

## STATUS OF APPLICATIONS FOR RETAIL PRICE

| Sl. No. | Acknowledgement Number | IPDMS Reference Number | Name of the Formulation / Brand Name                                                                          | Strength                                                                                                                                                                                                                      | Unit      | Manufacturer & Marketing Company                                                     | Date of receipt of application | STATUS                                                         |
|---------|------------------------|------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|--------------------------------------------------------------------------------------|--------------------------------|----------------------------------------------------------------|
| 1       | RPON2023080384         | 123080015              | Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets | Each uncoated bilayer tablet contains:<br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg<br>Vildagliptin (As Sustained release) IP 100mg<br>Metformin Hydrochloride (as Sustained Release) IP 500mg          | Tablet    | M/s Mascot Health Series Pvt. Ltd. /<br>M/s Macleods Pharmaceuticals Ltd.            | 28-08-23                       | working sheet uploaded                                         |
| 2       | RPON2023100437         |                        | Pantoprazole sodium and Levosulpiride sustained release Capsules                                              | Each hard gelatin capsule contains:<br>Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as enteric coated pellets)<br>Levosulpiride 75mg (as sustained release pellets)                                                       | Capsule   | M/s Skymap Pharmaceuticals Pvt. Ltd.<br>/M/s Quality Bestochem Formulations (P) Ltd. | 17-10-23                       | Clarification sought from SLA Uttarakhand                      |
| 3       | RPON2023120509         | 123120002              | Leuprolide acetate injection                                                                                  | Each ml contains:<br>Leuprolide acetate 4mg                                                                                                                                                                                   | Injection | M/s Relience Life Sciences Private Limited                                           | 01-12-23                       | Clarification received from DCGI case under examination        |
| 4       | RPON2023120515         | 123120005              | Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets                                           | Each film coated tablet contains:<br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Metformin Hydrochloride IP 500mg (extended release)  | Tablet    | M/s Synokem Pharmaceuticals Limited<br>/ M/s Unison Pharmaceuticals Pvt. Ltd.        | 09-12-23                       | Refer to M&E Division                                          |
| 5       | RPON2023120516         | 123120006              | Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets                                           | Each film coated tablet contains:<br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Metformin Hydrochloride IP 1000mg (extended release) | Tablet    | M/s Synokem Pharmaceuticals Limited<br>/ M/s Unison Pharmaceuticals Pvt. Ltd.        | 09-12-23                       | Refer to M&E Division                                          |
| 6       | RPON2023120564         |                        | Bictegravir, Emtricitabine & Tenofovir Alafenamide Tablets                                                    | Each film coated tablet contains:<br>Bictegravir Sodium eq. to Bictegravir 50mg<br>Emtricitabine IP 200mg<br>Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25mg                                              | Tablet    | M/s Hetero Labs Limited / M/s Emcure Pharmaceuticals Limited                         | 27-12-23                       | working sheet uploaded                                         |
| 7       | RPON2024020081         |                        | Diclofenac Sodium Injection                                                                                   | Each ml contains:<br>Diclofenac Sodium IP 75mg water for Injection                                                                                                                                                            | Ampoule   | M/s Fast Pharma Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.                          | 22-02-24                       | Clarification received from company and case under examination |
| 8       | RPON2024030109         | 124030014              | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                             | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)                           | Tablet    | M/s Theon Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.                    | 14-03-24                       | To be placed in MDC                                            |
| 9       | RPON2024030110         | 124030015              | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                             | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form)                          | Tablet    | M/s Theon Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.                    | 14-03-24                       | To be placed in MDC                                            |
| 10      | RPON2024030111         |                        | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                             | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)                           | Tablet    | M/s Theon Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.                         | 15-03-24                       | To be placed in MDC                                            |

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|----|----------------|--|-------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|-----------------------------------------------------------------|----------|------------------------|
| 11 | RPON2024030112 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.    | 15-03-24 | To be placed in MDC    |
| 12 | RPON2024030113 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd.      | 15-03-24 | To be placed in MDC    |
| 13 | RPON2024030114 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd.      | 15-03-24 | To be placed in MDC    |
| 14 | RPON2024030115 |  | Omeprazole + Domperidone Tablets                                  | Each gastro-resistant tablet contains:<br>Omeprazole Magnesium eq. to Omeprazole BP 20mg<br>Domperidone IP 10mg                                                                                      | Tablet | M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.        | 18-03-24 | working sheet uploaded |
| 15 | RPON2024030118 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s MSN Laboratories Pvt. Ltd. | 20-03-24 | To be placed in MDC    |
