### 1.0 **PURPOSE**:

This document has been prepared to evaluate the Patient Information Leaflet for the products manufactured at site to identify the maximum daily dose of the product.

### 2.0 Methodology:

- 2.1 This document shall be used for identifying the maximum daily dose of the product which is required for the calculation of Maximum Allowable Carry over (MACO) as part of cleaning validation.
- 2.2 The daily dose for different therapeutic usage of the product shall be identified through a review of Patient Information Leaflet under "Dosage section or equivalent" for each product.
- 2.3 The dosage of product for different therapeutic usage shall be presented in a table I (Tablet and Capsule) and table II (Liquid) of this document.
- 2.4 Based on the review of all the data, the maximum daily intake by the patient among all the different therapeutic use shall be selected as a maximum daily dose for a particular product.
- 2.5 The data from this document shall be used for cleaning validation where maximum daily dose for each product shall be presented in the "Cleaning Validation Evaluation Matrix" and the maximum value shall be selected for a MACO calculation.

Table I- Identification of Maximum daily dose for products manufactured in Tablet and Capsules

Name of Product			Strength   Source of information	Dosage for Therapeutic use		Maximum Daily dose Average w		
		in mg	i mg	Dosage	Maximum Number of daily intake of tablets			considering product matrix (g)
	Dicyclomine Hydrochloride	20	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	Dicycloverine Hydrochloride 20 mg Tablets: Adults and children 12 years of age or older  One 20 mg tablet 3 times each day.  Children 2 to 11 years of age Dicycloverine Hydrochloride 20 mg Tablets should not be used in this age group. For administration in this age group, other pharmaceutical strengths/forms may be available.  If you take more Dicycloverine Hydrochloride than you should  Talk to your doctor or go to a hospital Straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.	3 Tablets  Half tablets two times in 24 hours.			
	Paracetamol	500	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The recommended dose is: Adults (including the elderly): Take 2 tablets up to 4 times a day, as required. Wait at Least 4 hours between doses. Do not take more than 8 Tablets in any 24 hour period.  Children aged 10 – 15 years: One tablet to be taken every 4-6 hours, when necessary, up to a maximum of 4 tablets in any 24-hour period.  Children under 10 years: Paracetamol 500 mg Tablets is not recommended for Use in children under 10 years of age. A liquid form of this medicine	8 Tablets 4 Tablets NA	3 Tablets	0.61127	
	Phenylephrine Hydrochloride	10	Summary of Drug administration for the	Adults and adolescents 12 years of age and older: 2or 4 tablets every 12 hours as directed by a physician.	4 Tablets	4 Tablets		

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose		Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
			product (From site of- <a href="http://www.drugs.com">http://www.drugs.com</a> )	Children 6 to 12 years: 2 tablet every 12 hours, as directed by a physician.  Not recommended for children under 6 years.				
			Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product	The recommended dose is: Adults (including the elderly): Take 2 tablets up to 4 times a day, as required. Wait at Least 4 hours between doses. Do not take more than 8 Tablets in any 24 hour period.	8 Tablets			
	Paracetamol	500	(From site of- http://www.mhra.gov. uk/spc-pil)	Children aged 10 – 15 years: One tablet to be taken every 4-6 hours, when necessary, up to a maximum of 4 tablets in any 24-hour period.	4 Tablets			
			ик/ѕрс-рп	Children under 10 years: Paracetamol 500 mg Tablets is not recommended for Use in children under 10 years of age. A liquid form of this medicine	NA		0.625	
	Chlorpheniramin		Summary of Drug administration for the	Children aged 6- 11 years: One tablet to be taken every 4 to 6 hours.	6 Tablets			
	e Maleate	2	product (From site of- <a href="http://www.drugs.com">http://www.drugs.com</a> )	12 years or older: Two tablets to be taken every 4 to 6 hours.	12 Tablets			
	Gliclazide	40	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The recommended dose is from one to eight tablets. This depends on the response to treatment. When the total daily dose exceeds four tablets, it should be divided Into two equal doses taken morning and evening. Gliclazide tablets are for oral use. Take your tablet(s) with a glass of water before a meal	8 Tablets	7 Tablets		4.800
	Metformin Hydrochloride	400	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The usual starting dose is one tablet 2 or 3 times daily given during or after meals.  - After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of Metformin hydrochloride is 3 g daily.	7 Tablets		0.600	
	Gliclazide	80	Summary of Product Characteristics (SPC) and patient information leaflet	The recommended dose is from one to four tablets. This depends on the response to treatment. When the total daily dose exceeds two tablets, it should be divided Into two equal doses taken morning and evening.	4 Tablets	4 Tablets	0.74505	

