MACO Value/ swab in mg as per PDE	MACO Value/ swab in mg as per Dose	MACO Value/ swab in mg as per 10ppm
764.081	1.834	611.27	0.27931723	0.0279317	1.741
			0.18630459	1.3965862	
781.250	3.750	625.00	0.51207228	0.0279317	1.780
			0.18630459	1.3965862	
			0.03351807	0.0055863	
600.000	1.200	600.00	1.11726892	0.1117269	1.367
			0.05586345	1.3965862	
745.050	1.490	745.05	1.11726892	0.1117269	1.697
			0.05586345	1.3965862	
374.000	0.561	187.00	0.16619375	0.0013966	0.852
			139.65861513	0.0279317	
			0.05586345	0.0006983	
484.020	0.968	484.02	1.86304593	0.2793172	1.103
698.924	0.699	698.92	1.86304593	0.2793172	1.592
510.900	2.555	1277.25	3.49146538	1.1172689	1.164
			0.00698293	0.0000140	
			0.00698293	0.0013966	
			139.65861513	0.0279317	
			0.05586345	0.0006983	
75.000	0.600	150.00	0.00547462	0.0027932	0.171
75.000	1.200	150.00	0.00547462	0.0027932	0.171
78.132	0.260	130.00	0.00000000	0.0139659	0.178
			0.04189758	0.1396586	
100.000	0.500	250.00	1.86304593	0.2793172	0.228
749.500	5.996	749.50	0.18630459	1.3965862	1.707
132.000	1.200	1200.00	0.05586345	1.3965862	0.301
568.560	4.548	568.50	0.18630459	1.3965862	1.295
440.200	1.321	440.20	0.27931723	0.0279317	1.003
			0.00000000	0.6982931	
175.000	1.050	350.00	0.00000000	0.6982931	0.399
			0.27931723	0.0279317	
84.114	0.280	140.19	0.00000000	0.0139659	0.192
570.000	2.850	950.00	0.27931723	0.0279317	1.299
			0.18630459	1.3965862	
			0.00000000	0.6982931	
217.500	4.640	580.00	0.18630459	1.3965862	0.495

Batch Size in Kg	Daily Intake	Highest unit dose weight (mg)	MACO Value/ swab in mg as per PDE	MACO Value/ swab in mg as per Dose	MACO Value/ swab in mg as per 10ppm
264.980	0.530	264.98	0.03723299	0.0698293	0.604
			139.65861513	0.0279317	
144.00	1.440	480.00	0.22345378	0.2793172	0.328
144.00	0.480	160.00	0.22345378	0.2793172	0.328
105.00	0.600	150.00	4.02216812	0.0279317	0.239
487.49	3.250	812.48	0.00000000	0.5586345	1.111
			0.18630459	1.3965862	
487.49	3.250	812.48	0.00000000	0.5586345	1.111
			0.18630459	1.3965862	
189.85	3.038	379.70	34.91465378	0.6982931	0.432
189.85	3.038	759.40	34.91465378	0.6982931	0.432
917.48	6.117	1223.30	85.80625314	0.5586345	2.090
			111.72689210	0.5586345	
199.44	1.994	997.20	0.00000000	1.1172689	0.454
217.89	0.109	108.94	0.00000000	0.0069829	0.496
750.00	4.800	600.00	0.18630459	1.3965862	1.709
750.00	4.800	600.00	0.18630459	1.3965862	1.709