| 16 | RPON2024030119 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s MSN Laboratories Pvt. Ltd. | 20-03-24 | To be placed in MDC    |
| 17 | RPON2024030122 |  | Donepezil Hydrochloride and Memantine Tablets                     | Each film coated Tablet contains:<br>Donepezil Hydrochloride IP 10mg<br>Memantine IP 10mg                                                                                                            | Tablet | M/s Savi Health Science / M/s Alkem Laboratories Ltd.           | 21-03-24 | working sheet uploaded |
| 18 | RPON2024030126 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd. | 22-03-24 | To be placed in MDC    |
| 19 | RPON2024030127 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Micro Labs Limited         | 22-03-24 | To be placed in MDC    |
| 20 | RPON2024030128 |  | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Micro Labs Limited         | 22-03-24 | To be placed in MDC    |
| 21 | RPON2024030133 |  | Sitagliptin Phosphate and Glimepiride Tablets                     | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 1 mg                                                                            | Tablet | M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited      | 26-03-24 | To be placed in MDC    |

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| 22 | RPON2024030134 |           | Sitagliptin Phosphate and Glimepiride Tablets                                                                | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 2 mg                                                                            | Tablet | M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited         | 26-03-24 | To be placed in MDC    |
| 23 | RPON2024030135 |           | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                            | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Lupin Limited                 | 27-03-24 | To be placed in MDC    |
| 24 | RPON2024030136 |           | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                            | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Lupin Limited                 | 27-03-24 | To be placed in MDC    |
| 25 | RPON2024030140 | 124030025 | Potassium Chloride in (0.15% w/v) in Dextrose (5% w/v) and sodium chloride (0.9%w/v) water for injection IP  | Each 100ml contains:<br>Potassium Chloride IP 150mg<br>Dextrose Monohydrate IP 5000mg<br>Sodium Chloride IP 900mg                                                                                    | Tablet | M/s Otsuka Pharmaceutical India Pvt. Ltd.                          | 27-03-24 | To be placed in MDC    |
| 26 | RPON2024030141 |           | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                            | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)  | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Mankind Pharma Limited        | 28-03-24 | To be placed in MDC    |
| 27 | RPON2024030142 |           | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                            | Each film coated bilayer Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form) | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Mankind Pharma Limited        | 28-03-24 | To be placed in MDC    |
| 28 | RPON2024030149 | 124030032 | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets                                       | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 1000mg<br>Glimepiride IP 1 mg                                        | Tablet | M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd. | 29-03-24 | working sheet uploaded |
| 29 | RPON2024030150 | 124030033 | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets                                       | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 1000mg<br>Glimepiride IP 2 mg                                        | Tablet | M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd. | 29-03-24 | working sheet uploaded |
| 30 | RPON2024030151 | 124030034 | Potassium Chloride in (0.15% w/v) in Dextrose (5% w/v) and sodium chloride (0.45%w/v) water for injection IP | Each 100ml contains:<br>Potassium Chloride IP 150mg<br>Dextrose Monohydrate IP 5000mg<br>Sodium Chloride IP 450mg                                                                                    | Tablet | M/s Otsuka Pharmaceutical India Pvt. Ltd.                          | 29-03-24 | To be placed in MDC    |
| 31 | RPON2024030152 |           | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets                                            | Each film coated Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form)         | Tablet | M/s Theon Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.    | 29-03-24 | To be placed in MDC    |
| 32 | RPON2024030153 |           | Sitagliptin Phosphate and Glimepiride Tablets                                                                | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 1 mg                                                                            | Tablet | M/s Exemed Pharmaceuticals / M/s Mankind Pharma Limited            | 29-03-24 | To be placed in MDC    |

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| 33 | RPON2024030154 |           | Sitagliptin Phosphate and Glimepiride Tablets                                                                 | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 2 mg                                                                                                           | Tablet    | M/s Exemed Pharmaceuticals / M/s Mankind Pharma Limited                                 | 29-03-24 | To be placed in MDC                                            |
| 34 | RPON2024040156 | 124040001 | Calcitriol, Calcium & Zinc Softgel capsule                                                                    | Each soft Gelatin Capsule contains:<br>Calcium Carbonate IP 500mg eq. to Elemental Calcium 200mg<br>Calcitriol IP 0.25mg<br>Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 7.5mg                                                | Tablet    | M/s Titanium Technologies (India) Pvt. Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd. | 02-04-24 | working sheet uploaded                                         |
| 35 | RPON2024040157 |           | Calcium & Vitamins D3 Tablet                                                                                  | Each film coated tablet contains:<br>1.25g of Calcium Carbonate from an organic source (Oyster shell)<br>eq. to Elemental Calcium 500mg<br>Cholecalciferol IP (Vitamin D3) 500IU (as stabilized form)                               | Tablet    | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceutical Industries Limited        | 05-04-24 | working sheet uploaded                                         |
| 36 | RPON2024040164 |           | Mupirocin and Sucralfate Ointment                                                                             | Composition:<br>Mupirocin IP 2% w/w<br>Sucralfate IP 7% w/w                                                                                                                                                                         | Tablet    | M/s Stedman Pharmaceuticals Pvt. Ltd.                                                   | 08-04-24 | working sheet uploaded                                         |