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose	Average weight of	Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
			(PIL) for the product	Gliclazide tablets are for oral use. Take your tablet(s)				
			(From site of- http://www.mhra.gov. uk/spc-pil)	with a glass of water before a meal				
	Metformin Hydrochloride	500	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The usual starting dose is one tablet 2 or 3 times daily given during or after meals.  - After 10 to 15 days the dose should be adjusted on the basis of blood glucose measurements. A slow increase of dose may improve gastrointestinal tolerability. The maximum recommended dose of metformin hydrochloride is 3 g daily.	6 Tablets			
	Mecobalamin	0.5						
	Pyridoxine Hydrochloride	10					0.187	
	Folic Acid	5						
	Azithromycin	250	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The recommended dose is: Adults and children weighing more than 45 kg: Azithromycin is taken as a 3 day course. Azithromycin 250 mg  • 3 day course: Take 2 tablets once each day. Use in children Children weighing less than 45 kg should not take these tablets.	2 Tablets	2 Tablets	0.48402	0.96804
	Azithromycin	500	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The recommended dose is: Adults and children weighing more than 45 kg: Azithromycin is taken as a 3 day course. Azithromycin 500 mg  • 3 day course: Take 1 tablets once each day. Use in children Children weighing less than 45 kg should not take these tablets.	1 Tablets	1 Tablets	0.698924	0.698924
	Calcium Citrate	1000						
	Vitamin D3	2						
	Mecobalamin	0.5					1.27725	
	Pyridoxine Hydrochloride	10						
	Folic Acid	)	0 0 0	If control is unsatisfactory the dose should be increased, based on	0.7.11	0.7.11.4		4.500
	Glimepiride	2	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product	the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3 or 4 mg glimepiride per day.  A dose of more than 4 mg glimepiride per day gives better results	3 Tablets	3 Tablets	0.150	4.500

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose	Average weight of	Total daily intake	
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)	
			(From site of- http://www.mhra.gov. uk/spc-pil)	only in exceptional cases. The maximum recommended dose is 6 mg glimepiride per day.					
	Glimepiride	1	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	If control is unsatisfactory the dose should be increased, based on the glycaemic control, in a stepwise manner with an interval of about 1 to 2 weeks between each step, to 2, 3 or 4 mg glimepiride per day.  A dose of more than 4 mg glimepiride per day gives better results only in exceptional cases. The maximum recommended dose is 6 mg glimepiride per day.	6 Tablets	6 Tablets	0.150	9.000	
	Amlodipine Basilate	5	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	Adults One 5mg tablet once a day. Your doctor may increase the dose to one 10mg tablet once a day.  Children and adolescents For children and adolescents, (6-17 years old), the recommended usual starting dose is 2.5mg a day. The maximum recommended dose is 5mg a day. Amlodipine 2.5mg is not currently available and the 2.5mg dose cannot be obtained with Amlodipine 5mg or 10mg Tablets	2 Tablets 2 Tablets	2 Tablets		0.260	
			as these tablets are not manufactured to break into two equal halves.  Elderly As for adults (one 5mg tablet a day). Your doctor will closely monitor your response to any increase in the dose.	1 Tablets		0.130			
		tenolol 50 Cha		<b>Characteristics (SPC)</b>	High blood pressure 50mg tablets: the usual dose is one to two tablets, once a day.	2 Tablets			
	Atenolol			information leaflet	Angina 50mg tablets: the usual dose is two tablets once a day OR one tablet twice a day.	2 Tablets			
			http://www.mhra.gov. uk/spc-pil)	Irregular heart beats 50mg tablets: the usual dose is one to two tablets, once a day.	2 Tablets				
	Azithromycin	100		Below 12 years: Two tablets to be taken every 12 hours.	4 Tablets	4 Tablets	0.250		
	Paracetamol	650					0.7495		
	Metformin Hydrochloride	1000	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of-	Recommended dose  Children 10 years and over and adolescents usually The maximum daily dose is 2000 mg taken as 2 or 3 divided doses.  Treatment of children between 10 and 12 years of age is only recommended on specific advice from your doctor, as experience in this age group is limited.	2 Tablets	3 Tablets	1.200	3.600	

