

INDEUS LIFE SCIENCES PRODUCT LIST

| | | | COMMERCIAL PRODUCTS | | | | | | | |
|----|-------|---|---|-----------|----------------|-------------------|--|---|--|----------------------|
| S. | . No. | Projects | Commercialization | BE Status | Dossier Status | Samples status | Shelf life | MA Holder (Country) | Primary Packing | Secondary Packing |
| 1. | | Anagrelide tablets: 0.5mg, 0.75mg and 1mg Tablets | Commercialized | Available | Approved | Available | Shelf life 36M | | 1. PVC/PVDC Blister of 10 tablets 2HDPE bottles with CR cap- 100 tablets | Carton |
| 2 | | Loperamide HCl 2mg and Simethicone 125mg Tablets | Commercialized | Available | Approved | Availlable | Shelf life 36M | Phillipiines, UAE , Netherlands, Poland and Lativa | PVC/PVDC Blister of 06 tablets | Carton |
| 3 | | Betahistine dihydrochloride tablets: 8mg, 16mg, and 24mg | Under filing | Available | Available | Not Availlable | Shelf life 24M at storage condition NMT 25°C | | Alu/Alu Blister of 10 tablets | Carton |
| 4 | | Desloratadine Oral Solution 0.5mg/ml | Commercialized but discontinued CMO to be decided Site transfer to be initiated. Stability data for 6M to be generated for new site registration alongwith re-filling.Search for CMO Dossier to be compiled | NA | Available | Not Availlable | Shelf life 24M | - | Glass bottles with a child proof screw | Carton |

Product without BE study

| S. No. | Projects | BE Status | Dossier Status | Sample status | Time line | Shelf life | Primary Packing | Secondary Packing |
|--------|--|--|---------------------------|---------------------------|----------------|---|---------------------------------------|-------------------|
| 1 | Loperamide ODT 2 mg | To be performed | Dossier to be compiled | R & D sample Available | 8 to 9 Months | Shelf life 36M | PVC/PVDC Blister of 10 tablets | Carton |
| 2 | Loperamide HCl and Simethicone, 2- 125mg Chewable | To be performed | Dossier to be compiled | R & D sample Available | 8 to 9 Months | Shelf life 36M at storage condition 25°C. | tablets 2. PVC/Aclar Blister of 04 | Carton |
| 3 | Mesalamine Granules 1000 and 2000mg | Not required for enema (Requirement of BE study to be confirmed by country regulatory) | Dossier to be compiled | Not available | 9 to 10 Months | Shelf life 36M | Aluminium stick packs | Carton |
| 4 | Acetyl salicylic acid granules 500mg/1000mg | To be performed | Dossier to be compiled | R & D sample Available | 8 to 9 Months | NMT 25°C/60%RH at 60M | Aluminium stick packs | Carton |

Product Ready for Tech transfer

| S. | No. Projects | BE Status | Dossier Status | Sample status | Remark | Time line for data generation for filling | | Secondary Packing |
|----|---------------------------------|----------------------|-------------------|---------------|--|---|--------------------------------|-------------------|
| 1 | Gliclazide 60/90/120mg MR Table | Need to be performed | To be compiled | Not available | 12M data of one full scale up batch available | 9-10 Months | PVC/PVDC Blister of 10 tablets | Carton |

Product Ready with Prototype

| S. No. | Projects | BE Status | Dossier Status | Sample status | Remark | Time line for data generation for filling | Primary Packing | Secondary Packing |
|--------|--|----------------------|-------------------|-------------------------------|--------|---|--------------------|-------------------|
| 1 | Cabergoline Tablet 0.5 mg | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | HDPE BOTTLE | Carton |
| 2 | Solafinacin succinate tablet 10 mg | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 3 | Solafinacin succinate suspension 1mg/mL | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | AMBER GLASS BOTTLE | Carton |
| 4 | Levodopa + Carbidopa 200 mg + 50 mg Table | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 5 | Mirabegron prolonged released tablet 25 mg 5 | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 6 | Palbociclib 75,100,125 mg Tablet | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 7 | Alfuzosine SR Tablet 5 mg & 10 mg | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | HDPE BOTTLE | Carton |
| 8 | Posaconazole Delayed Release 100mg Table | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 9 | Pentoxyphyline SR 400 mg Tablet | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| | Methenamine hippurate 1 g Tablet | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |
| 11 | Bosentan 62.5 mg Tablets | Need to be performed | To be compiled | Can be provided on Request | | 9-10 Months | Blister | Carton |