| 37 | RPON2024040166 |           | Ceftriaxone and Sulbactam Injection                                                                           | Each vial contains:<br>Ceftriaxone Sodium 250mg<br>Sulbactam Sodium 125mg                                                                                                                                                           | Injection | M/s Zen Pharma (P) Limited / M/s Hetero Healthcare Ltd.                                 | 10-04-24 | working sheet uploaded                                         |
| 38 | RPON2024040167 |           | Ceftriaxone and Sulbactam Injection                                                                           | Each vial contains:<br>Ceftriaxone Sodium 1000mg<br>Sulbactam Sodium 500mg                                                                                                                                                          | Injection | M/s Zen Pharma (P) Limited / M/s Hetero Healthcare Ltd.                                 | 10-04-24 | working sheet uploaded                                         |
| 39 | RPON2024040168 | 124040006 | Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets | Each uncoated bilayer tablet contains:<br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg<br>Vildagliptin (As Sustained release) IP 100mg<br>Metformin Hydrochloride (as Sustained Release) IP 500mg                | Tablet    | M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.                | 10-04-24 | working sheet uploaded                                         |
| 40 | RPON2024040169 | 124040007 | Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets | Each uncoated bilayer tablet contains:<br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg<br>Vildagliptin (As Sustained release) IP 100mg<br>Metformin Hydrochloride (as Sustained Release) IP 1000mg               | Tablet    | M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.                | 10-04-24 | working sheet uploaded                                         |
| 41 | RPON2024040171 | 124040009 | Bisoprolol Fumarate and Telmisartan Tablets                                                                   | Each film coated tablet contains:<br>Bisoprolol Fumarate IP 2.5 mg<br>Telmisartan IP 40 mg                                                                                                                                          | Tablet    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited                              | 10-04-24 | working sheet uploaded                                         |
| 42 | RPON2024040172 | 124040010 | Bisoprolol Fumarate and Telmisartan Tablets                                                                   | Each film coated tablet contains:<br>Bisoprolol Fumarate IP 5 mg<br>Telmisartan IP 40 mg                                                                                                                                            | Tablet    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited                              | 10-04-24 | working sheet uploaded                                         |
| 43 | RPON2024040178 | 124040011 | Iron tonic with Vitamin B12 and Folic Acid                                                                    | Each 5ml contains:<br>Ferric Ammonium Citrate IP 80mg<br>Folic Acid IP 0.166mg<br>Vitamin B12 IP 1mcg                                                                                                                               | Syrup     | M/s Aagya Biotech / M/s J. B. Chemicals & Pharmaceuticals Ltd.                          | 16-04-24 | Refer to DCGI                                                  |
| 44 | RPON2024040179 | 124040012 | Linagliptin & Metformin Hydrochloride (ER) Tablets                                                            | Each film coated bilayered tablet contains:<br>Linagliptin 2.5mg<br>Metformin Hydrochloride IP 500mg (as extended release form)                                                                                                     | Tablet    | M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited                                    | 18-04-24 | Clarification received from company and case under examination |
| 45 | RPON2024040180 | 124040013 | Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet                             | Each film coated Bilayered Tablet Contain:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg<br>Metformin Hydrochloride IP 500mg (Sustained Release Form) | Tablet    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited           | 18-04-24 | working sheet uploaded                                         |
| 46 | RPON2024040181 | 124040014 | Tranexamic Acid and Mefenamic Acid Tablets                                                                    | Each film coated tablet contains:<br>Tranexamic Acid 500mg<br>Mefenamic Acid 250mg                                                                                                                                                  | Tablet    | M/s Aagya Biotech / M/s J. B. Chemicals & Pharmaceuticals Ltd.                          | 18-04-24 | working sheet uploaded                                         |

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| 47 | RPON2024040182 | 124040015 | Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet             | Each film coated Bilayered Tablet Contain:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg<br>Metformin Hydrochloride IP 1000mg (Sustained Release Form) | Tablet     | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited    | 18-04-24 | working sheet uploaded                                         |
| 48 | RPON2024040183 | 124040016 | Cefixime & Ofloxacin for Oral Suspension                                                      | Each 5ml of the reconstituted suspension contains:<br>Cefixime Trihydrate eq. to cefixime Anhydrous IP 50mg<br>Ofloxacin IP 50mg<br>(This pack contains 20ml of steril water for reconstitution)                                     | Suspension | M/s Theon Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.                | 22-04-24 | working sheet uploaded                                         |
| 49 | RPON2024040184 |           | Dextromethorphan Hydrobromide, Chlorpheniramine Maleate & Phenylephrine Hydrochloride Tablets | Each film coated tablet contains:<br>Dextromethorphan Hydrobromide IP 10mg<br>Chlorpheniramine Maleate IP 2mg<br>Phenylephrine Hydrochloride IP 5mg                                                                                  | Tablet     | M/s J.K. Prints Pack (Pharma Division) / M/s Cadila Pharmaceuticals Ltd.         | 22-04-24 | working sheet uploaded                                         |