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose	Average weight of	Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
			http://www.mhra.gov. uk/spc-pil)	Adults usually start with 500 mg or 850 mg Metformin two or three times a day. The maximum daily dose is 3000 mg taken as 3 divided doses	3 Tablets			
			Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product	The recommended dose is: Adults (including the elderly): Take 2 tablets up to 4 times a day, as required. Wait at Least 4 hours between doses. Do not take more than 8 Tablets in any 24 hour period.  Children aged 10 – 15 years:	8 Tablets	8 Tablets		4.548
	Paracetamol	500	(From site of- http://www.mhra.gov. uk/spc-pil)	One tablet to be taken every 4-6 hours, when necessary, up to a maximum of 4 tablets in any 24-hour period.  Children under 10 years:	4 Tablets		0.5685	
				Paracetamol 500 mg Tablets is not recommended for use in children under 10 years of age. A liquid form of this medicine	NA			
			Summary of Product Characteristics (SPC) and patient information leaflet	Dicycloverine Hydrochloride 20 mg Tablets: Adults and children 12 years of age or Older  • One 20 mg tablet 3 times each day.  Children 2 to 11 years of age	3 Tablets Half tablets			
	Dicyclomine Hydrochloride	nine 20 http://www.n	(From site of-	<ul> <li>Dicycloverine Hydrochloride 20 mg Tablets should not be used in this age group.</li> <li>For administration in this age group, other pharmaceutical strengths/forms may be available.</li> <li>If you take more Dicycloverine</li> <li>Hydrochloride than you should</li> </ul>	two times in 24 hours.		0.4402	
				Talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.				
	Mefenamic Acid	250	Summary of Drug administration for the product (From site of- http://www.drugs.com)	For relief of acute pain in adults and adolescents (Age More than 14 years) The recommended dose is 500 mg as an initial dose followed by 250 mg every 6 hours as needed, usually not to exceed one week.	4 Tablets			
	Mefenamic Acid	250	Summary of Drug administration for the product (From site of- http://www.drugs.com)	For relief of acute pain in adults and adolescents (Age More than 14 years) The recommended dose is 500 mg as an initial dose followed by 250 mg every 6 hours as needed, usually not to exceed one week.	4 Tablets			
	Dicyclomine Hydrochloride	10	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of-	Dicycloverine Hydrochloride 10 mg Tablets: Adults and children 12 years of age or Older  • Two 10 mg tablet 3 times each day.  Children 2 to 11 years of age  • Dicycloverine Hydrochloride 10 mg Tablets should not be used in this age group.	6 Tablets One tablets two times in 24 hours.		0.350	

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose		Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
			http://www.mhra.gov. uk/spc-pil)	• For administration in this age group, other pharmaceutical strengths/forms may be available.  If you take more Dicycloverine  Hydrochloride than you should  Talk to your doctor or go to a hospital  Straight away. Remember to take any  Medicine that is left with you so the doctor knows what you have taken.				
			Summary of Product Characteristics (SPC) and patient	Adults One 5mg tablet once a day. Your doctor may increase the dose to one 10mg tablet once a day.	2 Tablets	2 Tablets		
	Amlodipine Basilate	5	information leaflet (PIL) for the product (From site of- <a href="http://www.mhra.gov.uk/spc-pil">http://www.mhra.gov.uk/spc-pil</a> )	Children and adolescents For children and adolescents, (6-17 years old), the recommended usual starting dose is 2.5mg a day. The Maximum recommended dose is 5mg a day. Amlodipine 2.5mg is not currently available and the 2.5mg dose cannot be obtained with Amlodipine 5mg or 10mg Tablets as these tablets are not manufactured to break into two equal halves.	2 Tablets		0.14015	
				Elderly As for adults (one 5mg tablet a day). Your doctor will closely monitor your response to any increase in The dose.	1 Tablets			
	Etamsylate	250	Summary of Drug administration for the product (From site of- http://www.drugs.com)	Adults: As a continuous treatment: 6 Tablets/Day in 3 divided doses, 10-20 days/month, Pre operatively: 6 Tablets /Day for 3 days. Post operatively: 6 Tablets/ Day. Children: Same pattern as for adults, having the dose; i.e. 3 tablets / day in 3 divided doses.	6 Tablets			
	Etamsylate	500	Summary of Drug administration for the product (From site of- http://www.drugs.com)	Adults: As a continuous treatment: 3 Tablets/Day in 3 divided doses, 10-20 days/month, Pre operatively: 3 Tablets /Day for 3 days. Post operatively: 3 Tablets/ Day. Children: Same pattern as for adults, having the dose; i.e. 1 tablets / day in 2 divided doses.	3 Tablets			
	Dicyclomine Hydrochloride	20	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- <a href="http://www.mhra.gov.uk/spc-pil">http://www.mhra.gov.uk/spc-pil</a> )	Dicycloverine Hydrochloride 20 mg Tablets: Adults and children 12 years of age or Older  • One 20 mg tablet 3 times each day.  Children 2 to 11 years of age  • Dicycloverine Hydrochloride 20 mg Tablets should not be used in this age group.  • For administration in this age group, other pharmaceutical strengths/forms may be available.  If you take more Dicycloverine Hydrochloride than you should  Talk to your doctor or go to a hospital  Straight away. Remember to take any Medicine that is left with you so the doctor knows what you have taken.	3 Tablets  Half tablets two times in 24 hours.		0.950	