| 50 | RPON2024040185 |           | Clindamycin & Nicotinamide Gel                                                                | Composition:<br>Clindamycin Phosphate IP eq. to Clindamycin 1.0% w/w<br>Nicotinamide IP 4.0% w/w                                                                                                                                     | Gel        | M/s Pharma Force Labs / M/s Cadila Pharmaceuticals Ltd.                          | 22-04-24 | working sheet uploaded                                         |
| 51 | RPON2024040186 |           | Lidocaine & Prilocaine Gel                                                                    | Composition:<br>Lidocaine IP 2.50% w/w<br>Prilocaine IP 2.50% w/w<br>Sorbic acid IP (as preservative) 0.08% w/w                                                                                                                      | Gel        | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ra-Vish Wellness Pvt. Ltd.            | 24-04-24 | working sheet uploaded                                         |
| 52 | RPON2024040187 |           | Amoxycillin and Potassium Clavulanate Oral Suspension IP                                      | Each 5ml of the reconstituted suspension contains:<br>Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg<br>Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg                                                           | Dry Syrup  | M/s ALPS Communication Pvt. Ltd. / M/s Galpha Laboratories Ltd.                  | 25-04-24 | working sheet uploaded                                         |
| 53 | RPON2024040188 |           | Telmisartan, Chlorthalidone & Cilnidipine tablets                                             | Each film coated tablet contains:<br>Telmisartan IP 40mg<br>Chlorthalidone IP 6.25mg<br>Cilnidipine IP 10mg                                                                                                                          | Tablet     | M/s Mascot Health Series Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd. | 25-04-24 | working sheet uploaded                                         |
| 54 | RPON2024040189 |           | MFLOX-DM                                                                                      | Composition:<br>Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 0.5% w/v<br>Dexamethasone Sodium Phosphate IP 0.1% w/v                                                                                                             | Eye Drops  | M/s Aurolab                                                                      | 25-04-24 | working sheet uploaded                                         |
| 55 | RPON2024040190 |           | Dolutegravir, Emtricitabine and Tenofovir alafenamide Tablet                                  | Each film coated tablet contains:<br>Dolutegravir Sodium eq. to Dolutegravir 50mg<br>Tenofovir alafenamide 25mg,<br>Emtricitabine IP 200mg                                                                                           | Tablet     | M/s APL Healthcare Pvt. Ltd. / M/s Aurobindo Pharma Limited                      | 26-04-24 | Clarification received from company and case under examination |
| 56 | RPON2024040191 |           | Sitagliptin Phosphate and Glimepiride Tablets                                                 | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 2 mg                                                                                                            | Tablet     | M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited                        | 26-04-24 | To be placed in MDC                                            |
| 57 | RPON2024040192 |           | Sitagliptin Phosphate and Glimepiride Tablets                                                 | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg<br>Glimepiride IP 1 mg                                                                                                            | Tablet     | M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited                        | 26-04-24 | To be placed in MDC                                            |
| 58 | RPON2024040194 |           | Paracetamol Infusion IP                                                                       | Each 100ml contains:<br>Paracetamol 1IP 1000ml water for Injection                                                                                                                                                                   | Injection  | M/s Akums Drugs & Pharmaceuticals Ltd. / Dr. Reddy's Laboratories Limited        | 27-04-24 | working sheet uploaded                                         |
| 59 | RPON2024040195 |           | Tranexamic Acid Sustained Release Tablets                                                     | Each sustained release film coated tablet contains:<br>Tranexamic Acid IP 750mg                                                                                                                                                      | Tablet     | M/s Macleods Pharmaceuticals Ltd.                                                | 29-04-24 | working sheet uploaded                                         |
| 60 | RPON2024040196 |           | Methylprednisolone Dispersible Tablets                                                        | Each uncoated dispersible tablet contains:<br>Methylprednisolone IP 4mg                                                                                                                                                              | Tablet     | M/s JK Print Packs (Pharma Division) /M/s Biological E. Limited                  | 30-04-24 | Clarification sought from company                              |

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| 61 | RPON2024050197 | 124050003 | Combi pack of Clarithromycin Tablets IP, Esomeprazole Tablets IP & moxycillin Tablets USP | Each Strip contains:<br>A. Clarithromycin Tablets IP 2 Tablets<br>Each film coated tablet contains:<br>Clarithromycin IP 500mg<br>B. Esomeprazole Tablets IP 2 Tablets<br>Each Enteric coated tablet contains:<br>Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg<br>C. Amoxicillin Tablets USP 2 Tablets<br>Each Film coated tablet contains:<br>Amoxicillin Trihydrate IP eq. to Amoxicillin 1000mg | Tablets | M/s JK Print Packs (Pharma Division) /M/s Biological E. Limited                 | 02-05-24 | Clarification received from company and case under examination |
| 62 | RPON2024050198 | 124050004 | Atorvastatin & Aspirin Capsule                                                            | Each hard gelatine capsule contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules),<br>Aspirin (As Gastro-resistant tablet IP) IP 75mg                                                                                                                                                                                                                                                          | Capsule | M/s Unison Pharmaceuticals Pvt. Ltd.                                            | 02-05-24 | working sheet uploaded                                         |
| 63 | RPON2024050203 | 124050007 | Gliclazide & Metformin Hydrochloride Tablets                                              | Each uncoated bilayered sustained release tablets contains:<br>Gliclazide IP 60mg<br>Metformin Hydrochloride IP 500mg                                                                                                                                                                                                                                                                                               | Tablet  | M/s Unison Pharmaceuticals Pvt. Ltd.                                            | 06-05-24 | Under examination                                              |
| 64 | RPON2024050204 | 124050006 | Gliclazide & Metformin Hydrochloride Tablets                                              | Each uncoated bilayered sustained release tablets contains:<br>Gliclazide IP 30mg<br>Metformin Hydrochloride IP 500mg                                                                                                                                                                                                                                                                                               | Tablet  | M/s Unison Pharmaceuticals Pvt. Ltd.                                            | 06-05-24 | Under examination                                              |
| 65 | RPON2024050205 |           | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets                    | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 500mg<br>Glimepiride IP 1 mg                                                                                                                                                                                                                                                        | Tablet  | M/s Sun Pharma Laboratories Limited                                             | 06-05-24 | To be placed in MDC                                            |
| 66 | RPON2024050206 |           | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets                    | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 500mg<br>Glimepiride IP 2 mg                                                                                                                                                                                                                                                        | Tablet  | M/s Sun Pharma Laboratories Limited                                             | 06-05-24 | To be placed in MDC                                            |
| 67 | RPON2024050207 | 124050009 | Itraconazole Capsules 130mg (Supra- Bioavailable Formulation)                             | Each hard gelatin capsule contains:<br>Itraconazole BP 130mg                                                                                                                                                                                                                                                                                                                                                        | Capsule | M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.       | 07-05-24 | working sheet uploaded                                         |
| 68 | RPON2024050208 |           | Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine maleate Tablets               | Each uncoated tablet contains:<br>Paracetamol IP 500mg<br>Phenylephrine Hydrochloride IP 10mg<br>Chlorpheniramine maleate IP 2mg                                                                                                                                                                                                                                                                                    | Tablet  | M/s East African (india) Overseas / M/s Softdeal Pharmaceutical Private Limited | 07-05-24 | working sheet uploaded                                         |
| 69 | RPON2024050209 | 124050008 | Cefpodoxime & Potassium Clavulanate Tablets                                               | Each film coated tablet contains:<br>Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 200mg<br>Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg                                                                                                                                                                                                                                                    | Tablet  | M/s Malik Lifesciences Pvt. Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.        | 07-05-24 | Clarification received from company and case under examination |
| 70 | RPON2024050211 | 124050011 | Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet                    | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release)<br>Amlodipine Besilate IP IP eq. to Amlodipine 5mg<br>Telmisartan IP 40mg                                                                                                                                                                                                      | Tablet  | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.       | 08-05-24 | working sheet uploaded                                         |
| 71 | RPON2024050214 | 124050012 | Teneligliptin, Dapagliflozin & Metformin Hydrochloride (Sustained Release) Tablets        | Each film coated bilayer tablet contains:<br>Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (As Sustained Release)                                                                                                                                                                                 | Tablet  | M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.        | 08-05-24 | Clarification received from company and case under examination |
| 72 | RPON2024050212 |           | Escitalopram Oxalate Tablets                                                              | Each film coated tablet contains:<br>Escitalopram Oxalate IP eq. to Escitalopram 15mg                                                                                                                                                                                                                                                                                                                               | Tablet  | M/s Merrill Pharma Pvt. Ltd. / M/s Alkem Laboratories Limited                   | 13-05-24 | working sheet uploaded                                         |

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| 73 | RPON2024050213 |           | Flunarizine + Propranolol SR Tablet                                               | Each Uncoated bi-layered tablet contains:<br>Flunarizine Dihydrochloride IP Eq. to Flunarizine 10 mg<br>Propranolol Hydrochloride IP 40 mg (As Sustained release)                                              | Tablet    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited                      | 13-05-24 | Clarification sought from DCGI                                 |