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose	Average weight of	Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
			Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product	The recommended dose is: Adults (including the elderly): Take 2 tablets up to 4 times a day, as required. Wait at Least 4 hours between doses. Do not take more than 8 Tablets in any 24 hour period.	8 Tablets			
	Paracetamol	500	(From site of- http://www.mhra.gov.	Children aged 10 – 15 years: One tablet to be taken every 4-6 hours, when necessary, up to a maximum of 4 tablets in any 24-hour period.	4 Tablets			
			uk/spc-pil)	Children under 10 years: Paracetamol 500 mg Tablets is not recommended for use in children under 10 years of age. A liquid form of this medicine	NA			
	Mefenamic Acid	250	Summary of Drug administration for the product (From site of- http://www.drugs.com)	For relief of acute pain in adults and adolescents (Age More than 14 years) The recommended dose is 500 mg as an initial dose followed by 250 mg every 6 hours as needed, usually not to exceed one week.	4 Tablets			
		mol 500 Character and informa (PIL) for http://ww	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product	The recommended dose is: Adults (including the elderly): Take 2 tablets up to 4 times a day, as required. Wait at Least 4 hours between doses. Do not take more than 8 Tablets in any 24 hour period.	8 Tablets	8 Tablets		
	Paracetamol			Children aged 10 – 15 years:  One tablet to be taken every 4-6 hours, when necessary, up to a maximum of 4 tablets in any 24-hour period.	4 Tablets		0.580	
			шк/эрс-рп/	Children under 10 years: Paracetamol 500 mg Tablets is not recommended for use in children under 10 years of age. A liquid form of this medicine	NA			
	Doxylamine Succinate	10	Summary of Drug administration for the product (From site of- http://www.drugs.com	Usual adult dose for Nausea/Vomiting during Pregnancy: 2 Tablets orally at bed time, maximum daily dose is 8 tablets.	8 Tablets	5 Tablets		
			Summary of Product Characteristics (SPC) and patient	The recommended dose in adults and elderly: - to prevent nerve damage (peripheral neuritis) caused by isoniazid is one tablet per day,	5 Tablets		0.26498	
	Pyridoxine Hydrochloride	10	information leaflet (PIL) for the product (From site of- <a href="http://www.mhra.gov.uk/spc-pil">http://www.mhra.gov.uk/spc-pil</a> )	<ul> <li>to treat nerve damage (peripheral neuritis) caused by isoniazid is 5 tablets three times per day,</li> <li>to treat low levels of Vitamin B6 in the body is 2 to 5 tablets up to three times per day.</li> <li>Use in children over 12 years:</li> <li>The recommended dose:</li> <li>to prevent nerve damage (peripheral neuritis) caused by isoniazid is one tablet per day,</li> <li>to treat nerve damage (peripheral neuritis) caused by isoniazid is</li> </ul>			U.20490	

Name of Product	Generic Name	Strength	Source of information	Dosage for Therapeutic use		Maximum Daily dose	Average weight of	Total daily intake
		in mg		Dosage	Maximum Number of daily intake of tablets	in units among all therapeutic use	tablet (g)	considering product matrix (g)
				3 to 5 tablets two to three times per day, - to treat low levels of Vitamin B6 in the body is 2 to 5 tablets up to three times per day.				
				Pyridoxine tablets are not recommended for use in children under 12 years old.				
	Allopurinol	300	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	Adult: The starting dose is between 100mg to 300mg per day which may be taken as a single dose. Doses above 300mg should be taken in divided doses. Your doctor will adjust the dose according to the level of uric acid present in your blood. The maintenance dose is usually 200mg to 600mg daily. It is unlikely that you will be prescribed more than 900mg per day.  Children: 10-20mg/kg body weight/day.	3 Tablets	3 Tablets	0.480	
	Allopurinol	100	Summary of Product Characteristics (SPC) and patient information leaflet (PIL) for the product (From site of- http://www.mhra.gov. uk/spc-pil)	The recommended dose is:  Adults (over 18 years) The usual dose ranges from 100 to 900 mg each day. You will usually start on a dose of 100 to 300 mg each day.  Children (under 15 years) The usual dose ranges from 100 to 400 mg each day.  Elderly (over 65 years) Your doctor will prescribe the lowest dose of Allopurinol tablets that best controls your symptoms.	9 Tablets	9 Tablets	0.160	
			Summary of Drug administration for the	Age Below 17 year: Oral dose not allow to this age group,	NA	4 Tablets		
	Ketorolac Tromethamine	10	product (From site of-	Adult age 17 to 64 years: 20 mg once then 10 mg taken every 4-6 hours, but not exceed more than 40 mg in a day,	4 Tablets		0.150	
	Tromediamine		http://www.drugs.com/	Adult age above 65 years, and or weight less than 50 kg.: 10 mg once, then 10 mg taken every 4-6 hours, but not exceed more than 40 mg in a day,	4 Tablets			
	Amlodipine Basilate	2.5	Summary of Drug administration for the product (From site of- http://www.drugs.com)	The usual initial antihypertensive oral dose of Amlodipine Besylate is 5 mg once daily, and the maximum dose is 10 mg once daily.	4 Tablets	4 Tablets	0.115	

Prepared By:	Checked By
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