| 74 | RPON2024050215 |           | Paracetamol Tablet                                                                | Each uncoated tablet contains:<br>Paracetamol IP 1000mg                                                                                                                                                        | Tablet    | M/s Alkem Healthscience (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited | 16-05-24 | working sheet uploaded                                         |
| 75 | RPON2024050216 |           | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets            | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 1000mg<br>Glimepiride IP 2 mg                                                  | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited                     | 16-05-24 | Clarification received from company and case under examination |
| 76 | RPON2024050217 |           | Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets            | Each film coated tablet contains:<br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg<br>Metformin Hydrochloride IP 1000mg<br>Glimepiride IP 1 mg                                                  | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited                     | 16-05-24 | Clarification received from company and case under examination |
| 77 | RPON2024050218 | 124050015 | Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet            | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release)<br>Amlodipine Besilate IP IP eq. to Amlodipine 5mg<br>Telmisartan IP 40mg | Tablet    | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited                       | 16-05-24 | working sheet uploaded                                         |
| 78 | RPON2024050219 | 124050016 | Diclofenac Sodium, Paracetamol & Chlorzoxazone Tablets                            | Each uncoated tablet contains:<br>Diclofenac Sodium IP 50mg,<br>Paracetamol IP 325mg<br>Chlorzoxazone USP 250mg                                                                                                | Tablet    | M/s Innova Cptab Limited / Dr. Reddy Laboratories Ltd.                                       | 16-05-24 | Clarification sought from company                              |
| 79 | RPON2024050220 | 124050017 | Diclofenac Sodium, Paracetamol & Serratiopeptidase Tablets                        | Each film coated tablet contains:<br>Diclofenac Potassium BP 50mg,<br>Paracetamol IP 325mg<br>Serratiopeptidase IP 10mg (As enteric coated granules eq. to 20000 Serratiopeptidase Units)                      | Tablet    | M/s Innova Cptab Limited / Dr. Reddy Laboratories Ltd.                                       | 16-05-24 | Clarification sought from company                              |
| 80 | RPON2024050222 | 124050021 | Rosuvastatin and Clopidogrel Tablets                                              | Each film coated tablet contains:<br>Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg                                                                     | Tablet    | M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.                    | 17-05-24 | Under examination                                              |
| 81 | RPON2024050223 | 124050022 | Rosuvastatin and Clopidogrel Tablets                                              | Each film coated tablet contains:<br>Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg                                                                     | Tablet    | M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.                    | 17-05-24 | Under examination                                              |
| 82 | RPON2024050224 |           | Drotaverine Hydrochloride & Mefenamic Acid Tablets                                | Each film coated tablet contains:<br>Drotaverine Hydrochloride IP 80mg<br>Mefenamic Acid IP 250mg                                                                                                              | Tablet    | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Albert David Limited                              | 17-05-24 | Clarification sought from DCGI                                 |
| 83 | RPON2024050225 | 124050023 | Meropenem and Sulbactam for Injection                                             | Each vial contains:<br>Sterile Meropenem Trihydrate IP eq. to Anhydrous Meropenem 1gm<br>Sterile Sodium Carbonate IP E. to Sodium 90.2mg (as buffer)<br>Sterile Sulbactam Sodium IP eq. to Sulbactam 1gmmg     | Injection | M/s GMH Organics /M/s Orchid Pharma Limited                                                  | 18-05-24 | Under examination                                              |
| 84 | RPON2024050226 | 124050024 | Ceftazidime and Avibactam powder for concentrate for solution for infusion        | Each vial contains:<br>Sterile Ceftazidime Pentahydrate IP eq. to Ceftazidime 2.0gm (added Sodium carbonate as buffering agent)<br>Sterile Avibactam Sodium eq. to Avibactam 0.5gm                             | Injection | M/s GMH Organics /M/s Orchid Pharma Limited                                                  | 19-05-24 | Under examination                                              |
| 85 | RPON2024050228 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (As Extended release)<br>Glimepiride IP 1 mg                        | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.                          | 20-05-24 | Under examination                                              |
| 86 | RPON2024050229 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (As Extended release)<br>Glimepiride IP 2 mg                        | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.                          | 20-05-24 | Under examination                                              |

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| 87  | RPON2024050232 |           | Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet            | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release)<br>Amlodipine Besilate IP IP eq. to Amlodipine 5mg<br>Telmisartan IP 40mg | Tablet    | M/s Akums & Drugs Pharmaceutical Ltd. / M/s Mankind Pharma Ltd.                      | 20-05-24 | working sheet uploaded                                         |
| 88  | RPON2024050233 |           | Omeprazole Injection                                                              | Each vial contains:<br>Omeprazole IP (Sterile) 40mg                                                                                                                                                            | Injection | M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd. | 20-05-24 | working sheet uploaded                                         |
| 89  | RPON2024050234 |           | Fexofenadine Hydrochloride and Montelukast tablets                                | Each film coated bilayer tablet contains:<br>Fexofenadine Hydrochloride IP 180mg<br>Montelukast Sodium IP eq. to Monte likast 10mg                                                                             | Tablet    | M/s Exemed Pharmaceuticals / M/s Sun Pharmaceuticals Industries Limited              | 21-05-24 | Clarification received from company and case under examination |
| 90  | RPON2024050235 | 124050020 | Levosulbutamol & Ipratropium Bromide respirator solution                          | Each 2.5ml contains:<br>Levosulbutamol IP 1.25mg<br>Ipratropium Bromide IP 500mcg                                                                                                                              | Respules  | M/s Axa Parenterals Limited / M/s Workcell Solution Private Limited                  | 21-05-24 | Clarification sought from company                              |
| 91  | RPON2024050236 |           | Pantoprazole sodium and Levosulpiride sustained release Capsules                  | Each hard gelatin capsule contains:<br>Pantoprazole Sodium IP eq. to Pantoprazole 40mg (as enteric coated pellets)<br>Levosulpiride 75mg (as sustained release pellets)                                        | Capsule   | M/s Pure & Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Limited              | 22-05-24 | Under examination                                              |
| 92  | RPON2024050237 |           | Paracetamol and Mefenamic Syrup                                                   | Each 5ml contains:<br>Paracetamol IP 250mg,<br>Mefenamic Acid IP 100mg Suspension                                                                                                                              | Syrup     | M/s Windlas Biotech Limited / M/s Biological E. Limited                              | 22-05-24 | Clarification sought from company                              |
| 93  | RPON2024050238 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (As Extended release)<br>Glimepiride IP 1 mg                        | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited                   | 23-05-24 | Under examination                                              |
| 94  | RPON2024050239 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (As Extended release)<br>Glimepiride IP 2 mg                        | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited                   | 23-05-24 | Under examination                                              |
| 95  | RPON2024050240 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (As Extended release)<br>Glimepiride IP 1 mg                       | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited                   | 23-05-24 | Under examination                                              |
| 96  | RPON2024050241 |           | Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets | Each film coated bilayered tablet contains:<br>Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (As Extended release)<br>Glimepiride IP 2 mg                       | Tablet    | M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited                   | 23-05-24 | Under examination                                              |
| 97  | RPON2024050242 | 124050029 | Atorvastatin and Ezetimibe Tablets                                                | Each film coated tablet contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 20mg<br>Ezetimibe IP 10mg                                                                                                     | Tablet    | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ipca Laboratories Limited                 | 23-05-24 | Under examination                                              |
| 98  | RPON2024050243 |           | Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet            | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release)<br>Amlodipine Besilate IP IP eq. to Amlodipine 5mg<br>Telmisartan IP 40mg | Tablet    | M/s Akums & Drugs Pharmaceutical Ltd. / M/s Intas Pharmaceuticals Limited            | 23-05-24 | Clarification sought from company                              |
| 99  | RPON2024050244 | 124050031 | Ceftriaxone and Sulbactam Injection                                               | Each vial contains:<br>Ceftriaxone Sodium IP (Sterile) eq. to Anhydrous Ceftriaxone 1000mg<br>Sulbactam Sodium IP (Sterile) eq. to Sulbactam 500mg                                                             | Injection | M/s Aqua Laboratories /M/s Orchid Pharma Limited                                     | 22-05-24 | Under examination                                              |
| 100 | RPON2024050245 | 124050030 | Atorvastatin and Ezetimibe Tablets                                                | Each film coated tablet contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 40mg<br>Ezetimibe IP 10mg                                                                                                     | Tablet    | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ipca Laboratories Limited                 | 23-05-24 | working sheet uploaded                                         |
| 101 | RPON2024050246 | 124050034 | Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet            | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release)<br>Amlodipine Besilate IP IP eq. to Amlodipine 5mg<br>Telmisartan IP 40mg | Tablet    | M/s Akums & Drugs Pharmaceutical Ltd. / M/s Glenmark Pharmaceuticals Ltd.            | 23-05-24 | Clarification received from company and case under examination |



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| 102 | RPON2024050252 | 124050026 | Linagliptin and Metformin Hydrochloride Tablet                             | Each film coated bilayered tablet contains:<br>Linagliptin 5mg<br>Metformin Hydrochloride IP 500mg (As Extended release form)                                                                                                  | Tablet  | M/s Mascot Health Series Pvt. Ltd. /<br>M/s La Renon Healthcare Pvt. Ltd.        | 24-05-24 | Under examination                 |
| 103 | RPON2024050247 | 124050035 | Atorvastatin, Clopidogrel & Aspirin Capsule                                | Each hard gelatine capsule contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 10mg (Asfilm coated tablet),<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg,<br>Aspirin IP 75mg (As gastro-resistant Tablet)         | Capsule | M/s Unison Pharmaceuticals Pvt. Ltd.                                             | 25-05-24 | Under examination                 |
| 104 | RPON2024050248 | 124050036 | Atorvastatin, Clopidogrel & Aspirin Capsule                                | Each hard gelatine capsule contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 20mg (Asfilm coated tablet),<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg,<br>Aspirin IP 75mg (As gastro-resistant Tablet)         | Capsule | M/s Unison Pharmaceuticals Pvt. Ltd.                                             | 25-05-24 | Under examination                 |
| 105 | RPON2024050253 | 124050037 | Ceftazidime and Avibactam powder for concentrate for solution for infusion | Each vial contains:<br>Sterile Ceftazidime Pentahydrate IP eq. to Ceftazidime 2.0gm (added Sodium carbonate as buffering agent)<br>Sterile Avibactam Sodium eq. to Avibactam 0.5gm                                             | Tablet  | M/s GMH Organics /M/s Zyphars Pharmaceuticals Pvt. Ltd.                          | 26-05-24 | Under examination                 |
| 106 | RPON2024050249 | 124050038 | Magnesium Hydroxide, Vitamin D3, Zinc Sulphate & Calcium Carbonate Tablet  | Each film coated tablet contains:<br>Magnesium Hydroxide IP eq. to Elemental Magnesium 50mg<br>Vitamin D3 IP 1000IU<br>Zinc Sulphate Monohydrate IP Elemental Zinc 10mg<br>Calcium Carbonate IP eq. to Elemental Calcium 500mg | Tablet  | M/s Unison Pharmaceuticals Pvt. Ltd.                                             | 27-05-24 | Under examination                 |
| 107 | RPON2024050250 |           | Cefadroxil and Clavulanic Acid Tablet                                      | Each uncoated dispersible tablet contains:<br>Cefadroxil Monohydrate IP eq. to Cefadroxil 250mg<br>Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.5mg                                                              | Tablet  | M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Indoco Remedies Limited | 27-05-24 | Under examination                 |
| 108 | RPON2024050251 |           | Cefadroxil and Clavulanic Acid Tablet                                      | Each uncoated dispersible tablet contains:<br>Cefadroxil Monohydrate IP eq. to Cefadroxil 500mg<br>Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg                                                               | Tablet  | M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Indoco Remedies Limited | 27-05-24 | Under examination                 |
| 109 | RPON2024050254 | 124050013 | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets          | Each film coated Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 500mg (as sustained release form)                                    | Tablet  | M/s Theon Pharmaceuticals Ltd. / M/s La Renon Healthcare Pvt. Ltd.               | 27-05-24 | Clarification sought from company |
| 110 | RPON2024050255 | 124050014 | Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets          | Each film coated Tablet contains:<br>Linagliptin 5mg<br>Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg<br>Metformin Hydrochloride IP 1000mg (as sustained release form)                                   | Tablet  | M/s Theon Pharmaceuticals Ltd. / M/s La Renon Healthcare Pvt. Ltd.               | 27-05-24 | Clarification sought from company |
| 111 | RPON2024050256 | 124050032 | Atorvastatin and Clopidogrel Capsule                                       | Each hard gelatine capsule contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As pellets form),<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets form),,                                           | Capsule | M/s Aeon Formulations Pvt. Ltd. / M/s Ipca Laboratories Limited                  | 27-05-24 | Clarification sought from company |
| 112 | RPON2024050257 | 124050033 | Atorvastatin and Clopidogrel Capsule                                       | Each hard gelatine capsule contains:<br>Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As pellets form),<br>Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets form),,                                           | Capsule | M/s Aeon Formulations Pvt. Ltd. / M/s Ipca Laboratories Limited                  | 27-05-24 | Clarification sought from company |
| 113 | RPON2024050258 |           | Telmisartan and Hydrochlorothiazide Tablets                                | Each Uncoated Bilayered Tablet Contains:<br>Telmisartan IP 40mg<br>Hydrochlorothiazide IP 12.5mg                                                                                                                               | Capsule | M/s Hetero Labs Limited / M/s Hetero Healthcare Ltd.                             | 28-05-24 | Clarification sought from company |

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| 114 | RPON2024050259 |           | Calcium Citrate Malate and Vitamin D3 Tablets                              | Each film coated Tablet Contains:<br>Calcium Citrate Malate IP eq. to elemental Calcium 250mg<br>Vitamin D3 IP 1000mg                                                                                       | Tablet          | M/s Alkem Healthscience (A unit of aAlkem Laboratories Ltd.) / M/sAlkem Laboratories Limited | 29-05-24 | Under examination |
| 115 | RPON2024050260 | 124050042 | Cholecalciferol Vitamin D3 Oral solution                                   | Each 5ml contains:<br>Cholecalciferol IP 60000 IU                                                                                                                                                           | Oral Solution   | M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.                        | 30-05-24 | Under examination |
| 116 | RPON2024050261 | 124050041 | Telmisartan and Cilnidipine tablet                                         | Each film coated tablet contains:<br>Telmisartan IP 40mg<br>Cilnidipine IP 20mg                                                                                                                             | Tablet          | M/s Macleods Pharmaceuticals Limited                                                         | 29-05-24 | Under examination |
| 117 | RPON2024050262 |           | Amlodipine, Telmisartan and Metoprolol Succinate (Extended Release) tablet | Each film coated bilayered tablet contains:<br>Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (as extended release)<br>Telmisartan IP 40mg<br>Amlodipine Besilate IP eq. to Amlodipine 5mg | Tablet          | M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Akumentis Healthcare Ltd.                       | 31-05-24 | Under examination |
| 118 | RPON2024050263 |           | Cefixime and Ofloxacin Oral suspension                                     | Each 5ml of reconstituted suspenssion contains:<br>Cefixime Trihydrate IP eq. to Cefixime 50mg<br>Ofloxacin IP 50mg                                                                                         | powder for susp | M/s Saitech Medicare Pvt. Ltd. / M/s Biological E. Limited                                   | 31-05-24 | Under examination |
| 119 | RPON2024050264 |           | Telmisartan and Cilnidipine tablet                                         | Each film coated tablet contains:<br>Telmisartan IP 40mg<br>Cilnidipine IP 20mg                                                                                                                             | Tablet          | M/s Saitech Medicare Pvt. Ltd. / M/s Biological E. Limited                                   | 31-05-24 | Under examination |
| 120 | RPON2024050265 | 124050044 | Lactulose Enema 20%                                                        | Each ml contains:<br>Lactulose Concentrate USP eq. to Lactulose 200mg<br>Benzyl Alcohol IP 3ml (Preservatives )                                                                                             | Liquid          | M/s Alkem Laboratories Limited                                                               | 31-05-24 | Under examination |
| 121 | RPON2024050267 | 124050043 | Calcium Citrate Malate and Vitamin D3 Tablets                              | Each film coated Tablet Contains:<br>Calcium Citrate Malate IP eq. to elemental Calcium 250mg<br>Vitamin D3 IP 1000mg                                                                                       | Tablet          | M/s Alkem Laboratories Limited                                                               | 31-05-24 | Under examination |